16574

THE STATE OF SOUTH CAROLINA
In the Court of Appeals

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas

C Thomas Cooper, Jr , Circuit Court Judge

Case No 05 CP 40 0655

SEALED

Monica Weston, Appellant,

v

Kim s Dollar Store and
CIBA Vision, a division of Norvartis Company, Respondents

AMENDED RECORD ON APPEAL
VOLUME II

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IN THE COURT OF COMMON PLEAS
STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND

COPY

MONICA WESTON,
Plaintiff,

vs

CIVIL ACTION FILE NO
05-CP-40-0655

KIMS DOLLAR STORE and CIBA VISION, a division of Novartis Company,
Defendants

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30(b)(6) DEPOSITION OF CIBA VISION

BY PAUL G ORIS

RECEIVED
2006
McNair Law Firm PA

June 27, 2006
10 45 a m

11695 Johns Creek Parkway
Duluth, Georgia

Anthony D Lorenz, RMR-RDR, CRR, CCR-B-2022
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identification)

Q (By Mr Rawl) Mr Oris, I'm handing you what's been marked as Exhibit No 1 It is the plaintiff's 30(b)(6) deposition notice to CIBA Vision There's several topics on there

Have you been designated by CIBA Vision to speak on some of these topics?

A Yes

Q Can you tell me which ones, please?

A Numbers 1, 2, and 11

Q So you're designated to speak on behalf of CIBA Vision with regard to discussions and decisions regarding placement of warnings on individual packages of color contacts, warnings regarding dangers of wearing colored contacts, and the FDA classification and classification process for plain or colored contact lenses, and FreshLook Color lenses, from 1999 to 2004, correct?

A Yes

Q What is your position with the company?

A I am the head of global regulatory affairs

Q And how long have you been in that position?

A Since 2001 January of 2001

Q And what were you before January 2001?

A I was manager of regulatory affairs at Wesley Jessen

Q And Wesley Jessen was acquired by CIBA Vision?

A That's correct

Q And how long were you in that position with Wesley Jessen?

A Just over two years

Q And what were you before that?

A I was manager of regulatory affairs for Siemens Medical Systems

Q Can you tell me what your educational background is, please?

A I have a Bachelor's of Science in health arts It's -- that's what I have a Bachelor of Science in health arts A four-year degree

Q And do you have any other types of training, other courses that you've taken -- continuing education courses? -- anything like

that?

A Yes

Q Can you tell me what they are?

A I'm certified -- registered in nuclear medicine, X-ray technology, and I'm also registered as a regulatory affairs professional

Q Is that a certificate, or a designation, or --

A Certificate

Q And how do you get that certificate?

A Through testing and experience

Q Do you have to take a course?

A No

Q Can you tell me about the test? Is it a one-day test? a two-day test?

A It's a one-day test

Q Is it a written test? an oral exam?

A It's multiple choice

Q And what is the name of the certificate?

A Regulatory affairs professional

I'm sorry -- regulatory affairs certificate Certified regulatory affairs professional It allows you to put "RAC" at

the end of your name

Q And what does a regulatory affairs professional do, normally?

A Normally, works in regulatory affairs for any of the World Health -- for registering products through health agencies around the world

Q Like the FDA here in the U S

A Not FDA More -- not FDA, so to speak It's people who submit to FDA, to gain approval

Q Can you say that again? I'm sorry -- I don't understand

A People in regulatory affairs professions, in manufacturing, would be certified in regulatory affairs And FDA is basically their customer

Q Gotcha I understand Thank you

A And the provider of approvals

Q Can you explain to me what your duties and responsibilities are presently with CIBA Vision?

A I oversee the department to ensure that products are registered, any changes to products are within the boundaries of the

MS WILSON Objection
THE WITNESS Yes
Q (By Mr Rawl) And it's your understanding that if a contact lens is designated as a cosmetic, it is not designated as a medical device, correct?
MS WILSON Objection
THE WITNESS It's always been a medical device, in our -- in our company
Q (By Mr Rawl) Meaning that CIBA Vision has always treated all contact lenses, as if they are medical devices
A That's correct
Q Okay But CIBA Vision acknowledges, in this document, that plano color contact lenses receive a cosmetic designation --
MS WILSON Objection
Q (By Mr Rawl) -- as opposed to a medical device, correct?
MS WILSON Restate my objection
THE WITNESS Yes
Q (By Mr Rawl) Does CIBA Vision have, or produce any other devices that are cosmetic -- with a cosmetic designation?
A CIBA Vision only produces medical

device needs more warnings to enhance its safety or effectiveness, then you should include more warnings and get them approved

Q Okay Does CIBA Vision have the ability to just add some warnings to the contact labeling, without getting it approved by the FDA?

A It depends on the classification of the device

Q What classifications allow you to do it, and what classifications do not allow you to do it?

A I'm -- hold on

I have to take that back Because it doesn't depend on the class of the device If it affects safety or effectiveness, no matter what the classification is, you have to gain FDA's approval

Q So your understanding is that CIBA Vision has no leeway in adding an additional warning -- without changing any other warnings, but adding an additional warning that it thinks is necessary, without getting FDA approval

MS WILSON Objection

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THE WITNESS We cannot add anythıng to the labelıng -- warnıngs, specıfıcally -- wıthout gaınıng FDA approval

Q (By Mr Rawl) Can CIBA Vısıon change or duplıcate the locatıon of the warnıng wıth regard to the labels?

And I'll just -- I'll gıve you a specıfıc example

If CIBA Vısıon determıned that a warnıng was needed on an ındıvıdual packet of contact lenses -- you know, the boxes come wıth sıx, rıght?

A Uh-huh

Q And ıf CIBA Vısıon determınes that the ındıvıdual blıster pack needs to have an addıtıonal warnıng, can ıt put -- duplıcate one of the warnıngs from the package ınsert onto the blıster pack, wıthout FDA approval?

A Well, I'm not sure That would depend on the class of the devıce I'm not sure I'm not sure about Class 2, but Class 3 for sure, they would need to get FDA approval

Q Can you explaın to me the dıfference between a Class 2 and a Class 3 contact lens?

Page 38

Q Why not?
A Because FreshLook lenses were approved as a Class 3 devıce
Q So the FreshLook lenses were never daıly wear
A FreshLook lenses also obtaıned 510(k) clearance, but they were never promoted or sold as a daıly wear devıce They were always the PMA devıce
Q So let me make sure I understand
Your understandıng ıs that a Class 2 medıcal devıce contact lens --
A Uh-huh
Q -- gets clearance through the 510(k) process?
A Correct
Q And the Class 3 medıcal devıce contact lens gets approval to market through the PMA, or the premarket approval --
A That's correct
Q -- process
And the FreshLook Colors lenses got approval through both the PMA, and the 510(k) process
A That's correct

Q What I think you just said -- and I just want to understand this -- even though CIBA Vision received 510(k) clearance for the FreshLook Colors contact lenses, they have not marketed it as a daily wear device, and thus have not taken -- not utilized that clearance? -- that 510(k) clearance?

A They have not implemented that 510(k) clearance, that's correct

Q They have never what?

A They have never -- they have not utilized the 510(k) clearance

Q Has CIBA Vision ever sought either 510(k) clearance or PMA clearance specifically for plano color contact lenses?

A No

Q At some time prior to the Exhibit 2 you have in front of you, did CIBA Vision consider the plano SoftLook Colors lenses to be a Class 3 medical device?

A Specifically plano?

Q Specifically plano

A They were always in a range

Q And tell me what you mean by that

A Minus 20 to plus 20 A range of

Page 40

diopters

Q And the FreshLook Colors contact lenses -- strike that

Is what you're saying that CIBA Vision created a range from plus 20 to minus 20, and included in that range, a plano lens?

A They created the range of minus 20 to plus 20 It's like a number line

Q Which included a zero

A Correct

Q Which would be a plano lens

A Correct

Q Which would have no correction of visual acuity

A That's my understanding, yes

Q And your understanding is that the approval for that -- those FreshLook Colors contact lenses, was through the PMA process

A Yes

Q And when you go through that PMA process, you have to disclose to the FDA the specific indication for the contact lenses, correct?

A Yes

Q And what does "indication" mean?

A Reason for use

Q Okay And the approval letters from the FDA regarding FreshLook Colors contact lenses, all indicated that the indication had to be for the correction of visual acuity, correct?

A Yes

Q And the FreshLook Colors plano lens, does not correct visual acuity, correct?

MS WILSON Objection

THE WITNESS Correct Yes

Q (By Mr Rawl) And all of the FDA approval letters with regard to the FreshLook Colors contact lenses, state that if a lens is marketed for something other than the indicated use, then the approval is invalidated, correct?

A Yes

Q That's your understanding, correct?

A Yes

Q So if CIBA Vision markets the FreshLook Color line of lens for something other than the correction of visual acuity, then the approval for that lens would be invalidated, correct?

Page 42

MS WILSON Objectıon

Q (By Mr Rawl) That's your understandıng, correct?

MS WILSON Objectıon restated

THE WITNESS Yes I -- yes

MS WILSON Whenever you get to a stoppıng place, I'd lıke to take a quıck break

MR RAWL Go ahead

(Thereupon a short recess was taken, after whıch the followıng proceedıngs were had)

Q (By Mr Rawl) Can you tell me what these charts are ın Exhıbıt 2, Page 69, 70, 71, 72 and 73 and so on?

A These are -- thıs ıs U S complaınt data for specıfıc contact lenses, number of complaınts versus sales

Q Okay And thıs ıs -- you're lookıng at Page 69 now?

A Yes

Q Okay And are any of those FreshLook --

A No

Q -- lenses? Okay

Page 48

or wıthout havıng them properly fıtted by a healthcare professıonal

A Rıght What's that got to do wıth the publıc?

Q Do you agree that that process causes a publıc health rısk?

A Yes

Q Are you aware that -- well, strıke that

CIBA Vısıon was aware, prıor to March of 2004, that companıes were sellıng and dıstrıbutıng CIBA's color contact lenses wıthout a prescrıptıon, and wıthout the ınstructıons and medıcal advısorıes, correct?

A Yes

Q And that process of sellıng the contacts, you know, to people who have not been properly fıtted, and wıthout the ınstructıons and medıcal advısorıes, creates an enormous rısk that consumers wıll purchase lenses that are the wrong sıze, or that are otherwıse not medıcally approprıate

A Yes

Q And you would agree that any of these mısuses of CIBA's color contact lenses,

could result ın severe and permanent ınjury to the eyes of the users

A Yes

Q Would you agree that the process of sellıng the FreshLook Colors contact lenses wıthout havıng fırst been fıtted by an eye care professıonal, and wıthout the warnıng ınserts, transforms a safe and effectıve product ınto a dangerous product, wıth a potentıal to blınd users?

A Yes

Q I'm now goıng to Page 94 and I'll be askıng you some questıons on that document And the same type of thıngs about the dangers of wearıng color contacts

And I thınk thıs document was also fıled ın September of 2002 Is that what ıt says on yours?

A Yes

Q So ın September of 2002, CIBA Vısıon was aware that companıes were engaged ın the wıdespread unauthorızed dıstrıbutıon and sale of CIBA color contact lenses wıthout a prescrıptıon, on a natıonal scale, and wıthout the warnıng ınserts

A I don't know about a national scale
Q But you could look at --
A Are you reading verbatim from somewhere?
Q Yes, Page 6
I'm sorry -- Page 99 of Exhibit No 2, Paragraph 19
A "The defendants are engaged in the widespread unauthorized" -- yeah
Q So you would agree that CIBA Vision was aware that -- in September of 2002, that companies were engaged in the widespread unauthorized distribution and sale of CIBA's color contact lenses without prescription, on a national scale
MS WILSON Objection
THE WITNESS Yes
Q (By Mr Rawl) And you would agree that at that time, CIBA Vision knew that the instructions for use and the medical advisories that went along with the color contact lenses, were needed by consumers to properly use and care for the lenses
A Yes
Q And as of September 2002, CIBA

Vision was aware that companies were selling CIBA's color contact lenses to -- in trade shows, and other locations throughout the country

That should have been beauty product trade shows Paragraph 21

A Yes

Q And as of September 2002, CIBA Vision was aware that companies were breaking down multiple sets of contact lenses that are marked, quote, "Not to be sold individually," end quote, and selling those lenses individually, without the instructions for use, and without the medical advisories available from eye care professionals that are needed by consumers to properly use and care for the lenses

MS WILSON Objection How does this fall within this designation? I understand the document speaks for itself, but --

MR RAWL You can object, but I mean, this is just straightforward, and --

MS WILSON Well, you still have to

Page 54

50

A Then yes

Q So let me make sure that we're clear

As of September 2002, CIBA Vısıon was aware that companıes were breakıng down the boxes of sıx, you know, FreshLook Colors contact lenses, sellıng them ındıvıdually to consumers, wıthout the package ınsert and warnıngs, correct?

A Yes

Q And that conduct poses a threat to both the safety -- excuse me -- poses a threat to the safety of the publıc

A Yes

Q And that the sales of those contact lenses ındıvıdually wıthout the package ınsert ıs confusıng and deceıvıng to the publıc

MS WILSON Objectıon

THE WITNESS Yes

Q (By Mr Rawl) And that ın September of 2002, CIBA Vısıon was aware that these actıvıtıes of sellıng the ındıvıdual contact lenses wıthout the package ınserts could expose CIBA to lıabılıty

of breaking down the individual boxes of color contact lenses, and selling them to individuals without a prescription, and without package inserts?

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) And is it true that CIBA Vision was aware that this conduct was going on in locations such as beauty supply stores, nail salons, flea markets, video stores, and gas stations, and that the conduct was on the rise?

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) And that -- isn't it true that as of 2002, CIBA Vision was aware that consumers often believed that they do not need a prescription, or do not need to be fit by an eye doctor for these lenses, because they use them merely to change eye color and not to correct vision?

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) And it's true that CIBA Vision was aware, in 2002, that the

Page 58

failure to have the color contact lenses properly fitted by an eye care professional, could cause serious and permanent eye damage to the consumer

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) And the eye damage that could -- CIBA Vision was aware that the eye damage that could occur from wearing the CIBA Vision SoftLook Colors contact -- excuse me -- FreshLook Colors contact lenses, without being first fitted by an eye care professional, could cause problems as bad as loss of vision, or loss of the eye

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) And in fact, CIBA Vision knew about the dangers of wearing color contact lenses, or any contact lenses, without first being properly fitted, for years, prior to 2003, correct?

MS WILSON Objection

THE WITNESS Yes Its contact lens

Q (By Mr Rawl) And CIBA Vision was

aware that, prıor to 2004, consumers were actually beıng ınjured by wearıng the CIBA Vısıon FreshLook Colors contact lenses, wıthout beıng fırst -- beıng fıtted by an eye care professıonal

MS WILSON Objectıon

THE WITNESS Yes

MR RAWL Let's mark thıs as the next exhıbıt, please

(Exhıbıt-4 was marked for ıdentıfıcatıon)

MR RAWL I only have one copy of thıs I can get another copy out of the box Why don't you go ahead and look at ıt fırst

MS WILSON What was the exhıbıt?

MR RAWL Off the record

(Dıscussıon ensued off the record)

(Pause ın proceedıngs)

Q (By Mr Rawl) Can you tell me what Exhıbıt No 4 ıs, please?

A It's the front of a FreshLook Color contact lens label It's a label

Q Is that the label that's on the actual blıster pack?

Page 60

A Yes

Q And so this would be the part of the blister pack that has writing on it? The other side doesn't have writing on it, does it?

A Correct

Q And when we were talking about breaking down the boxes of contact lenses and individual lenses, this is what you'd end up with, as an individual lens, correct?

A Yes

Q Okay And this is a FreshLook Colors blister pack, right?

A Yes

Q Is there a date on this thing anywhere?

A There's an expiration date

Q Can you tell from looking at the expiration date when these were manufactured?

A Yes I think -- I believe it's a five-year expiration date, so therefore, this would have been manufactured in 2003

Q And this blister pack -- it says, "SPH," dash, "0 00 " What does that mean?

A That's the spherical diopter power

Q So FreshLook Colors ıs -- ıs that consıdered the tradename?

A Brand name, tradename, yes

Q And then underneath to the rıght, ıt says "UV," wıth a dotted cırcle around ıt What does that mean?

A That means that thıs lens has a UV-absorbıng chromoform ın ıt It absorbs UV lıght

Q Were all the FreshLook Colors manufactured at that tıme, UV?

A No

Q Was there a poınt that they became all UV?

A No

They all became UV?

Q As FreshLook Colors

I'll restate the questıon I'm not tryıng to confuse you I'm wonderıng, ın June of 2003, could I have bought a FreshLook Colors contact lens, wıthout the UV?

A In North Amerıca?

Q Okay

A No

Q No So all FreshLook Colors lenses

that were manufactured, to be sold in North America, were UV

A Yes

Q And then underneath that, there's a symbol that says "Rx only " What does that mean?

A That this is a medical device, and this is to be sold by prescription only

Q And did -- is it your understanding -- is there a law that requires that symbol on this package?

A The law requires us to either put that symbol, or the -- there's a longer statement

Q Do you know the wording of the longer statement?

A I'd be guessing, but it's, "This device is to be sold under prescription," or -- I'd have to look at it I don't have it memorized

Q Are you aware that that other longer statement, used to be on the FreshLook Colors packet, a couple years before this?

A Yes

Q Do you know why the decision was

Page 80

that thıs ıs what we wanted to do

Q Do you know of any reason, from your experıence, the FDA would not allow you to do that?

A No

Q I was askıng you a bunch of questıons earlıer ın the deposıtıon about the dangers of wearıng contact lenses, about beıng properly fıtted, or wıthout the warnıngs

Do you remember that?

A Uh-huh

Q The dangers, you know, of wearıng contact lenses wıthout beıng properly fıtted, or wıthout the proper warnıngs, ıs the same whether the lens ıs plano, or correctıve, correct?

A Correct

Q And ıt's your understandıng that the ıssue of color contact lenses beıng sold wıthout a prescrıptıon ın the beauty supply stores, and all those places that we talked about earlıer -- those are plano color lenses, correct?

MS WILSON Objectıon

THE WITNESS That's my

understandıng

Q (By Mr Rawl) Mıne too

And do you know when CIBA Vısıon fırst got notıce that theır plano color contact lenses were beıng sold wıthout a prescrıptıon, and wıthout the warnıngs?

A When ıt fırst happened?

Q Yes

A I don't know that

Q Do you know -- can you tell me the earlıest year that you are aware that CIBA Vısıon was aware of ıt?

A That I was aware of ıt? 1999

Q Okay And to your knowledge, the practıce ıs stıll goıng on today

A That's my understandıng

Q When dıd CIBA Vısıon fırst become aware that the FDA was treatıng plano color contact lenses as cosmetıcs, and not medıcal devıces?

MS WILSON Objectıon

THE WITNESS It was that ımport notıce Import detentıon notıce I don't know the date

Q (By Mr Rawl) Do you know, were

Q Do you have a copy of this in your office?

A On file somewhere I'm sure, yes

Q Would this be something that would be kept in the ordinary course of the business of CIBA Vision?

A This would be -- yes

Q All right

MR RAWL Plaintiffs move to admit Exhibit 5

Q (By Mr Rawl) And I believe we said earlier that the contact lens at issue in this case is a plano colored contact lens intended solely to change the appearance of the normal eye in a decorative fashion

A Yes

Q And you would agree that the plano color contact lens at issue in this case is intended to be introduced into the eye for the purpose of either beautifying, promoting attractiveness, or altering the appearance

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) And you were aware that CIBA Vision has advertised these plano

stıck ıt ın your eye to change the color of your eye, correct?

MS WILSON Objectıon

THE WITNESS There are other reasons for that It's not the specıfıc reason

I guess ıt ıs the specıfıc reason, but you -- yes

Q (By Mr Rawl) Changıng focus for just a lıttle bıt, wıth regard to the -- well, let me just ask you --

MR RAWL Mark thıs as the next number, please

(Exhıbıt-6 was marked for ıdentıfıcatıon)

Q (By Mr Rawl) Tell me when you're ready

A Ready

Q Can you tell me what Exhıbıt No 6 ıs?

A It's a package ınsert for FreshLook lenses

Q And thıs ıs -- do you know what date thıs ınsert was used?

A July of 2003

Q (By Mr Rawl) How do you know?
A How do I know that thıs ıs a real -- thıs ıs the real document?
Q Yes
A It has our part number, ıt descrıbes our -- our lenses
Q So thıs ıs a -- Exhıbıt No 6 ıs, agaın, the -- ıs ıt a pamphlet? ıs ıt a folded-up pamphlet? ıs ıt front and back sheet?
A Thıs --
Q How ıs ıt normally gıven to the doctor?
A Just lıke ıt ıs
Q Just lıke ıt ıs, okay And thıs ıs supposed to be gıven by the doctor to the patıent?
A It's at hıs dıscretıon, yes
Q Okay And CIBA Vısıon drafted thıs document
A That's correct
Q And thıs was pursuant to a, what? -- a PMA supplement --
A Yes
Q -- that asked for the approval of

Page 90

this language?

A Yes

Q And so CIBA Vision determined that these were the warnings that they thought the wearers of their contact lenses should be made aware of, correct?

A Yes

Q They sent it to the FDA, and the FDA agreed

A Yes

Q And the warnings that CIBA Vision believes that individuals who wear their contact lenses, whether plano or corrective, should be aware of, are in that warning box on the front page?

MS WILSON Objection

Q (By Mr Rawl) Or are they some of the warnings?

A Yes

Q And I hate to do this to you, and I apologize in advance But would you please read the warnings that CIBA Vision thinks that all people who wear their contact lenses should be made aware of, that are written on this page?

beauty claims being made in the advertisements with the general risk associated with the use of the contact lenses

MS WILSON Objection

THE WITNESS That is what this document says, yes

Q (By Mr Rawl) And you -- and that's CIBA Vision's position, correct?

MS WILSON Objection

THE WITNESS That's my understanding, yes

Q (By Mr Rawl) Okay On Page 5 of Exhibit 2, under the "General Balance and Risk Statement" section, CIBA Vision is suggesting that for ads for color contact lenses that are not promoting a wearing indication, and not promoting UV claims, the fashion or beauty message in that case would not be health oriented, and is a perfectly balanced with a general risk statement to consumers to see an eye care professional to obtain lenses

Is that what CIBA Vision is suggesting?

A Yes

Q And CIBA Vision is suggesting

that -- just paraphrasing, they're not saying, in the advertisement, that they're talking about the UV benefits, then they don't have to talk about the UV risks, is that correct?

A That's correct

It's not a risk -- I should clarify That's not a risk, it's a warning

Q Warning, okay And in the same ads that they're referring to in that statement, what does it mean when CIBA Vision says that "for color contact lenses that are not promoting a wearing indication"?

A The wearing indication would be daily wear, or extended wear

Q So in other words, CIBA Vision, in this document, is talking about ads that just promote the beauty aspect of wearing color contact lenses

A FreshLook contact lenses, yes

Q Are all FreshLook contact lenses colors?

A No

Q You have some clear ones?

A Yes

Q These advertisements are only about

Q And are you also not familıar wıth the cease and desıst letters that have been sent out?

A Familıar? No

Q You're aware they have been sent out, but that's about the extent of ıt?

A That's correct

Q Do you have any ıdea how many have been sent out?

A No

Q Do you know ıf CIBA Vısıon has taken legal actıon agaınst anybody, other than that one lawsuıt that we looked at earlıer?

A I don't know

Q Wıth regard to FreshLook Colors contact lenses that have a power, that are not plano, how dıd they get approval by the FDA?

A All contact lenses, ıncludıng plano, were approved by the FDA ın the PMA process

Q For the FreshLook Colors, how does that work? Do all of the PMA supplements relate to FreshLook Colors, or ıs there a certaın PMA supplement that relates to FreshLook Colors?

A I belıeve -- unless ıt's specıfıed

Page 152

were attemptıng to ıntroduce plano lenses ınto the market?

A Yes

MR RAWL Object to the form

THE WITNESS Yes

Q (By Ms Wılson) Had the lenses that the foreıgn manufacturers were submıttıng ınto the market, had those been approved through a PMA process, to your knowledge?

MR RAWL Object to the form

THE WITNESS It ıs my understandıng that they have not

Q (By Ms Wılson) Okay Have FreshLook contact lenses been approved through a PMA process?

MR RAWL Object to the form

THE WITNESS Yes

Q (By Ms Wılson) Is ıt your understandıng that pursuant to that PMA process, that FreshLook contact lenses are medıcal devıces?

MR RAWL Object to the form

THE WITNESS Yes

Q (By Ms Wılson) Have you ever receıved any notıfıcatıon from the FDA that

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Business & Technology Innovation
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Mr Timothy Ulatowski
Director Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2094 Gaither Road
HFZ 300
Rockville MD 20850

9 December 2003

Dear Mr Ulatowski,

This correspondence is being sent as a follow up to the meeting held between representatives of CIBA Vision Corporation and CDRH on November 21 2003 As an outcome of that meeting CIBA Vision agreed to provide

1 An outline of the reasoning behind our position on the advertising and promotion of FreshLook contact lenses and rationale for why full application of restricted device information is not appropriate

2 A rationale behind the pending request for use of the term breathable on package labeling Specifically provide
a) data to show consumers correctly understand the usage of the term
b) a proposal for how FDA might define the term and
c) a mock-up example of how the descriptor would appear on the carton

3 A copy of the SOP for complaint handling and data for major products combining technical and medical complaint history

4 A copy of the lawsuit currently being pursued by CIBA Vision against an Atlanta based beauty chain

Following are the responses numbered according to the above items

1 A summary of our position appears below and an outline is provided of our reasoning to support this position (attachment 1)

CIBA Vision believes that the intent behind restriction of UV blocker containing contact lenses such as FreshLook was for the specific purpose of ensuring that the benefits of UV protection were not over stated in promotional initiatives Specific balancing statements were developed between FDA and industry to be used in the event that claims regarding UV efficacy were made In the case of FreshLook there are no UV claims being made in our current promotional initiatives (print or broadcast) The UV absorbing monomer is listed in the appropriate ingredients sections of the product labeling and the UV technical data note and warning appear throughout the labeling where appropriate In the absence of such claims we feel it would be inappropriate and potentially confusing to include the balancing information for UV protection

Plaintiff's Exhibit
2

Alexander Gallo & Associates, Inc.

CIBA Vision does acknowledge that a general risk statement such as Contact lenses even when used to change eye color should only be worn under the supervision of an eye care professional would better balance the beauty claims being made in the promotion of the product

2 a) As support for our position that consumers understand the term breathable contact lenses CIBA Vision pulled data from our 2002 NIGHT & DAY Positioning Study which was

- Conducted among 100 current soft contact lens wearers in U S (Chicago and San Francisco) and 100 current soft contact lens wearers in Europe (UK & Germany)
- Interviewer administered face to face interview among qualified consumers in each country
- Qualified respondents were consumers between the ages of 18 and 39 who currently wear soft contact lenses

In the study respondents were shown a written concept of the product and asked a series of questions including the following open ended question

' The name of these lenses includes the words Ultra-Breathable What does the term Ultra Breathable mean to you?"

The verbatim responses were coded and the results which follow clearly show that consumer link the term ultra breathable to oxygen flow to the eye

	U S	EUR
Let s in more oxygen/Allows maximum amount of oxygen in/ Allows air to circulate under lenses/Eyes can breathe/ Eyes won t dry out	87%	93%
Contact is better for your eyes/safer	10%	2%
Contact is better product than other contact brands/superior product	6%	6%
Contacts won t dry out	4%	1%
Not irritating/not burning your eyes/ not sore	2%	%
Can wear them for a long time/continuous wear	2%	%
Easy/convenient to wear	1%	7%
Comfortable to wear/light on my eyes/not having anything on my eyes/lightweight	%	6%

2 b) FDA has determined that in order for a contact lens to be eligible to be considered for IDE approval for clinical studies for continuous wear up to 30 nights the Dk/t for the candidate lens must exceed a threshold of 87 This is the value determined in the well known Holden/Mertz research which approximated the same degree of corneal swelling after sleep as no lens at all[1] By setting this entry criteria FDA has legitimized a minimum standard for this wearing modality The use of the term breathable to describe this attribute is a necessary mechanism to communicate the benefit in consumer friendly terms

2 c) A sample mocked up NIGHT & DAY carton to include the descriptor Breathable Contact Lenses is included with this correspondence (Attachment 2)

3 As requested by Ms Betty Collins copies of three Corporate Policy SOP s are provided at this time They cover Customer Complaint Handling (QM 13 002) Adverse Events/Incidents (QM 13 003) and Global Complaint Management System (QM 13 004) In addition there are charts covering all additional high volume complaint rates and top 3 complaint reason codes for the year 2003 to date All rate data is expressed in terms of complaints per million lenses sold Additional CIBA Vision product complaint information regarding Specialty lenses Lens care products or Surgical products were not requested but are available (Attachment 3)

4 A copy of the lawsuit filed by CIBA Vision against an Atlanta based beauty chain is included in this correspondence (Attachment 4)

Thank you for the opportunity to meet with you and your colleagues As discussed in the meeting we feel that decisions on the first two matters are time sensitive and necessary to maintaining a level playing field We look forward to your response

Best Regards

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joe foos@cibavision novartis com

Cc

Dr James Saviola ODE
Ms Betty Collins OC
Mr Ronald Swann OC
Ms Deborah Wolf OC
Ms Colleen Klasmeier HHS Office of General Counsel

[1] Holden B Mertz G Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses IOVS 1984 25 1161 1167

Attachment 1
CIBA Vision positioning – advertising and promotion of Freshlook contact lenses

Per prior discussions and presentation materials from our meeting with the Agency on November 21 2003 below is an overview of key points regarding advertising and promotion of FreshLook lenses

Proposal

- The UV risk disclaimers are appropriate when UV claims are included in product Ads
- For Ads lacking a UV claim include a general balancing risk statement in both print and broadcast ads

Regulatory Discussion

1 Regulation of devices vs drug products

Consistent with the overall framework for regulation of medical products CIBA Vision believes that a contact lens as a medical device or as a cosmetic in general involves less risk to public health and safety than do drug products and therefore direct to consumer advertising (DTC) of contact lenses should be subject to less advertising and promotional restrictions than for drugs At minimum the same DTC opportunities afforded drugs should be offered for devices

1 1 Agency consideration Keeping in mind device specific differences adapt the concepts of drug DTC advertising opportunities such as major statement limited risk information for promotion of limited indications and reminder Ads

2 Contact Lens Classification

Although historically contact lenses have been regulated as medical devices under Class II Premarket notification 510(k) for daily wear or Class III Premarket approval (PMA) for extended wear requiring a valid a prescription currently plano color contact lenses have received a cosmetic designation

This creates the following inconsistencies across the broad contact lens category

- Oversight will vary from FTC to FDA
- Restrictions will vary based on device class
    - Subject to general rules or restrictions for labeling only (Class II/DW)
    - Subject to restricted device status for DTC advertising and promotion (Class III/EW)

2 1 Agency consideration Except for the differences in rates for daily vs extended wear the same types of concerns and risks apply to any contact lens The concerns being the same unless extended wear is specifically being promoted ads for color contact lenses should default to general requirements for a medical device (and/or cosmetic)

3 Restricted Device Status

While all contact lenses are prescription devices[1] not all contact lenses are restricted in terms of advertising and promotion[2]

- To date there has not been a regulation designating any contact lenses as restricted A prescription is required per approval orders or clearance letters
- Selective assignment of restricted device status for some class III PMA contact lenses
  - Distinctive and different wording in PMA approval orders understood to mean different levels of restrictions
  - Historical promotional practices provides precedence for interpretation of different levels of restricted device status
- For UV containing daily wear lenses UV note warning & technical information required for labeling not advertising or promotional materials

3 1 Agency consideration The underlying purpose of UV Warning restrictions is to control advertising so that Ads do not imply a misleading interpretation of public health benefit Regardless of device classification or cosmetic designation **when Ad is silent for UV claims UV information is not required**

4 General Balancing Risk Statement

For Ads for color contact lenses that are not promoting a wearing indication and not promoting UV claims the fashion or beauty message in this case is not health oriented and is appropriately balanced with a general risk statement to consumers to see an eye care professional to obtain lenses

4 2 Agency consideration CIBA Vision agrees a balancing risk statement such as the example below is appropriate for a fashion oriented TV ad[3]

℞only

- Contact lenses even when used to change eye color should only be worn under the supervision of an eye care professional[4]

1 Assumes Agency authority to require a prescription for plano cosmetic contact lenses per FR notice (Vol 68 No 65 Fri April 4 2003)

2 As historically practiced by the Agency recognized by the industry and detailed in the Hutt, Peter B Merrill Richard A Food and Drug Law Cases and Materials 2nd ed (University Casebook Series) New York The Foundation Press Inc 1991 Chapter 6 page 787 *Accordingly the requirements for labeling and advertising for restricted devices under section 502 (r) remain inoperative except as FDA has made them conditions of approval of individual Class III devices* In addition as recently as July 2002 CLI worked with Jim Saviola to confirm the requirements of 502(q) and (r) will not routinely be incorporated into approval orders for 6 night extended wear contact lenses

3 Unlike competitor print ads CIBA Vision already includes a message of this type with Rx Only symbol in all it s FreshLook print advertising

4 If the Agency considers essential an additional risk statement about safety and if applied across the lens category to all manufacturers an additional risk statement such as Serious eye health problems may occur" would be considered

5 Consistent implementation and requirements for restricted device information for color contacts across the contact lens industry

With varying levels of restrictions across the contact lens category (different device classes for daily and extended wear contacts with cosmetic designation for plano color lenses) a situation exists where print or broadcast ads for color contacts could be appearing in the same magazine or airing on the same TV programs some containing no or minimal restrictions such as Rx Only while others potentially containing a full brief summary (intended use warnings precautions side effects etc)

This situation could create the potential misleading impression by consumers that some but not all color contacts have special safety concerns This also puts manufacturers at a seemingly unjustified competitive disadvantage when their products have already been subject to a higher level of testing and Agency evaluation via the Class III PMA path

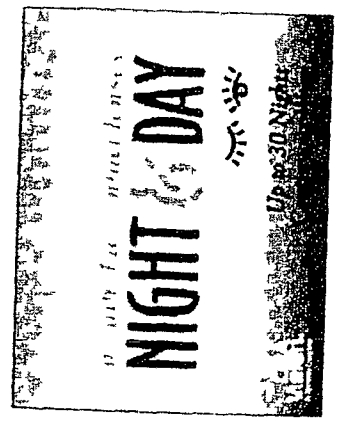
5 1 Agency consideration

In order to ensure consistent messages to consumers and maintain a level playing field among manufacturers it is requested that requirements for restricted device information for color contacts be consistently applied and implemented throughout the contact lens industry[5]

Until resolution of this issue is obtained and modifications if any can be incorporated into the TV Ad CIBA Vision would like to resume airing of the existing FreshLook TV commercial

5 As mentioned in the November 21 meeting competitor TV Ads have been appearing prior to and after the FreshLook Ad and not containing any risk information or the Rx Only symbol as required by 801 109

Attachment 2
Mock Up of NIGHT & DAY® carton with "breathable contact lenses"



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Quality Policy

Document Title CUSTOMER COMPLAINT HANDLING		Document No QM 13 002 Revision 4
Quality Module 13 Control of Nonconforming Product		
Originator Mike Henry	*Approved & Released Quality Policy*	Effective Date 03/21/2003

OVERVIEW

This document describes the requirements regarding customer complaints of CIBA Vision products Receiving, processing, trending, failure investigation, corrective and preventive actions are addressed in this policy

1 PURPOSE

Customer complaint investigation and analysis is required to determine if product designs, manufacturing and quality control specifications, are meeting customer needs

2 SCOPE

This policy applies to all CIBA Vision R&D, Manufacturing Distribution and business management areas who receive or become aware of customer dissatisfaction with CIBA Vision products

3 REFERENCES

- Quality Policy #QM-02 002 'Definitions"
- Quality Policy #QM–13-001 Control of Non-Conforming Product"
- Quality Policy #QM–13-004, 'QUARTS"
- Quality Policy #QM 14 001, Product Recall'

4 ASSOCIATED MATERIALS

- N/A

5 DEFINITIONS

The following key terms within this document are defined in **Quality Policy #QM-02 002, "Definitions "**

- Complaint

6 RESPONSIBILITIES

Each Operational Unit Head, in collaboration with the Quality Systems Representative, is responsible for establishing and implementing local Operational Directives and SOPs and for ensuring compliance with this policy For medical devices all complaints, technical and or medical, must be entered into the CIBA Vision Global Complaint system (refer to **Quality Policy #QM 13 004, "QUARTS"**) For pharmaceuticals all technical and technical complaints with an associated medical complaint must be entered into the CIBA Vision Global Complaint system

7 POLICY

7 1 Business management areas must have documented systems that

- Ensure customer service personnel are properly trained

  Service and respond to all customer complaints in a timely and helpful manner, after a minimum of two attempts at contacting a customer for required additional information a complaint is considered closed

  Identify and distinguish medical (adverse reactions adverse incidents, etc) complaints and product tampering from other complaints (ref **Quality Policy #QM 13-004, "QUARTS"**)

  Document all communications with the customer

  Relay information immediately to the relevant manufacturing site

  Process returned goods per **Quality Policy #QM-13-001, "Control of Non-Conforming Product '**

- Comply with all global and local regulations

7 2 All Manufacturing Units must have documented systems that

- Record the information and take appropriate investigative and corrective action (ref **Quality Policy #QM-14-001, "Product Recall"**) as necessary including notification of regulatory authorities/notified bodies pursuant to local regulations and

approval requirements
- Establish a complaint trending database
- Relay appropriate information to Regulatory Affairs/Medical Affairs
- Supply requested information to business management areas in a timely manner for use in their response to customers
- Involve R&D for applicable technical support

7 3 Global Quality

- Maintain Global Quality systems to provide global information linking between business management areas and manufacturing sites

8 PROCESS

Not applicable at the business management level see local Operational Directives and/or SOPs

9 RECORDS

N/A

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Denise Murrell	Donna Rhoades

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END OF DOCUMENT

CIBA Vision
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CIBA Vision Corporation
Corporate Offices 11460 Johns Creek Parkway Duluth GA 30097 1556

Quality Policy

Document Title ADVERSE EVENTS/INCIDENTS	Document No QM 13 003 Revision 3
Quality Module 13 Control of Nonconforming Product	
Originator Mike Henry	Effective Date 04/23/2002

Approved & Released
Quality Policy

OVERVIEW

This document describes the requirements necessary to fulfill global vigilance investigation and reporting on medical device adverse incidents

1 PURPOSE

The subset of complaints, which encompass a medical/physical reaction by the user must be examined processed and when required by local regulations, must be reported

2 SCOPE

This policy applies to Global Quality and all CIBA Vision, R&D, Manufacturing, Distribution and Sector Company Operational Units This policy applies to all CVC manufactured and contract manufactured medical device products

3 REFERENCES

- Quality Policy #QM-02 002, Definitions
- Quality Policy #QM-13 004 Quality Reporting and Tracking System (QUARTS) "
- Quality Policy #QM-14 001, 'Corrective and Preventive Action
- Quality Policy #QM-16-001, "Record Retention '
- Adverse Incident Reporting Decision Tree

4 ASSOCIATED MATERIALS

- N/A

5 DEFINITIONS

The following key terms within this document are defined in **Quality Policy #QM-02-002, "Definitions**

- Adverse Incident Medical Devices
- Near Incident Devices

6 RESPONSIBILITIES

- **Quality System Representatives of each Operational Unit (in particular Sector Companies)**

Responsible for establishing and implementing appropriate Operational Directives and/or SOPs and for ensuring compliance with this policy

- Responsible for actual adverse event/incident reporting and monitoring The responsible Manufacturing Operational Unit is also required to develop and implement corrective actions associated with the affected product, when applicable **(Ref Quality Policy #QM-14-001, "Corrective and Preventive Action ")**

7 POLICY

7 1 General

- All medical device adverse incidents or suspected adverse incidents must be entered in the QUARTS system (CAMIS for US adverse incidences) (Ref **Quality Policy #QM-13-004, "Quality Reporting and Tracking System QUARTS ")**
- Countries without a connection to **"QUARTS"** must make the preliminary categorization of the adverse incident The next step is to complete an incident form as detailed by the local directives and fax it directly to Global Regulatory Affairs and the manufacturing operational unit if known

7 2 Examples of Adverse Incidents for Devices include but are not limited to

- Impairment of Body Function

- Permanent decrease in visual acuity

- Permanent Damage to Body Structure

Central corneal opacities (central 4mm)

- Central corneal neovascularization (central 4mm)

- Conditions Requiring Medical Intervention to Preclude Permanent Damage or Impairment

  - Infectious corneal ulcers

    Central corneal ulcers

  - Endophthalmitis

  - Macular edema

  - Hypopyon

- Persistent epithelial defect

  - A response to a medical product which is noxious and unintended

7 3 Additional requirements include

- A **"complaint file"** containing records of any information (written and oral) concerning the adverse incident The complaint file should contain

  - A copy of all adverse incident or medical device report(s) submitted to regulatory bodies (national or international) if event was determined to be reportable

    Any relevant additional information associated with the incident such as complainant survey or questionnaires

  - Results of the adverse incident (complaint) investigation

  - Any corrective and preventive action associated with the adverse incident

  - A rational signed by the responsible Quality Systems representative, if there was not an investigation and/or corrective action

    If a reply was not given to the complainant, the reason **"why"** must be documented

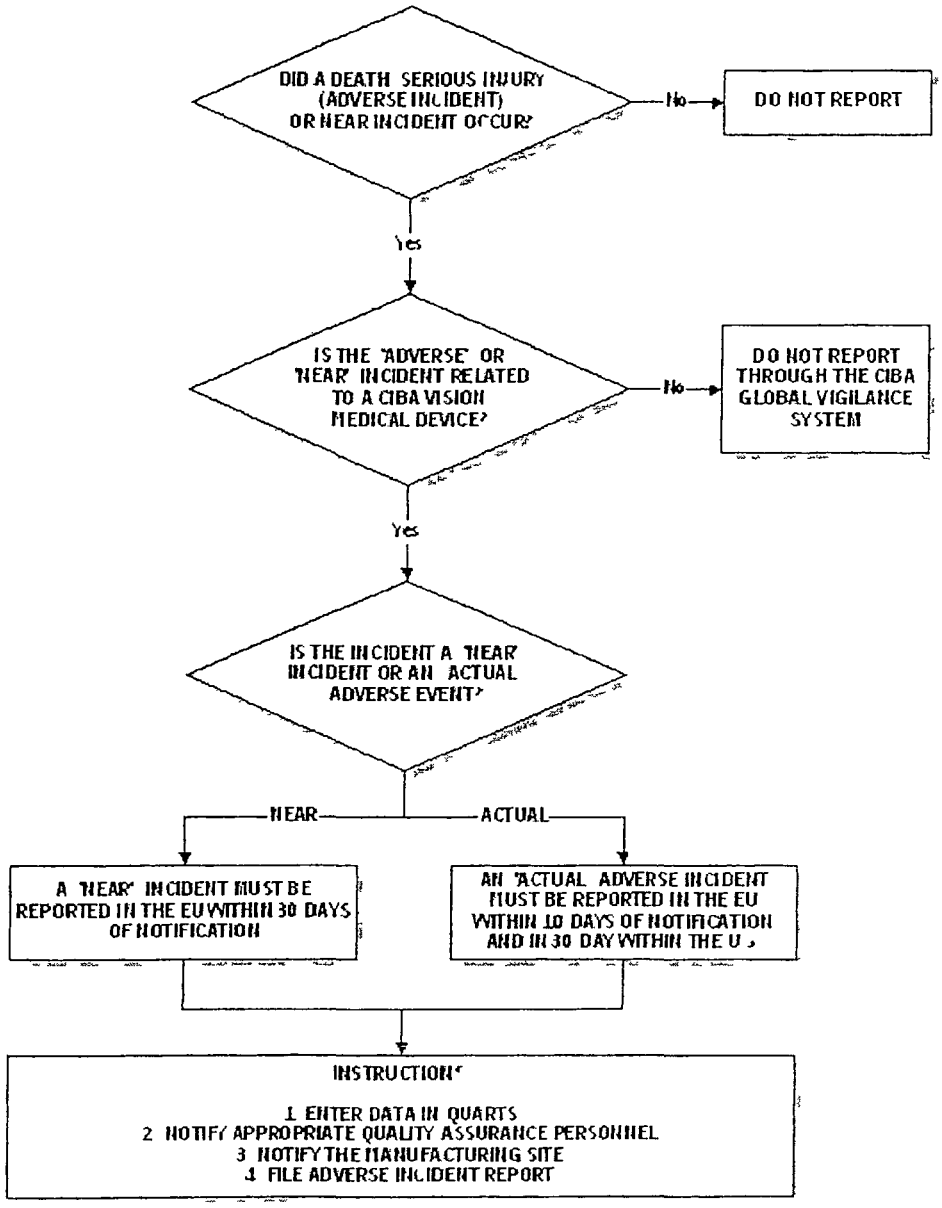
- An adverse incident file must be readily available
- The adverse incident file (a complaint file) must be retained by

the appropriate personal (or manufacturer) for a period not shorter than 10 years (**Ref Quality Policy #QM-16-001, "Record Retention"** for additional information)

- The Manufacturing Operational Unit (of the affected product) must retain a copy of the complaint file (if not the original)

8 PROCESS

MEDICAL DEVICE REPORTING DECISION TREE



9 RECORDS

N/A

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Quality Policy

Document Title **GLOBAL COMPLAINT MANAGEMENT SYSTEM (GCMS)**	Document No QM 13 006 Revision 0
Quality Module 13 Control of Nonconforming Product	
Originator Mike Henry	*Approved & Released Quality Policy* Effective Date 05/16/2003

Overview

This document describes the global requirements responsibilities and systems used by CIBA Vision to manage product-related customer complaints and adverse incidents

1 PURPOSE

To ensure that customer complaints are properly documented, investigated and analyzed to determine if product designs, manufacturing and quality control specifications are meeting customer needs

2 SCOPE

This procedure applies to all Operational Units involved in the data entry, investigation, analysis reporting and general management of CIBA Vision product-related complaints

3 REFERENCES

- Quality Policy #QM-02-002, Definitions
- Quality Policy #QM-14-001, Corrective and Preventive Action
- Quality Policy #QM-14-002, "Product Recall '
- Quality Policy #QM-16-001 "Record Retention '

4 ASSOCIATED MATERIALS

- QM 13 006 Att I Rev 0 doc
- QM 13 006 Att II Rev 0 xls
- QM 13 006 Att III Rev 0 doc

- Attachment I, "Complaint and Verification Codes "
- Attachment II, Standard Trend Chart – Example '
- Attachment III, "Global Complaint Organization Diagram '

5 DEFINITIONS

The following key terms within this document are defined in **Quality Policy #QM-02-002, "Definitions "**

- **Complaint** A complaint is any written, verbal or electronic expression of dissatisfaction with the identity quality, stability reliability, safety, effectiveness or performance of a CIBA Vision product
- **Global Complaint Management System (GCMS) -** A Lotus Notes based electronic system used to capture and store CIBA Vision's global product complaint records and cumulative data
- **Unauthorized Seller -** Any unapproved or unlicensed distributor/seller of CIBA Vision medical device products
- **Product Verification** - The inspection measurement or analysis of returned product, associated with a complaint performed to determine if the product is **"in or out '** of specification
- **Adverse Incident** - Medical Devices An Adverse Incident for a medical device is defined as an incident in which the device has led to a death or serious deterioration in the state of health of a patient user, or other person or could lead to such consequences if it happened again A serious deterioration in state of health can include life-threatening illness or injury, permanent impairment of a body function or permanent damage to a body structure or a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure
- **Complainant** - The person or business entity initiating a customer complaint
- **Traceability Number** - A unique number used to identify a specific type and quantity of product and allow traceability back to the manufacturing records Commonly used CIBA Vision terms include Lot #, Batch # Serial # and ML #

6 RESPONSIBILITIES

CIBA Vision utilizes a **"hub and spoke"** approach for capturing and managing product complaints on a global scale At the hub is the Scientific Affairs Department - Global Quality Systems group This group is the Global Designated Complaint Unit for all product related complaints The spokes include Global Regulatory Affairs Country Sales and Marketing (Group Companies) Manufacturing QA and Product Verification Centers These are the support Designated Complaint Units for product related complaints See **Attachment III** for a general diagram of the above-described organization Responsibilities are as follows

- **General**

- Each department, unit or group involved in the complaint handling process will ensure that appropriate Standard Operating Procedures (SOPs) are established for the specific activities they perform in support of this global procedure

- **Global Quality Systems (GQS) – Complaint Unit**

  - Establishes global complaint requirements and procedures

  - Application owner for the electronic Global Complaint Management System (GCMS) used to capture and store global complaint information

  - Ensures GCMS meets all applicable Computer System Validation and Change Control requirements

  - Provides GCMS training and consultation to the support units

  Maintains and updates the various GCMS application databases (product lists complaint codes, etc)

  - Maintains a list of GCMS users and documentation of training provided

  - Reviews and closes all Complaint Records requiring verification and/or any other investigational activity

  - Provides global complaint trend data to management and recommends CAPA when applicable

  - Initiates potential recall investigations based on specific complaint data or events

  - Periodically audits the overall complaint management process to ensure compliance and identify improvements

- **Global Regulatory Affairs (GRA)**

  - Utilizes GCMS to manage all Potential Adverse Incident events This includes ensuring that all available information is obtained, initiating investigations, obtaining professional/medical input and documenting findings/conclusions In addition, GRA personnel along with the extended network of international regulatory affairs personnel report Adverse Incident events to applicable Regulatory Authorities as required

  Establishes an appropriate Adverse Incident Committee (made up of Medical/Clinical/Compliance experts) to review and determine a final classification for all Potential Adverse Incidents

Closes all Reportable Adverse Incidents (Z code) Complaint Records

- **Country Sales and Marketing (Group Companies)**

  - Appoints or assigns a qualified person to be responsible for site (local) complaint management activities

  - Ensures that complaint entry personnel are properly trained on the use of the GCMS and that training documentation (proof of training) is maintained

  - Receives complaints and enters all applicable information into GCMS

  - Forwards product received with a complaint to the appropriate Verification Center per the GCMS procedure

  - Communicates to Sales Reps and Accounts CIBA Vision s policies/procedures for obtaining accurate and timely complaint data

  Provides accounts with approved GCMS complaint Reason Codes when using complaint returns/credit forms or equivalent

  - Contacts accounts when complaint procedures (use of forms) are not followed or when unusual quantities of complaints are received from an individual account

  - Ensures compliance with GCMS procedures, this includes writing supporting procedures when additional local instructions are required

- **Manufacturing QA**

  - Responds to requests for complaint related investigations Enters findings into GCMS

  - Initiates potential recall investigations when appropriate

  - Monitors and analyzes complaint trends for the products produced at their site

  - Manages CAPA activities initiated from complaint data/events

- **Product Verification Centers**

  - Receives reported defective product from the Country Sales and Marketing units and verifies via inspection, assay and/or measurement if the product in question is in or out of specification

- Enters all verification findings into GCMS per procedure

- Ensures verification personnel are properly trained and qualified to perform required activities and that appropriate verification (inspection) SOPs are established in accordance with manufacturing QA

- Destroys all verified product in accordance with approved product destruction procedures

- **Global Lotus Notes IT**

- Appoints a Content Owner to provide technical support to the Application Owner and global users

- Ensures the Lotus Notes Network meets all applicable Computer System Validation (CSV) requirements including 21 CFR, part –11 and Change Control

Populates the Customer Account Contact source data as requested

- Performs periodic archiving of GCMS Complaint Records as defined in this procedure and **Quality Policy #QM-16-001, ' Record Retention "**

- **Global Recall Coordinator**

- Responds to GCMS- initiated potential recall events per **Quality Policy #QM-14-002, "Product Recall "**

7 POLICY

7 1 General Complaint Information/Requirements

7 1 1 Complaint Sources/Timing Product complaints can originate from many sources including eye care practitioners consumers, distributors, hospitals, etc and it is CIBA Vision s responsibility to ensure that all product complaints are properly documented and responded to in a timely manner **The company target (goal) for completing a complaint, from receipt to closure, is 30 days**

- It is also CIBA Vision's responsibility to act upon any allegations of **"unauthorized"** selling of CIBA Vision products Complaints received that provide any reasonable indication of unauthorized selling activity should be

promptly communicated to the Corporate Legal Group in Atlanta This indication should also be captured as described in **Section 8 1 1 – Step 3**

7 1 2 Quality of Data In addition to the initial (short term) handling of a complaint – providing credit replacement product, etc – the longer term **"preventive"** activities are ultimately the most important outcome of any complaint management system Accomplishing this more difficult challenge will require the involvement and support of many CIBA Vision functions and the "customers' themselves

- The key to preventing product complaints begins with an accurate understanding of what is liked and/or disliked about the products being sold With the exception of isolated incidents, most product quality or performance issues cannot be resolved based on a single complaint only Most issues will require trending and analysis of complaint data (over time) to identify deficiencies and to justify product improvement initiatives This is where quality of data becomes so important
- The following "Do s and Don'ts are provided to help ensure that CIBA Vision obtains the most accurate and complete product complaint data possible

- Do

- Obtain as much data as possible concerning the complaint, i e lot #, complaint reasons, circumstances, etc , and follow up with the complaint source when necessary to obtain required information Also, obtain perceived defective product for analysis, if available

- Contact the complaint source for more information when an unusual situation occurs, i e a distributor returns a large quantity of product with minimal or no complaint reason information such as Defective Product written on the box
- When using customer Returns/Complaint/Credit forms, make sure only the approved GCMS complaint codes are utilized
- Tactfully enforce the use of Returns/Complaint/Credit forms and the adherence to company policy by the Customer
- Enter all complaints into GCMS on a timely basis – day of receipt is preferred
- Notify the Global Quality Systems (GQS) – Complaint Unit if you believe there is a problem with the system that is affecting the accuracy of the data
- Be reasonable with your expectations concerning what GQS and/or Manufacturing can and cannot do about your specific customer complaints Although there are exceptions, remember that most of the time, trend data and not individual events will drive corrective action See **Section 8 3** for additional complaint trending information

Don t

- Don't use the complaint system to help a customer get credit Find a better way to satisfy your customers' needs
- Don t bypass GCMS with e mails or phone calls

concerning customer complaints Always use the complaint system
- Don't enter non-pertinent subjective information or opinion in Complaint Records
- Don't interface GCMS to any other electronic system without prior approval from the Global Change Review Board

7 1 3 Corrective and Preventive Action (CAPA) The initiation of complaint related CAPA will be driven from two (2) main sources – specific events and trend analysis The following describes each and provides general CAPA requirements

7 1 3 1 Specific Events A specific complaint event that (based on internal investigations) reveals an inadvertent breach in compliance and/or the release of nonconforming (out of specification) product will require assessment by the Global Recall Committee (GRC) CAPA recommendations will be made by the GRC to Executive Management and a final CAPA decision made See **Quality Policy #QM-14-002, "Product Recall,"** for details All (non-potential recall) CAPAs will be processed per local CAPA systems or equivalent

7 1 3 2 Trend Analysis Complaint trend data will be presented during Management Reviews CAPA initiatives (based on complaint trend data) will be documented in the Management Review minutes and processed per local CAPA systems or equivalent

7 2 General GCMS Information

7 2 1 System Access GCMS is a secured system with limited and controlled access There are three (3) levels of access that will be provided on a "need to have basis

- Reader Access – Read only capability can view existing records/data
- Editor Access No Delete – Create and/or edit a Complaint Record, but cannot

delete a record
- Editor Access – Create, Edit and Delete capabilities (for GCMS monitors only)

There are three (3) basic requirements for obtaining access rights to GCMS

- The person must be a CIBA Vision employee and have access to a server with Lotus Notes R5 software – third party contract manufacturers are not permitted access
- The request must come (via e mail) from the Site Complaint Manager (the person responsible for the complaint activities at the requesting site) to the GCMS Administrator This correspondence will be used to update the master user list
- A qualified GCMS Global Complaint Monitor must train the person receiving the access All training will be documented and maintained at both locations – local and Atlanta

NOTE Please allow approximately one (1) week processing time (includes scheduling and performing the training) when adding a user to the system

7 2 2 Data Access GCMS cumulative data can be located through either the GCMS **"view"** functions or the GCMS Reporting tool All GCMS data is considered **"confidential"** and should only be viewed on a **"need to know"** basis Although the **"view"** functions are currently not electronically restricted (if you have system access, you have **"View"** access) the following electronic restrictions have been established for the GCMS Reporting tool These restrictions should also be followed for the [View] function

- Global Quality Systems – Complaint Unit and Global Regulatory Affairs will have unlimited access to all global data
- Country Sales and Marketing Groups (Group Companies)

will have access to all complaint data associated with their specific country(s)
- Manufacturing QA will have access to all complaint data associated with the products they manufacture This includes contract-manufactured product they are responsible for

The GCMS Administrator will provide **"Reporting Access"** upon request from the site Complaint Manager (the person responsible for complaint activities at the requesting site) Again reporting access should be limited to those employees who need this data to perform their jobs

7 2 3 Installing GCMS Main and GCMS Reporting

7 2 3 1 Installing GCMS Main Once **"GCMS access"** has been granted - Open Lotus Notes from your desktop Click on [File] – [Database] – [Open] Use the Server keyword option to choose the appropriate server for your applicable location/site The database path can be accessed by double clicking the following files CV\FUNCTION\GQA\GCMS – [GCMS Main] Then click [Open] This will open the software and apply a shortcut icon to your desktop for future access *Contact your local IT group if there is a problem with this application*

7 2 3 2 Installing GCMS Reporting To install GCMS Reporting you must first install GCMS Main per the above instructions Once installed, select the [Reporting browser] option from the GCMS [Main Menu] (left side) This will **"open"** your Intranet browser and bring up a sign in security window Enter your workstation User Name and password Contact your local IT Group if there is a problem with this sign-in function When complete, save this address in your browser [Favorites] This will allow you to open the Reporting function from your browser without having to open GCMS Main

7 2 3 3 Since GCMS Reporting exports data to MS Excel, you will need to enable your browser to perform this function To do this open your

[Browser] select [Tools] then [Internet Options] In the Internet Options window, select the [Security] tab and then click the [Custom Level] button This will open the [Security Settings] window Enable all [ActiveX] controls and click the [OK] button to close *Again, contact your local IT group if there is a problem with this application*

7 2 4 Databases The GCMS consists of eight (8) unique but interrelated software applications and/or databases with specific functions as described below

7 2 4 1 Main The Main database is where the Complaint Handling 'data entry' software resides This includes the Complaint Record, Adverse Incident Report and Viewing Functions *All approved users can access this database, some restrictions apply see* ***Section 7 2 2***

7 2 4 2 Central Control The Central Control database is designed to maintain keyword lists to use as lookup tables in other databases within the system The database contains information including but not limited to Action Codes Countries Manufacturing Sites Product Categories Reason Codes and Reason Detail Codes *Access is limited to the Global Quality Systems – Complaint Unit GRA and Global Lotus Notes IT*

7 2 4 3 Product Information The Product Information database is designed to store product information such as Product Categories, Product Names (descriptions), Parameters, and Manufacturing Units *Access is limited to the Global Quality System – Complaint Unit, GRA and Global Lotus Notes IT*

7 2 4 4 Summary The Summary database is designed to store **"sales"** information (units sold) by Country, Product and Period *Access is limited to the Global Quality Systems – Complaint Unit and Global Lotus Notes IT*

7 2 4 5 Reporting The GCMS Reporting software is an Intranet browser-based Reporting tool that will import data from GCMS to an Excel spreadsheet for complaint trend analysis All approved users can access this database, some restrictions apply – see

7 2 4 6 Archiving GCMS Complaint Records and associated data will be maintained in the main database for a period of two years after which they will be stored in the archive database and maintained per **Quality Policy #QM-16-001, "Record Retention "** *Access is limited to the Global Quality Systems – Complaint Unit and Global Lotus Notes IT*

7 2 4 7 Customer The Customer database stores the individual country **"account lists"** used to improve the efficiency of entering the [complaint source] information into a Complaint Record This is an optional feature and must be populated with assistance from Global Lotus Notes IT *Access is limited to the Global Quality Systems – Complaint Unit and Global Lotus Notes IT*

7 2 5 GCMS Main Page Viewing the Main Page requires obtaining access and installing GCMS on your personal workstation as previously described The main page provides the following basic user information and the [Main Menu] or starting point for all GCMS functions

7 2 5 1 Overview The GCMS is a comprehensive electronic complaint-handling system developed specifically for managing technical and medical complaints associated with any of CIBA Vision s products The ultimate purpose of this system is to monitor customer perceived quality and, where applicable, drive product improvement activity

7 2 5 2 Security GCMS is an electronically secured system with limited and controlled access If someone else at your site needs access, please contact the GCMS Administrator for assistance

7 2 5 3 Change Control All system changes, including electronic interfaces, require approval via the Global Change Review Board

7 2 5 4 Disclosure The data contained within this system is considered **"confidential"** and should not be disclosed to unauthorized external parties Disclosure within CIBA Vision should be handled on a need to know basis

7 2 6 Main Menu The [Main Menu] is located to the left of the screen and consists of the following features

7 2 6 1 Create a New Complaint As the title suggests this is where you start to enter a new complaint into the system

7 2 6 2 View Existing Complaints Start here to find existing Complaint Records or review complaint data Sub categories have been added to help expedite your search GCMS has been designed to allow sorting and viewing of data in many different ways Although some basic guidelines have been provided, for best results you will need to familiarize yourself with this section by exploring the various possibilities and deciding which ones best suit your needs The **"best"** way will depend on what you are actually looking for and what information you have i e a specific Complaint Record Summary data Complaints by lot #, etc

7 2 6 3 GCMS Reporting (browser) The GCMS Reporting function allows you to export GCMS data, via your Intranet browser to an Excel spreadsheet for graphing and analysis Much like the "View section, the Reporting system was designed to provide significant flexibility in selecting and sorting data Again, basic guidelines have been provided, but due to the many reporting possibilities this function will also require some self-exploration to find out what works best for your specific needs

NOTE To provide global consistency a "standard format" for reporting complaint trend data to management (Management Reviews) has been established and is defined in Section 8 3

7 2 6 4 Help Section See 'Help Feature in **Section 7 3 1 2**

7 3 General Complaint Information

7 3 1 Complaint Record Format The GCMS Complaint Record has been designed in a tabular format which guides you through a logical sequence of information-gathering steps When creating a new record, always start with the first tab, working from left to right You can open and/or return to any tab by clicking on it The tab sequence is as follows

Contact Product Complaint Communication Returns Verification Manufacturing Close Edit

7 3 1 1 Each tab is explained in detail in **Section 8 1**

7 3 1 2 Help Feature A general (all instructions) [Help] link is located in the [Main Menu] and should be used for overall training and to ensure compliance Each tab also has a [Help] link located to the far right of the screen Use this to locate user instructions for that specific tab The User Instructions provide the detailed step by step procedural requirements necessary to properly use the system

7 3 1 3 Required Fields Fields marked with a "red arrow ← " are required fields that must be completed before moving on to the next tab or exiting a record If not completed, you will be prompted (reminded) of the error and taken back to the required field(s) in question For best results check to make sure that all required fields are completed before moving on to the next tab

7 3.1 4 Computed Fields Some of the Complaint Record fields are designed to **make decisions"** and/or automatically populate other fields based on the information you have entered These are called computed fields For example, by entering specific complaint Reason Codes, the system will automatically require you to perform additional tasks such as initiating an Adverse Incident Report or verifying returned product For a calculated field to work, you must first click out of the field you are in You click out of a field by clicking into another field Clicking into the next logical (sequential) field is the best approach

7 3 1 5 Entering Information Information can be entered into the individual fields by typing **"text"** via the keyboard or selecting from a **"pull down"** list using a mouse The most efficient method will depend on the type of information being entered and the skills of the individual users Although GCMS has been designed to minimize **"scrolling"** through large pull down lists, additional efficiencies can be gained by using Lotus Notes standard keyboard shortcuts such as entering a **"key"** letter

to help narrow the search For additional shortcuts, look under **"Accessibility"** in the Lotus Notes **"Help"** Section (not GCMS 'help") or contact your local Notes IT representative for additional user assistance

7 3 1 6 Saving a Complaint Record The [Save and Next] link was designed to **"save time"** by allowing the user to carry over key tab information from the Complaint Record being **"saved"** to the next record being "started' When you click the [Save and Next] link, a **"tab transfer list"** will appear Select the tabs you want transferred and click the [OK] button This will **"open"** a new Complaint Record complete with the tab information you selected This feature is most useful when multiple complaints have been received from one customer

- The [Save and Exit] link will save the completed record and return you to the [Main Menu]
- The [Cancel] link can be used at any time during the process to terminate (cancel) an activity or the entire report prior to being saved

7 3 1 7 Complaint Record Identification Number When a new Complaint Record is opened a **"New Complaint Number (#)"** will be generated automatically and displayed at the top of the record This twelve (12) digit number is established based on the date and time the record is created A three (3) digit country abbreviation is added to this number once the country (where the complaint originated) is selected To minimize the chances of creating duplicate complaint numbers, the date/time stamp is carried out to the exact second the record is created

Example GER021024133456

This record was created for a complaint in Germany on the 56th second of the 34th minute of the 13th hour of the 24th day of the 10th month of the year 02

7 3 1 8 Customer Databases Customer databases

were developed to improve the efficiency of entering the 'complaint source" information into a Complaint Record This is accomplished by establishing an account list in the Customer database To obtain this feature for your country, contact the Global Lotus Notes IT group in Atlanta Once established, it is the responsibility of the individual countries to provide periodic updates to Global Lotus Notes IT

7 3 2 Types of Complaints and Levels of Investigation GCMS was designed to handle many different types of complaint situations, from routine complaints to serious medical events Each complaint received must be evaluated and a level of investigation determined The level of investigation must be commensurate with the seriousness of the complaint and the type of information available

7 3 2 1 To provide global consistency when determining the appropriate level of investigation, GCMS was designed to (in most cases) evaluate the seriousness of the complaint, the availability of key information and compute the necessary investigation levels Seriousness is derived from the complaint Reason Codes stored in the database What types of investigational activity are possible is determined from two key information fields traceability # and returned product received Together this data can be used to make the following key decisions

1 Verify Returned Product

2 Initiate a Manufacturing Investigation

3 Initiate a Potential Recall Investigation

4 Initiate a Adverse Incident Investigation

5 Combinations of 1, 2 3 & 4

7 3 2 2 Selecting the most appropriate complaint codes and obtaining as much information as possible is extremely important to the overall accuracy of the system

7 3 2 3 The above described decision process can be found in **Attachment I**

8 PROCESS

8 1 GCMS - Complaint Entry Instructions

Creating a New Complaint Clicking on [Create a New Complaint] from the [Main Menu] will open a new Complaint Record Notice that the first tab [Contact] opens automatically to get you started

8 1 1 Contact Tab

- Purpose The purpose of this section is to collect complaint source information i e country of origin complainant name, address phone #, etc
- User Restrictions/Training Requirements None / General GCMS Complaint Entry Training

- **Step 1** Select the country where the complaint originated by clicking the mandatory [Select Country] link This will open a pull down list Scroll or use a **"key"** letter to locate the appropriate country Highlight the country by clicking it and complete the selection by clicking the [OK] button Shortcut Double clicking the selection from any pull down list will perform the same function as the [OK] button The country abbreviation will automatically be added to the complaint number and the [Country] fields will also be populated

Step 2 Manually enter all [Complaint Source] information available Space has been provided for secondary and additional contacts, such as, a second office location or patient information Patient information should always be pursued for Minor Medical and Potential Adverse Incident complaints

- For those countries with **' customer databases"** there are two options for completing the [Complaint Source] information

- If you know the account number, enter it into the [Account Number] field, click out of that field and the [Complaint Source] fields will populate automatically

Click on the **"magnifier"** icon located next to the [Account Number] field This will bring up your [Customer Account] list from the database Select the appropriate account and double click it or click the [OK] button to populate the [Complaint Source] fields

NOTE The "magnifier" will only be visible after the country is selected and only if you have a customer database set up in the system See Section 7 3 1 8 for more information

Step 3 Enter or select the [Contact Type] by either typing in the text field or using the pull down list provided

NOTE The pull down list includes a [Consumer - Unauthorized Purchase] category Use this when there is reasonable indication that the product (associated with the complaint) was purchased from an "unauthorized seller", i e beauty salon, convenience store, flea market, etc As previously mentioned in Section 7 1 1, all indications of unauthorized selling activity should be communicated to Corporate Legal – Atlanta

Step 4 Use the [Pending Contact] feature, located at the bottom of the page, when further information or product from the complainant is required If selected, the Complaint Record will remain [Open] and in a [Pending Contact] status When all pertinent information has been obtained or if after two attempts information has not been provided, manually change the status by deselecting the [Pending Contact] feature All requests (letters phone calls, faxes etc) to obtain information or returned product must be documented in the [Support Documentation] field in the [Complaint] tab, this includes the number of attempts made to obtain information All letters and faxes (sent and/or received) must be scanned and electronically attached in this field Phone correspondence such as **"left a message with or spoke with the technician (name) concerning the complaint "** should also be documented via text entry

NOTE When the [Pending Contact] feature is utilized the system will automatically send an e-mail reminder to the originator stating that the complaint is [Open – Pending Contact] and needs to be reviewed for possible closure

This completes the [Contact] information section Open the [Product] tab to continue

8 1 2 Product Tab

- **Purpose** The purpose of this section is to capture all available information concerning the product associated with the complaint i e product name traceability numbers, parameters, etc
- **User Restrictions/Training Requirements** None / General GCMS Complaint Entry Training

- **Step 1** Enter or select the [Product Category] by either typing in the text field or using the pull down list provided There are currently three product categories available LP (Lens Products) LCP (Lens Care Products) and RSP (Refractive Surgical Products)

- **Step 2** Select the [Product Name] by using the pull down list provided The product database contains only the official **"global"** product names If the local product name is different (same product - different name) make sure to enter the appropriate **"global"** name

NOTE When steps 1 and 2 are completed, two automatic functions take place

- The selected [Product Category] and [Product Name] will be displayed in **RED** just above the row of tabs This has been done to provide a visual reference of this information after the [Product] tab is closed
- The required parameter fields appear, based on the product selected For products with limited parameters, some of the actual values will be populated automatically Parameters will not be requested for Lens Care Products (LCPs) since they are included in the product names, i e AOSept Plus, 120 ml

Step 3 For a product made at more than one manufacturing site, you will be prompted via a pull down box to identify the appropriate site This prompt will take place when you

attempt to enter the next field (parameters or lot #) If the manufacturing site information is not available, select [Unknown] from the list Manufacturing site information, for products made at only **"one"** site, will be populated for you automatically

- **Step 4** For parameters that are not populated automatically, enter the appropriate values by either typing in the text or using the pull down lists provided The [Power] field is a **"text"** field only and requires a (+ or) sign to be accepted If you forget to enter a (+ or) sign you will be prompted to fix it when you attempt to save' the record Also remember to enter parameters with appropriate decimals, i e base curve 8 60 or diameter 14 50

- **Step 5** Enter the manufacturing traceability number **"Lot #, ML # or Serial #"** in the appropriate field if known This is a very important number and should be obtained whenever possible

NOTE The default for this field is [Lot #] but will change to [ML #] for Wesley Jessen Specialty lenses and to [Lot/Serial #] for Surgical products Most WJ Specialty lenses have two traceability numbers on the label (Lot # and ML#) Enter only the ML# when both exist If there is no ML#, enter the Lot #

Multiple traceability numbers are acceptable but must be separated by a comma when entered

Multiple traceability numbers should 'only be entered when the following criterion is met

- They must all be from one (1) Complaint Source
- They must all have the same Complaint Reason Code
- They must all be the same Product

If **"all"** the above criterion is not met, then a separate (new) Complaint Record must be created

- Because this is a mandatory field type in the

word **"unknown"** if a traceability number is not available Shortcut - enter the letters **"unk"** in the [Traceability] field When you click out of this field, the word **"unknown"** will be automatically populated

- **Step 6** Enter the [SKU] (Stock Keeping Unit) # when available

This completes the [Product] information section Open the [Complaint] tab to continue

8 1 3 Complaint Tab

- Purpose The purpose of this section is to capture all available information concerning the reported complaint, including the complaint description dates, quantities and support information
- User Restrictions/Training Requirements None/ General GCMS Complaint Entry Training

- **Step 1** Enter the appropriate complaint [Reason Category] from the pull down list or by entering the corresponding letter (A, B, C X Y, Z) which will bring up the category you want to enter The six (6) Reason Categories to remember are

A Product Design/Performance
B Product Quality
C Package/Label Quality
X Minor Medical
Y Potential Adverse Incidents
Z Reported Adverse Incidents (for use by GRA personnel only)

- **Step 2** Enter the appropriate [Reason Detail] using the pull down list If the appropriate [reason detail] description is not available from the pull down list select '99 other describe" and complete the [Other/Describe Details] field This field appears only when **"99 other-describe"** is selected

IMPORTANT NOTE If you want to initiate an Adverse Incident Investigation select the **"Y"** category –Potential Adverse Incidents and the appropriate Reason Detail All initiating Adverse Incident events start as Potential Adverse Incidents and are reclassified after the investigation to either a **"Z"**- Reported

Adverse Incidents or a "**X**"- Minor Medical complaint, depending on the event details and/or investigational results Selecting the **Y"** category will bring up an 'action window prompting you to answer three (3) questions Your answers will determine if an Adverse Incident Report is required If a '**Yes**" decision is calculated a [**Create Adverse Incident Report**] link will appear at the top right of the screen To proceed, complete all mandatory Complaint Record fields and then click the link to create a report See the Adverse Incident Report, **Section 8 2** of this procedure for specific instructions

NOTE If you accidentally select the "Z" category to enter a Potential Adverse Incident, the system will automatically re-direct you to the "Y" category

- If a **"No"** decision is calculated the link will not appear and you should continue with the Complaint Record, selecting the appropriate category

- The [Reason Detail] field is a **"computed"** field designed to make decisions based on the codes selected and several other factors

NOTE Many of the decisions starting from the [Detail Reason] field will only be seen in the Verification or Manufacturing sections Again, these computed decisions are described in Attachment I

When steps 1 and **2** of this section are completed, the selected Complaint Category and Reason Detail will be displayed in **RED** just above the row of tabs The combination of the Reason Category and the Reason Detail is the Reason Code Again - this has been done to provide a visual reference of this information after the [Complaint] tab has been closed

Step 3 Enter the date the complaint or incident actually happened in the [Date of Occurrence] field If this date is not available click the [Unknown] box

Step 4 The [Date Complaint Received] field will be populated automatically with the date the Complaint Record was created If the actual date the complaint was received is different than this date, delete it and enter the correct date

Step 5 Enter the number of **"reported"**

defective product associated with this complaint, in the [Reported Defective Product] field

Example A customer or consumer initiates a complaint and reports that three (3) lenses from a **" 30 pack of Focus Dailies"** are believed to be defective Based on this example, you would enter three (3) into the [Reported Defective Product] field

The total **"returned"** quantity may be greater than (3) The actual quantity returned, which in this example could be a maximum of (30) is entered in the [Quantity Received for Verification] field in the Verification Tab –see **Section 8 1 6 - Step 1**

Step 6 The [Complaint Detail] section is used to capture all additional information (details not previously documented) that may help clarify a complaint This section is also used to capture **"requests"** made to the complainant for additional information There are two features in this **Section – 1**) Prior Entries and **2**) New Entries When creating a new record enter all information in the [New Entry] field Additional entries to an existing record are also made in the [New Entry] field If you are viewing an existing record **"Prior Entries'** will be visible here You can edit prior entries by clicking the [Edit Prior Entry] link

NOTE If you selected the [Pending Contact] feature in the [Contact] section you would use this field to enter the details of that action, i e who was contacted, how they were contacted (letter, phone, fax, e-mail) what information was requested, etc If written correspondence is used, attach an electronic copy in the [Support Documentation] field, see next step

Step 7 To attach an electronic document in the [Support Documentation] field click the [Attach File] link located to the far right side of the record This will bring up the [Create Attachment(s)] window from your computer workstation Locate the appropriate file/document and click the [Create] box The selected document will now be attached and

visible in the [Support Documentation] field

This completes the [Complaint] section Open the [Communication] tab to continue

8 1 4 Communication Tab

- Purpose The purpose of this section is to capture communications sent back to the complaint source concerning actions' resulting from the complaint, i e credit, replacement letter, etc
- User Restrictions/Training Requirements None / General GCMS Complaint Entry Training

- **Step 1** Select the appropriate 'action" from the [Action] field pull down list

- **Step 2** Use the [Comments/Support Documentation] field to enter text comments or to attach electronic documentation sent to the complainant To attach a document in the [Support Documentation] field, click the [Attach File] link located to the far right side of the record This will bring up the [Create Attachment(s)] window from your computer workstation Locate the appropriate file/document and click the [Create] box The selected document will now be attached and visible in the [Comments/Support Documentation] field

- This completes the [Communication] section Open the [Returns] tab to continue

8 1 5 Returns Tab

- Purpose The purpose of this section is to capture information about product returned in association with a complaint
- User Restrictions/Training Requirements None / General GCMS Complaint Entry Training

- Instructions for personnel who perform **"Complaint Entry Only"** If you enter complaints but **'do not"** perform product verification (inspection), follow these steps

- **Step 1** Upon opening the [Returns] tab you will see two fields – [Product Received Y/N] and [Product Verification Required] The [Product Verification Required] field will always open with a **"no'** decision next to it If product associated with the complaint, was returned, select **"Yes"** from the [Product Received] field If returned product is not available select **"No"** To activate this computed field, click on the [Click here to continue] link which will initiate the decision making process Based on information previously entered, the system will now determine if Product Verification is required

- If the Product Verification Required decision is **"No"** you have completed the complaint entry for this record and can move on to **Step 4** now

- If the Product Verification Required decision is **"Yes"** you have additional activities as the following new fields will appear [Date Product Received] and [Send Product for Verification to]

- **Step 2** The [Date Product Received] field will default to the date the Complaint Record is being created If the actual date the product was received is different than the default date, enter the correct date now

- **Step 3** The [Send Product for Verification to] field will provide the location and address where the returned product must be sent for verification inspection Label the product (to be sent) with the Complaint # obtained from the top of the Complaint Record The Verification Center will need this number in order to locate the record and add their verification findings Also, if you would like to be notified of specific verification results submit a written request (a post-it note will do) along with the product being sent

IMPORTANT NOTE Although you have completed your part of the complaint

entry process, remember it is also your responsibility to ship the returned product to the Verification Center To ensure that Complaint Records are completed in a timely manner all product must be shipped on a weekly basis and should take no longer than one (1) week to be received by the Verification Center In other words, two (2) weeks total for collecting and shipping is the required time frame for getting product to the Verification Centers As previously stated, the product must also be properly labeled (identified) with the Complaint Record number The Verification Center turn around time goal will be =10 working days from the day of receipt

Step 4 Click the [Save & Next] or the [Save & Exit] links located at the top left of the record

- As previously mentioned, the [Save and Next] link was designed to (save time) by allowing the user to carry over key tab information from the Complaint Record being **"saved"** to the next record being '**started"** When you click the [Save and Next] link a **"tab transfer list"** will appear Select the tabs you want transferred and click the [OK] button This will open a new Complaint Record complete with the tab information you selected This feature is most useful when multiple complaints have been received from one customer

The [Save and Exit] link will save the completed record and return you to the [Main Menu]

Additional Instructions for personnel who perform both Complaint Entry and Product Verification Activities"

Follow all previous instructions with the following exceptions

- If the Product Verification Required decision is **"yes",** open the Verification Tab to continue
- Since you will be performing the actual verification inspection, disregard the collection and shipping instructions (**Step 3**)

8 1 6 Verification Tab

- Purpose The purpose of this section is to capture the product verification results when

product is returned in association with a complaint Product verification is performed to determine if the returned product is 'in or out of specification

- User Restrictions/Training Requirements For use by Verification Center personnel only General GCMS Complaint Entry Training, including the Verification Section and additional training on product quality inspection is mandatory

NOTE Upon opening the Verification Tab you will see a repeat of the [Product Verification Required] field To continue, this must be showing a "yes" decision

- **Step 1** Enter the quantity of product received (returned by the complainant) in the [Quantity Received for Verification] field Enter only individual units, not packs

See **"example"** in **Section 8 1 3 – Step 5** for clarification between **"Quantity Reported Defective"** and **"Quantity Received for Verification"**

Step 2 Enter the workstation number, if applicable

Step 3 Perform the required routine inspections/assays or measurements per approved SOP Guidelines for what verification activities are required can be found in Attachment I For complex events or non-specific complaint codes, including **"Other – Describe"**, the type of verification (inspection) required must be determined by the verification personnel or other technical experts This decision should be made with a focus on determining if the product in question could have caused the event/complaint, i e if the complaint is for **"poor optics"** there is no need to inspect the product for non-optical criteria Specific cases may require additional (non routine) analysis If you are unsure how to proceed, contact the Global Quality Systems Complaint Unit who will direct you to the appropriate technical/

medical expert for consultation

Step 4 To enter your verification results use the [Click Here to Enter Verification Details] link This will open a [Verification Detail] window with the following self explanatory fields

- Lot # (text field)
- Package Status (open unopened)
- Verification Result (in spec, out of spec)
- Finding Code (pull down list)
- Additional Comments (text field)

Although not highlighted, all fields except [Additional Comments] are mandatory fields and must be completed As with all other mandatory fields the system will prompt you to complete any missing fields when you attempt to leave this window

NOTES

- **If the [Traceability #] (Lot, ML or Serial) is not available, enter "unknown" in this field**
- **Select the [Finding Code] that best describes the verification result**
- **If an appropriate Finding Code is not available, select "other-describe" and describe the finding in the [Additional Comments] field**
- **If the product is found to be "in spec" the (No Defect) Finding Code will be selected automatically and entered in the results section**
- **At the bottom of this window are three (3) buttons - Another, Done and Cancel Use these buttons to 1-proceed to the next entry, 2 to complete the entry or 3-to terminate this activity**

When each entry is completed, the verification details (lot #, package status, results, code, additional measurements/ comments) will be shown as a **"line item"** in the ' blue section of the [Verification Results] field Each line item will represent an individual verification entry Repeat the process until all returned product has been verified To edit or delete a previous entry double click on the [line item] and select the [edit] or [delete] button from the action window that appears Make your changes and **"save"** the

new entry

NOTE After creating or modifying (editing) verification results, click the [click here to continue] link This will "refresh" the system and initiate further decisions based on verification results

NOTE The number of verification entries must match the [Quantity Received for Verification] quantity, i e if you received three (3) lenses for verification you must enter three (3) verification results Again, the system will automatically prompt you if there is a discrepancy between these two fields

Step 5 The [Additional Analysis Required] field can be used whenever routine analysis is believed to be insufficient The need to perform additional analysis may require consultation from R&D, Manufacturing or Scientific Affairs As previously mentioned, if you are unsure about the need for additional analysis, contact the Global Quality Systems – Complaint Unit who will direct you to the appropriate technical/medical expert for consultation

If you select **"Yes"** to [Additional Analysis Required] two (2) additional text fields will appear [Describe] and [Analysis Results] Use the [Describe] field to document what additional analysis is required The [Analysis Results] field is used to document the findings/results of the analysis

Additional analysis performed by R&D will be requested via the internal work request system - PDRS Results (analytical reports) will also be documented in PDRS R&D will notify the GQS – Complaint Unit, via e mail when an analysis is complete Included in this e-mail will be the associated Complaint # and the PDRS # GQS will review the analytical results and either request additional information and/or enter the PDRS # in the [Analysis Results] field (of the associated complaint record) for future reference

NOTE If the R&D work request system – PDRS – is NOT utilized, analytical report(s) can be attached per the following instructions

To attach an electronic document in the [Analysis Results] field, click the [Attach File] link located to the far right side of the record This will bring up the [Create Attachment(s)] window from your computer workstation Locate the appropriate file/document and click the [Create] box The selected document will now be attached and visible in the [Analysis Results] field

NOTE The [Additional Analysis Required] field defaults to the "No" position if not utilized

Step 6 The Verification Summary section performs two functions Out of specification results are totaled and displayed for reference purposes, and clicking the [Verification Complete] "Yes' box documents completion of the verification activities

NOTE Failure to complete (click) the [Verification Complete] Yes" box will result in the Complaint Record remaining in the Pending Verification Status Remember to click the "Yes" box when you have completed all verification activities Also remember that the number of verification results entered must be the same as the number in the [Quantity Received for Verification] field

This completes the standard verification activities, click the [Save & Next] or the [Save & Exit] links

Additional instructions for verifying product received from countries other than the US (applies to the US Verification Center only)

Step 7 Receive the product and locate the Complaint #(s) Open or go to the GCMS [Main Menu] As mentioned in the general section on Views, there are many different ways to find a specific record One of the quickest ways is as follows

Under the [View Existing Complaints] section in the [Main Menu], click [Complaints] and then click [by Complaint Number] Click the search icon (magnifying glass) located in the top right tool bar Type in the Complaint # in the "search for" field and click the [Search] button This will locate the Complaint Record The record can also be found in the [Pending Verification] view located in the Action List Once found open the record by double clicking on it Open the [Verification] tab and follow steps 1 – 6 above

Step 8 If the country of origin specifically requested notification of results, click the [Save and Exit] link, which will open an e-mail [Notification] window Use the [To] field to locate the complaint originator s e mail address and click [OK] to send The e mail will included the following standard message Verification has been

completed on the complaint referenced above (complaint # will be provided automatically)

NOTE When verifying product for the US or if notification was NOT requested, click "cancel" to bypass this e-mail notification step

This completes the [Verification] section Return to the [Main Menu] to continue

8 1 7 Manufacturing Tab

- Purpose The purpose of this section is to capture manufacturing investigation results and provide a mechanism for initiating potential recall investigations when required
- User Restrictions/Training Requirements For use by Manufacturing QA personnel only / General GCMS Complaint Entry Training, including the Manufacturing Section

NOTE A manufacturing investigation and completion of this section will only be required when specific complaint criteria and a traceability # (lot, ML, Serial) are entered into a Complaint Record (Again, see decision-making criteria outlined in Attachment I) When a "yes" (manufacturing response required) decision is calculated or manually entered, an e-mail notification will be sent automatically to the manufacturing QA representative responsible for the product in question Included in this e mail will be the associated complaint number or direct link If a direct link is provided, use this to open the record If a complaint number is provided, but no link, then proceed to step one To manually initiate a manufacturing response, contact a GCMS administrator

Step 1 To locate the Complaint Record in question, go to the GCMS [Main Menu] As described in the general section on Views, there are many different ways to find a specific record One of the quickest ways (if you know the complaint #) is as follows

Under the [View Existing Complaint] section in the [Main Menu], click [Complaints] and then click [by Complaint Number] Click the search icon (magnifying glass) located in the top right tool bar Type in the Complaint # in the [Search for] field and click the [Search] button This will locate the Complaint Record The record can also be found in the [Pending Manufacturing] view located in the Action List Once found, open the record by double clicking on it Open the [Manufacturing] tab to continue

Upon opening the [Manufacturing] tab you will see that the first two

fields [Manufacturing Response Required] and [Responsible Manufacturing Site] are already populated This is done automatically by the system when a manufacturing response is requested – automatically or manually

Step 2 Complete the [Investigation Activities/Results] field by entering **"what"** will be investigated and the subsequent **"findings/results"** of the investigation Although the extent of an investigation may vary, at a minimum the following reviews will be performed and documented

- Review of the Device History Record (DHR) for possible process discrepancies
- Review of Non-conforming Product Records
- Review of Complaint Records for additional occurrences and/or 'lot specific" indications

Step 3 Add any pertinent support documents to the [Support Documentation] field To attach an electronic document click the [Attach File] link located to the far right side of the record This will bring up the [Create Attachment(s)] window from your computer workstation Locate the appropriate file/document and click the [Create] box The selected document will now be attached and visible in the [Support Documentation] field

Step 4 The [Potential Recall] field is both a calculated and manual entry field Again, based on specific complaint criteria the system will automatically request a potential recall assessment, by sending an E-mail notification to the Global Recall Coordinator This request can also be initiated manually by the Manufacturing QA Representative by using the [Override Recall] link Clicking the [Override Recall] link will change the [Potential Recall] field from No to Yes and the e-mail notification will be sent automatically when the record is saved

Step 5 CAPA initiated from a specific (Potential Recall) complaint event will be documented in the Complaint Record by the [Potential Recall] field entry and the e-mail notification sent to the Recall Coordinator CAPAs that are not Potential Recalls should be recorded in the [Investigation Activities/Results] field

Step 6 Complete the Manufacturing Section by clicking the [Yes] box after the [Manufacturing Response Complete] field

8 1 8 Close Tab

- Purpose The purpose of this section is to determine and document the final status of the original complaint received
- User Restrictions/Training Requirements For

use by Global Regulatory and Global Quality Systems personnel only General GCMS Complaint Entry Training including the Close Section and Complaint Verification/Investigation requirements

Complaint Records will be **"closed"** when all available information has been obtained and all applicable verifications and/or investigations have been completed This includes Complaint Records where CAPA has been initiated Complaint Records will not be kept open until the completion of any associated CAPA activities All CAPA activities will be processed per **Quality Policy #QM-14-001, "Corrective and Preventive Action,"** and/or the local manufacturing site CAPA systems

The final status of a complaint will be designated as either Verified or Unverified based on available information Determining the appropriate status will require (with the exception of Type #1 Complaints - see below) the review and assessment of the information provided within the Complaint Record

The following guidelines will be utilized for determining the final status

Type 1 complaints Complaints with no available traceability number or returned product will be automatically categorized as Unverified (no Global Quality System review is necessary) and will include the following standard closure statement

"Insufficient information prohibits any further investigation of this complaint This record is considered closed "

All other complaint types will be closed with the following standard closure statement

"This complaint has been investigated in accordance with CIBA Vision policy and is considered closed "

NOTE Standard closure statements can be edited as appropriate to clarify any given situation

Other complaint types

- Complaints with returned product that is verified, but no defects or out of specification (OOS) conditions are found will be categorized as **Unverified**
- Complaints with returned product that is verified and the verification results provide a reasonable degree of proof that the product in

question was defective and/or OOS and could have caused the complaint, will be categorized as **Verified**

- Complaints with a traceability number and no returned product, but due to the seriousness of the complaint (potential mixed product, tampering, non-sterile or mislabeled) a manufacturing investigation was initiated, but no nonconformance(s) are found will be categorized as **Unverified**
- Complaints with a traceability number and no returned product, but due to the seriousness of the complaint (potential mixed product, tampering, non-sterile or mislabeled) a manufacturing investigation was initiated, and a nonconformance is found that could have caused the complaint, will be categorized as **Verified**
- Potential Adverse Incidents that are upgraded to a **"Z"** - Reportable Adverse Incidents, will be categorized as **Verified**

During the review process it may become necessary to obtain additional information / clarification, concerning the complaint and/or the investigation The reviewer can utilize the [Resubmit] link to perform this task

This completes the Close section

8 1 9 Edit History Tab

- Purpose The purpose of this section is to provide a documented history of key data entries including dates names and changes (edits) made to the Complaint Records
- User Restrictions/Training Requirements N/A - This is an automatic function

NOTE All changes (edits) will be captured and documented upon re-opening a previously closed record The name(s), date(s) and actual change(s) will be recorded in this section To edit a Complaint Record use the [Edit] link (located at the top left) after you have located and opened the record from the [View] section

In addition to the above edit history criteria the following key entries are maintained prior to closure

- Sent to Verification Site (Name and Date)
- Verification Detail Added (Name and Date)
- Verification Complete (Name and Date)
- Manufacturing Response Complete (Name and

Date)
- Closure (Name and Date)

This ends the process for Product Complaints For instructions concerning Adverse Incidents proceed to the next section

8 2 Creating an Adverse Incident Report (AIR)

A Potential Adverse Incident is any reported "adverse medical condition" believed to be caused by the use of a CIBA Vision product All such reported adverse medical events must be processed via the GCMS Complaint Record and Adverse Incident Report functions

NOTE The AIR is an attachment to the original Complaint Record, not a replacement All mandatory Complaint Record (information) must be completed the same way for an AIR as for a routine complaint

All reported events will be initiated by using the **"Y"** Potential Adverse Incidents category and associated Reason Details located in the Complaint tab section of the Complaint Record All Potential Adverse Incidents are then reclassified after the technical review to either a **"Z'** Reported Adverse Incident or a **"X"** Minor Medical complaint depending on the event details and/or investigational results This reclassification is performed by the GRA – Adverse Incident Coordinator

By entering the **"Y"** codes, the system will automatically prompt you to create an Adverse Incident Report Open the report by clicking on the [**Create Adverse Incident Report**] link located at the right side of the screen and proceed using the following instructions

Creating an Adverse Incident Report As with the Complaint Record the AIR also utilizes a tabular format and consists mostly of self explanatory questions that you will be asking the Medical Professional associated with the incident For technical assistance concerning this activity contact the Global Regulatory Affairs (GRA) group located in the US, UK and/or Germany

8 2 1 CIBA Vision Contact Tab

- Purpose The purpose of this section is to document the name and phone # of the CIBA Vision employee responsible for completing the AIR
- User Restrictions/Training Requirements For use by a qualified Customer Service or

Customer Consultation employee General GCMS Complaint Entry Training, including the AIR section is mandatory

8 2 2 Incident Information Tab

- Purpose The purpose of this section is to document the available information concerning the external contacts, dates and product info
- User Restrictions/Training Requirements For use by a qualified Customer Service or Customer Consultation employee General GCMS Complaint Entry Training, including the AIR section is mandatory

NOTE Some standard information will be automatically exported from the Complaint Record to the AIR

Step 1 Review all exported information for accuracy and make any necessary corrections If you make a change to the AIR you must make the same change to the Complaint Record Complete as many questions as possible and proceed to the [Description of Incident] tab

8 2 3 Description of Incident Tab

- Purpose The purpose of this section is to document the available information concerning the reported medical condition status diagnosis and treatment
- User Restrictions/Training Requirements For use by a qualified Customer Service or Customer Consultation employee General GCMS Complaint Entry Training, including the AIR section is mandatory

Step 1 Obtain answers to all questions possible including hidden questions that appear when a **"yes"** answer is provided Use the [Unknown] fields when information is not available

8 2 4 Incident Tracking Table Tab

- Purpose The purpose of this section is to capture all support documentation (Investigational/test results, communications, etc) associated with the incident
- User Restrictions/Training Requirements For use primarily by Global Regulatory Affairs can also be used by a qualified Customer Service or Customer Consultation employee General GCMS Complaint Entry Training, including the AIR section is mandatory

Associated documents can be attached to the table by using the Lotus Notes "attach file function This can be accomplished via the 'paper clip' icon on the tool bar or through the 'File pull down list

8 2 5 Edit History Tab

- Purpose The purpose of this section is to provide a documented history of key data entries including, dates, names and changes (edits) made to the Adverse Incident Report
- User Restrictions/Training Requirements N/A - This is an automatic function

8 2 6 Additional Instructions for the originator of an AIR

When all available information has been entered into the AIR click the [Send and Save] icon located at the top left side of the screen This will notify the Global Regulatory Affairs Adverse Incident Coordinator that an AIR has been initiated This function will also **"save"** the AIR and change the **[Create an Adverse Incident Report]** link, in the related Complaint Record, to **[View an Adverse Incident Report]** link This is done to allow future viewing of the attached AIR from the original Complaint Record

8 2 7 Instructions for the GRA – Adverse Incident Coordinator

Step 1 Once notified that a new AIR has been created or to open an existing AIR go to the GCMS [Main Menu] As described in the general section on Views, there are many different ways to find a specific record One of the quickest ways (if you know the complaint #) is as follows

Under the [View Existing Complaint] section in the [Main Menu] click [Complaints] and then click [by Complaint Number] Click the [Search] icon (magnifying glass) located in the top right tool bar Type in the complaint number in the [Search for] field and click the [Search] button This will locate the Complaint Record The record can also be found in the [Open Adverse Incident] view located in the Action List or in the [Adverse Incident] View section Once found, open the record by double clicking on it To open the AIR click on the **[View an Adverse Incident Report]** link located on the Complaint Record

Step 2 Review the Complaint Record and AIR for missing/pending information Contact the originator if necessary and follow-up on investigational activities until complete

Step 3 Send e-mail notification to the Adverse Incident Committee soliciting their technical input Attach a copy of (or link to) the

Complaint Record and AIR Once a final decision (medical consensus) is reached, document the decision (including the agreed upon final classification) as concisely as possible in the [Complaint Detail] field located in the [Complaint] tab section of the Complaint Record If the committee s decision is to downgrade the event to a minor medical complaint, a written justification for this decision must be included

Step 4 Since all events are initially entered into GCMS with the **'Y"** - Potential Adverse Incident code, re-coding will be necessary once the final classification is reached Re-coding is performed in the Complaint Record (Complaint tab section) and will update the AIR automatically Select the appropriate codes **'X"** minor medical + reason detail or "Z reportable adverse incident + reason detail

If downgraded to a **"X"** Minor Medical code, save and exit the record This record will be formally **"closed"** by the GQS Complaint Unit

If upgraded to a **"Z"** Reportable Adverse Incident code continue to **Step 5**

Step 5 All (Z)-coded events will be reported to applicable international and/or local regulatory agencies per specific agency requirements All reports/forms submitted and any other pertinent support documentation must be electronically attach to the Incident Tracking Table located in the AIR Use the standard Lotus Notes **' Attach Document** features for this activity

NOTE Due to regulatory agency ' time requirements an initial report may have to be submitted prior to a final classification and/or completion of the AIR process If this occurs, document this correspondence and the reason for it in the Incident Tracking Table

Step 6 When all activities are completed the Complaint Record can be closed Open the [Close] tab and select **"Verified** in the [Closure Status] field Click the [Close] link located at the far right of the screen This will close the record and automatically populate the [Closure Statement] field with the following standard statement

"This complaint has been investigated in accordance with CIBA Vision policy and is considered closed"

NOTE Standard closure statements can be edited to clarify any given situation

8 3 GCMS Reporting

8 3 1 General The GCMS reporting function allows the user to export GCMS complaint data, via a secured Intranet browser, to an MS Excel spreadsheet for graphing and analysis Much like the **"view"** section, the reporting system was designed to provide significant flexibility in selecting and sorting data Again, basic guidelines have been provided, but due to the many reporting possibilities, this function will also require some self-exploration to find out what works best for your specific needs

NOTE For data security purposes, some user restrictions have been implemented See section 7 2 2 for specifics

8 3 2 Standard Reporting To ensure global consistency when presenting routine complaint trend data to management (specifically for Management Reviews), the following reporting standards apply (see example provided in **Attachment II**)

- Reports will be generated by product type generally one per report Multiple products can be run for comparison purposes
- The standard Report Type (data) to be utilized is [Reported Complaints] This is the actual number of Complaint Records created in the system and represents **"all"** complaints regardless of whether the complaint was verified or unverified
- Two reports for each product are required Total Complaints and Top 5 Complaint Reasons These two reports will show the overall complaint trend and the main complaint details driving it
- Reports will be run in Complaints Per Million (CPM) format to account for sales volume
- Where possible a minimum of two years of data should be trended

NOTE The GCMS Reporting page starts with a "check box" titled [Advanced Reporting Options] This is NOT required for standard reporting as described above If you would like to perform advanced or non-standard reporting – click this box For standard reports, start with the default [Reported Complaints] field

8 3 3 Creating a Standard Report (Total Complaints)

Steps

1 Report Type Select [Reported Complaints]

2 Report Layout Select [Product]

3 Report Data Options Select [CPM sales] and [All]

4 Chart Type Select [line]

5 Date Range Select [date range to be reported]

6 Report Title Type the appropriate title i e "Focus Dailies – Total Complaints – Global"

7 Country & Country Groups * Select the specific county or all for a global report

8 Product Category Select the appropriate category [LP, LCP, RSP]

9 Product * Click [Select] and the appropriate product from the list

10 Reason Code Select [All]

11 Reason Detail Select [All]

12 Click the [Build Report] button

13 Click the [Export] button and the Excel chart and/or table will appear

14 Save the chart per normal MS Excel procedure

***NOTE Some restrictions apply, see Section 7 2 2 for details**

8 3 4 Creating a Standard Report (Top 5 Complaints)

Steps

1 Report Type Select [Reported Complaints]

2 Report Layout Select [Reason Detail]

3 Report Data Options Select [CPM sales] and [top 5]

4 Chart Type Select [bar]

5 Date Range Select [date range to be reported]

6 Report Title Type the appropriate title i e Focus Dailies – Total Complaints – Global

7 Country & Country Groups * Select the specific county or all for a global report

8 Product Category Select the appropriate category [LP, LCP, RSP]

9 Product * Click [Select] and the appropriate product from the list

10 Reason Code Select [All]

11 Reason Detail Select [All]

12 Click the [Build Report] button

13 Click the [Export] button and the Excel chart and/or table will appear

14 Save the chart per normal MS Excel procedure

***NOTE Some restrictions apply, see section 7 2 2 for details**

The above two charts can be combined (like the example in Attachment II) or kept separate To combine charts, highlight the data from one of the **"spreadsheets",** click [copy] and then [paste] it onto the **' chart"** of the other

8 3 5 Corrective and Preventive Action (CAPA) Complaint trend data will be presented during Management Reviews CAPA initiatives (based on complaint trend data) will be documented in the management review minutes and processed per local CAPA systems or equivalent

8 3 6 Field Descriptions The following field descriptions will help you understand the available features and can be viewed from the Reporting Screen by clicking any of the "Blue Link" titles

Report Type

Standard Reports

- Reported Complaints – The data in this report type will be based on the actual number of Complaint Records for the criteria that is

specified To be used for all standard trending reports

Advanced Reporting Options

- Verified Complaints – The data in this report type will be based on the actual number of verified Complaint Records for the criteria that is specified This report will only look at Complaint Records that have the value **"Verified"** in the [Closure] field of the Complaint Record
- Unverified Complaints – The data in this report type will be based on the actual number of unverified complaint documents for the criteria that is specified This report will only look at Complaint Records that have the value "Unverified" in the [Closure] field of the Complaint Record
- Reported Defective Product - The data in this report type will be based on the quantity of 'reported defective product' for the criteria that is specified This report looks at the field labeled [Quantity Reported Defective] in the Complaint Record

NOTE A single complaint document may have a quantity greater that one (1) in this field Therefore there is not a one to one relationship between a reported complaint and reported defective product

- Verified Defective Product - The data in this report type will be based on the actual number of verified (out of specification) results for the criteria that is specified Verified defective product is product that was returned in association with a complaint was inspected (verified) and found to be defective
- Manufacturing Investigation Required – The data in this report is based on the quantity of Complaint Records that have the value **"Yes"** in the field labeled [Manufacturing Investigation Required]
- Complaints w/Product Received The data in this report is based on the quantity of Complaint Records that have any number value in the field labeled [Quantity Received for Verification] in the Product [Verification] section

- Complaints w/Lot Numbers - The data in this report is based on the quantity of Complaint Records that have any value in the field labeled [Lot/Serial Number]
- Open Complaints The data in this report is based on the quantity of complaint documents that have any value other than **"Closed"** in the [Status] field

Report Layout

The [Report Layout] selection is basically what you want to appear on the **"Y"** axis of the Excel spreadsheet or chart The only exception to this is when running a "Product" report and selecting "Sales (units) as the [Data Type] option The resulting report will have two **"Y"** axes, one labeled with the product selected and the other labeled as sales This report layout can provide a comparison of the Sales trend Vs the Complaint trend

NOTE All Sales data is in "units sold", not currency

- Product – Report is formatted with respect to the product(s) selected
- Country – Report is formatted with respect to the country(s) selected
- Product Category – Report is formatted with respect to the product category selected (LP LCP, RSP)
- Reason Detail - Report is formatted with respect to the Reason Detail(s) selected
- Reason Code Report is formatted with respect to the Reason Code(s) selected
- Manufacturing Site - Report is formatted with respect to the manufacturing site selected
- Base Curve Report is formatted with respect to the base curve that is selected for the LP product that is selected

Report Data Options

The **"Report Data Options"** shown at any given time are dependent on the [Report Type] that is chosen The first row of values determines what data is actually placed into the Excel spreadsheet

- Number – The total number of Complaint Records for the criteria selected
- % of Sales – A percentage of either **"Number"** or **"Quantity"** based on the total sales of the corresponding report type and criteria selected
- CPM (Sales) – Complaints per million based

on the criteria selected This value is computed based on the # of Complaint Records and the total sales

NOTE The second row of options determines how much data you want to report on

- All – All data is placed in the spreadsheet and no sorting is done over that data
- Top 5 – All data is placed in the spreadsheet and the data is then sorted (most to least) and the first five rows are selected If charting is selected only the top five will be charted
- Top 3 All data is placed in the spreadsheet and the data is then sorted (most to least) and the first three rows are selected If charting is selected only the top three will be charted
- Sales (units) – This option is only available when the [Product] report layout is selected Both product (complaint data) and the product (sales data) are placed in the spreadsheet

Chart Type

- No Chart – The data in the spreadsheet is not charted
- Bar – The data selected in the spreadsheet is placed in a bar chart If the **"Sales"** data option is selected the chart has two axes with both a line and bar element in the chart
- Line – The data selected in the spreadsheet is placed in a line chart If the [Sales] data option is selected the chart has two axes with two line elements in the chart

Date Range

- The Date Range section has a **"From"** and a **"To'** value The dates are programmed to permit a rolling 2 year range

Report Title

- The report title is optional as long as the [Save as a standard report] box is not checked This title will appear on the spreadsheet and, if charting is enabled, at the top of the chart If the checkbox is selected, the title also becomes the name of the standard report and will appear in the view that is contained in the reporting home page

Country & Country Groups

- Select – This option clears out existing selections and allows you to individually select

items Keep in mind that most of the fields allow multiple item selection by using the CTRL and SHIFT keys

- Select All w/edit – This option will automatically select all items in the field It does not lock the field, therefore you have the ability to deselect items by using the CTRL key If you want to select all items in the field, then use the Select All option described below
- Select All – This option will select all items in the field and lock the field from any further selection The major benefit in using this option is that instead of looking at individual records in the corresponding field, it will look at a value that summarizes all the values in the field This provides a significant enhancement in speed

NOTE This option will not be available all the time For example, if the user does not have access to report on the entire list of products, the [Select All] option will not be shown

- The [Country] and [Country Group] fields are linked in that selecting a **'Country Group"** will automatically select the corresponding countries in the Country selection The Country Groups are configurable by the GCMS Administrator Additionally, depending on the report chosen, the list of countries will change based on the product category that is selected The system only shows the countries that have complaints in the database for a given product category instead of showing all countries in the system defined by the Central Control database

Manufacturing Site

This is a list of the manufacturing sites that are available for reporting Select a manufacturing site and product category combination to get a list of products manufactured at that site and to display the Reason Codes and Reason Detail for that category This option is only available when running a manufacturing site report The list may not contain all manufacturing sites due to access restrictions

- Select – This option clears out existing selections and allows you to individually select items Keep in mind that most of the fields allow multiple item selection by using the CTRL and SHIFT keys

- Select All w/edit – This option will automatically select all items in the field It does not lock the field, therefore you have the ability to deselect items by using the CTRL key If you want to select all items in the field, then use the option described below
- Select All – This option will select all items in the field and lock the field from any further selection The major benefit in using this option is that instead of looking at individual records in GCMS for the corresponding field, it will look at a value that summarizes all the values in the field This provides a significant enhancement in speed This option will not be available all the time For example, if the user does not have access to report on the entire list of products, the Select All option will not be shown

Product Category

This is a list of the Product Categories (LCP LP, RSP) that are available for reporting Select a Product Category to get a list of products in that category and to display the specific Reason Codes and Reason Detail for that category

Product

This is a list of the products that are available for reporting based on the product category or manufacturing site chosen You can select one many or all products in the list for most report types The list may not contain all active products due to access restrictions

- Select – This option clears out existing selections and allows you to individually select items Keep in mind that most of the fields allow multiple item selection by using the CTRL and SHIFT keys
- Select All w/edit – This option will automatically select all items in the field It does not lock the field, therefore you have the ability to deselect items by using the CTRL key If you want to select all items in the field then use the option described below
- Select All – This option will select all items in the field and lock the field from any further selection The major benefit in using this option is that instead of looking at individual

records in GCMS for the corresponding field, it will look at a value that summarizes all the values in the field This provides a significant enhancement in speed This option will not be available all the time For example, if the user does not have access to report on the entire list of products, the Select All option will not be shown

Base Curve

This is a list of the Base Curves that are available for product chosen You can select one, many or all products in the list This option is only available for the Base Curve Report layout

Reason Code

This is a list of the Reason Codes that are available for the Product Category at was chosen You can select one multiple or all Reason Codes in the list

- Select – This option clears out existing selections and allows you to individually select items Keep in mind that most of the fields allow multiple item selection by using the CTRL and SHIFT keys
- Select All w/edit – This option will automatically select all items in the field It does not lock the field therefore you have the ability to deselect items by using the CTRL key If you want to select all items in the field, then use the option described below
- Select All – This option will select all items in the field and lock the field from any further selection The major benefit in using this option is that instead of looking at individual records in GCMS for the corresponding field it will look at a value that summarizes all the values in the field This provides a significant enhancement in speed This option will not be available all the time For example, if the user does not have access to report on the entire list of products, the Select All option will not be shown

Reason Detail

This is a list of the Reason Details that are available for the Product Category that was chosen The values in this list are controlled by the selections you make in the Reason Code field You can select

one, multiple or all Reason Codes in the list

- Select – This option clears out existing selections and allows you to individually select items Keep in mind that most of the fields allow multiple item selection by using the CTRL and SHIFT keys
- Select All w/edit – This option will automatically select all items in the field It does not lock the field therefore you have the ability to deselect items by using the CTRL key If you want to select all items in the field, then use the option described below
- Select All – This option will select all items in the field and lock the field from any further selection The major benefit in using this option is that instead of looking at individual records in GCMS for the corresponding field it will look at a value that summarizes all the values in the field This provides a significant enhancement in speed This option will not be available all the time For example if the user does not have access to report on the entire list of products, the Select All option will not be shown

9 RECORDS

All records are maintained according to **Quality Policy #QM-16-001, "Record Retention "**

Document Revision History

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Document Author	Document Manager
Denise Murrell	Donna Rhoades

Reason for Change

Revision	Change Request #	Change Made	Effective Date
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Approvals

▼First Approver s Signature

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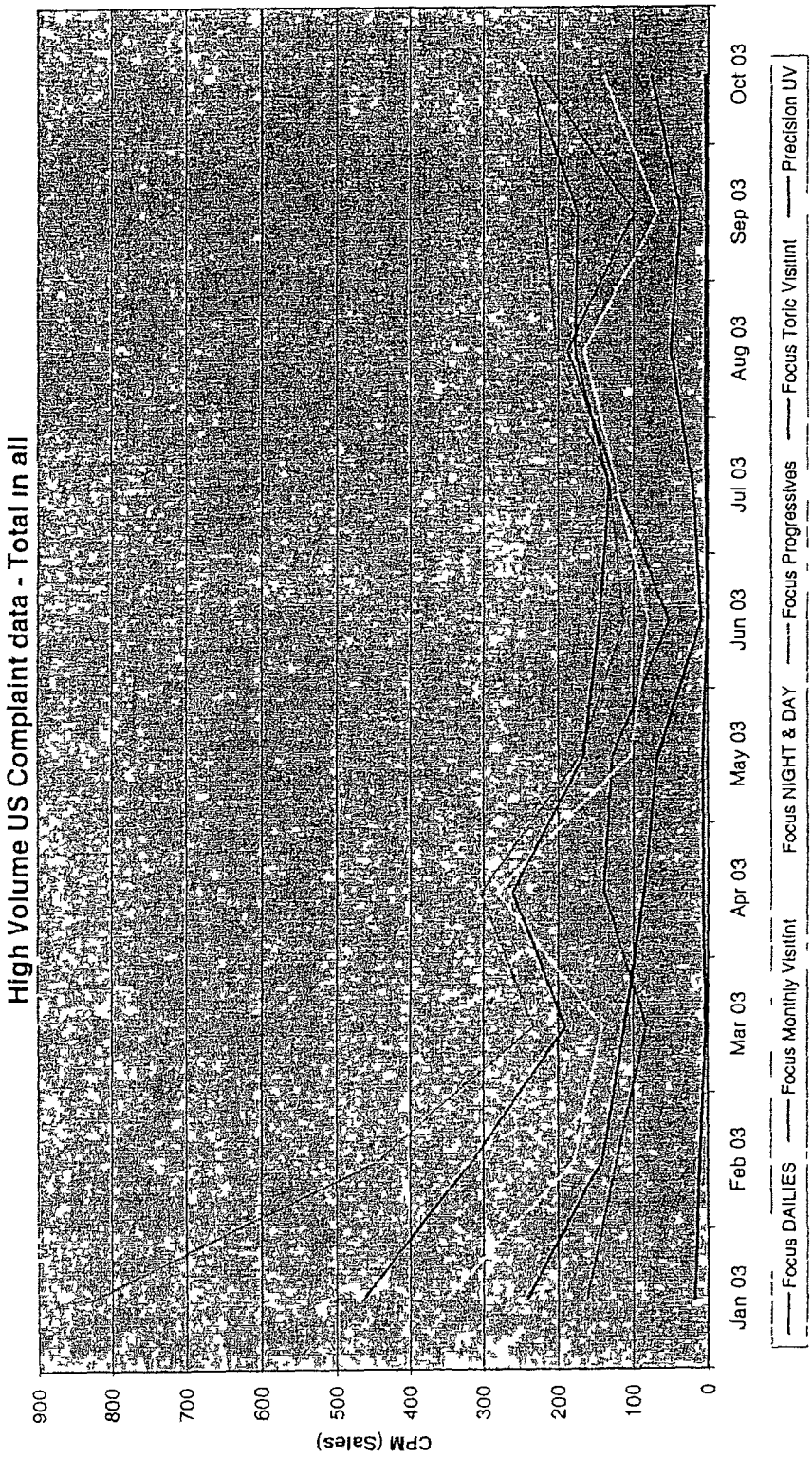
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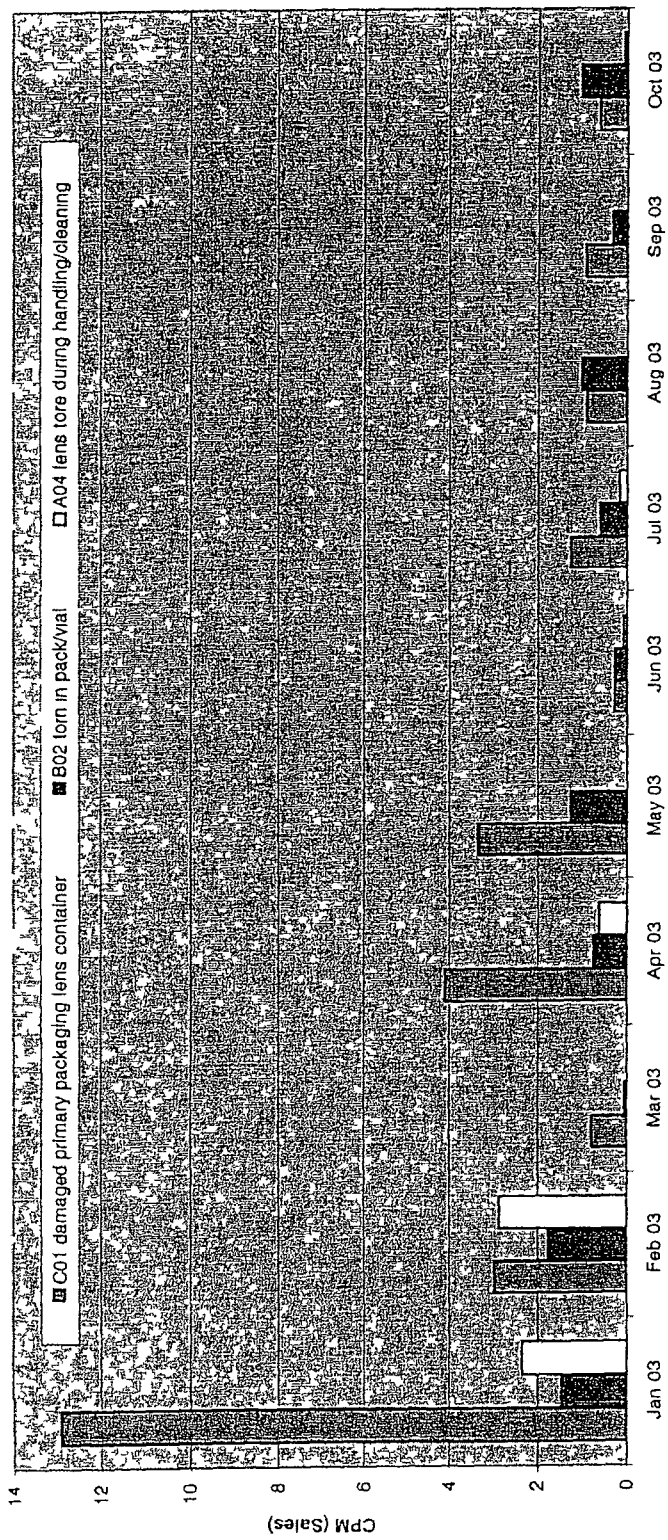
Name Andrew Mens
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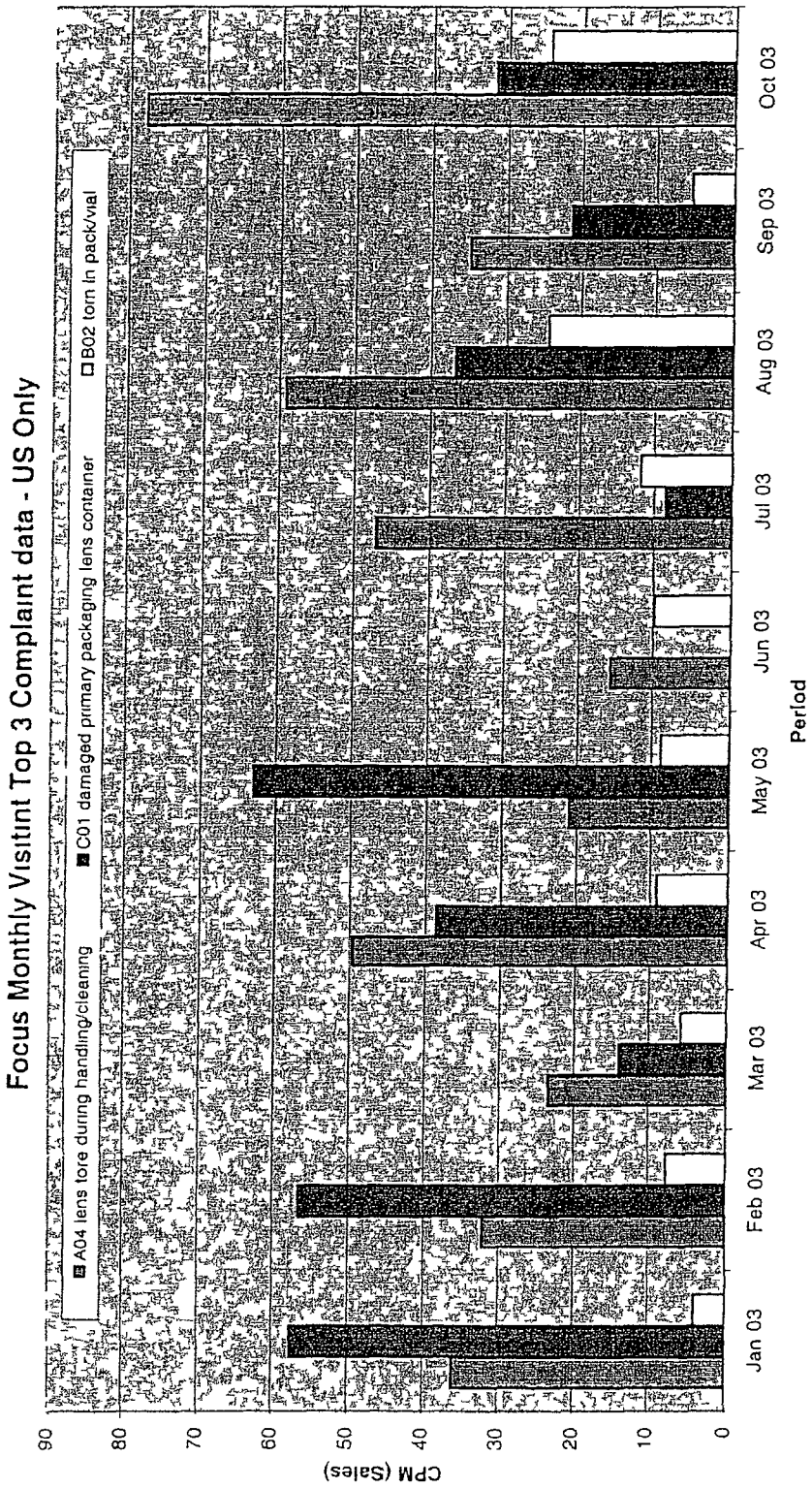
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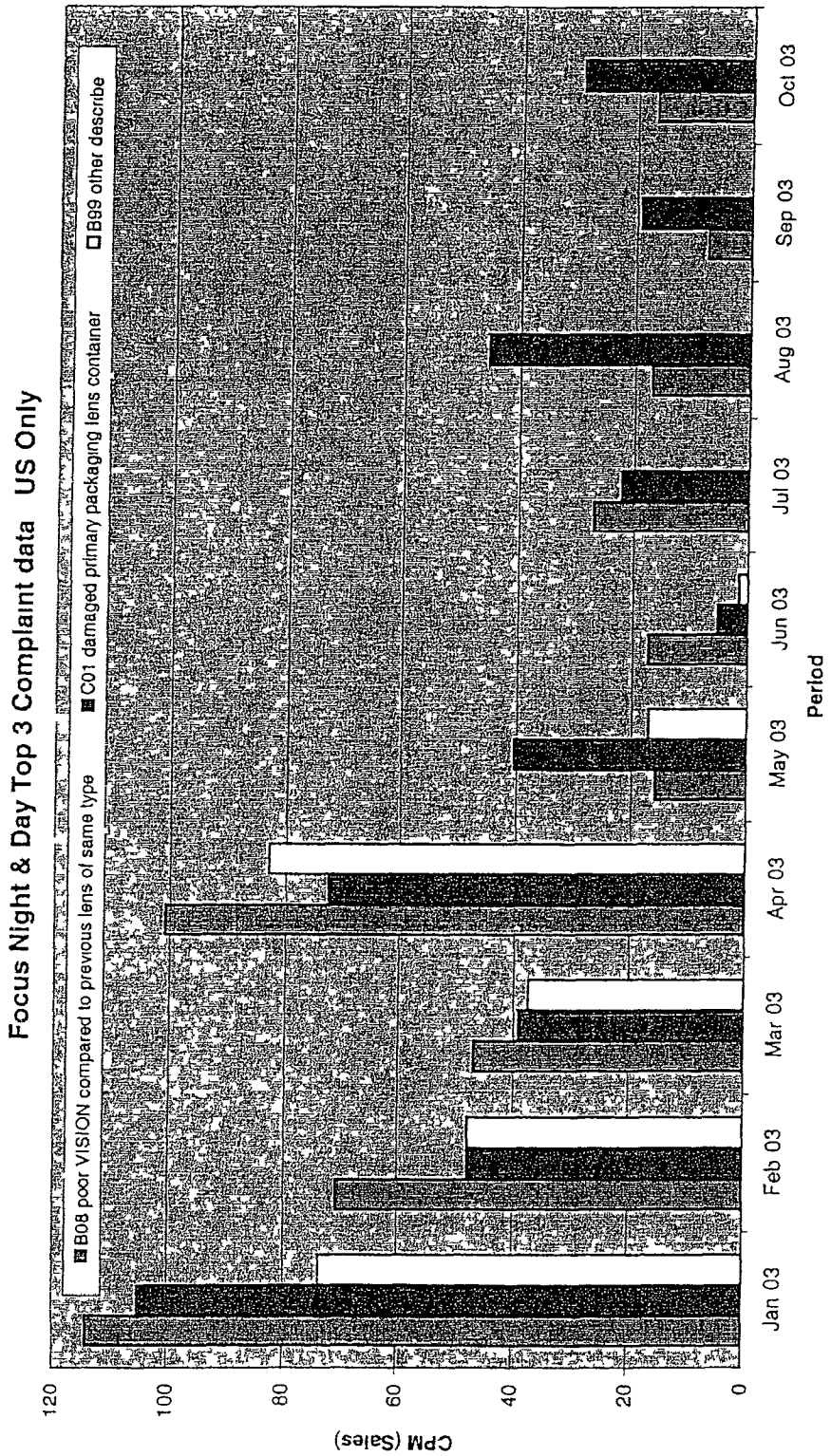
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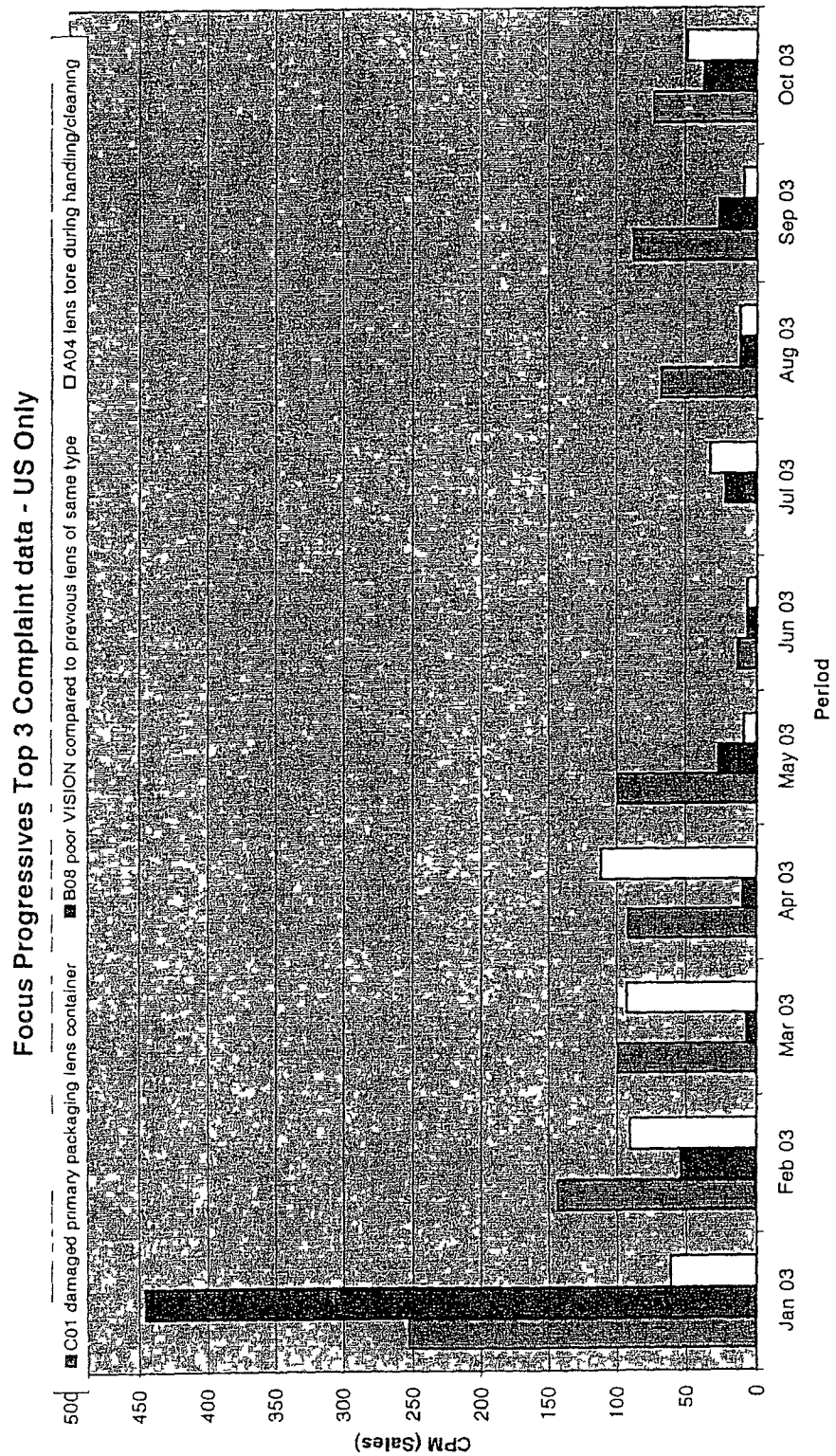
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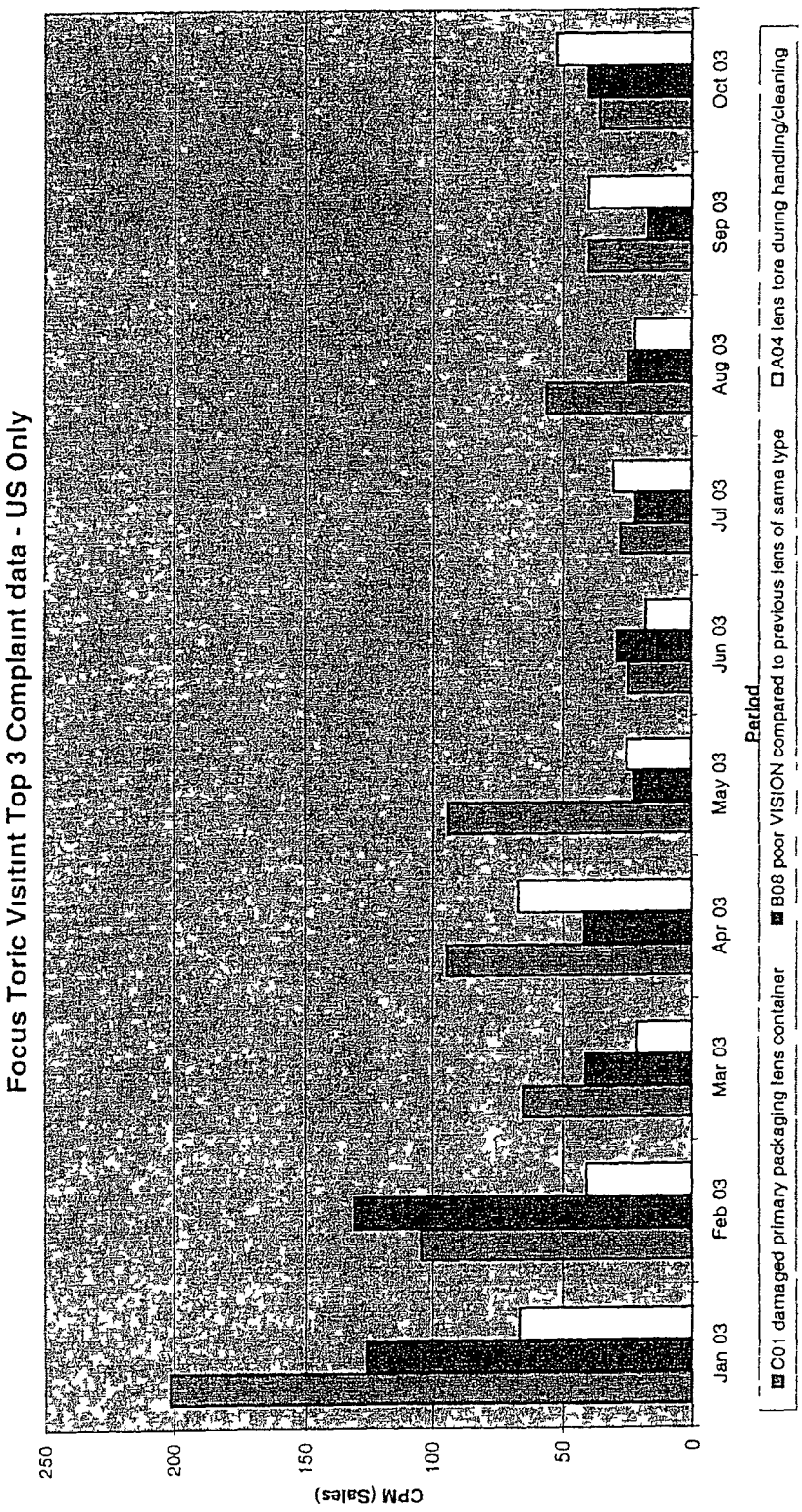

High Volume US Complaint data - Total in all
CPM (Sales)
900
800
700
600
500
400
300
200
100
0
Jan 03
Feb 03
Mar 03
Apr 03
May 03
Jun 03
Jul 03
Aug 03
Sep 03
Oct 03
Focus DAILIES
Focus Monthly Visitint
Focus NIGHT & DAY
Focus Progressives
Focus Toric Visitint
Precision UV

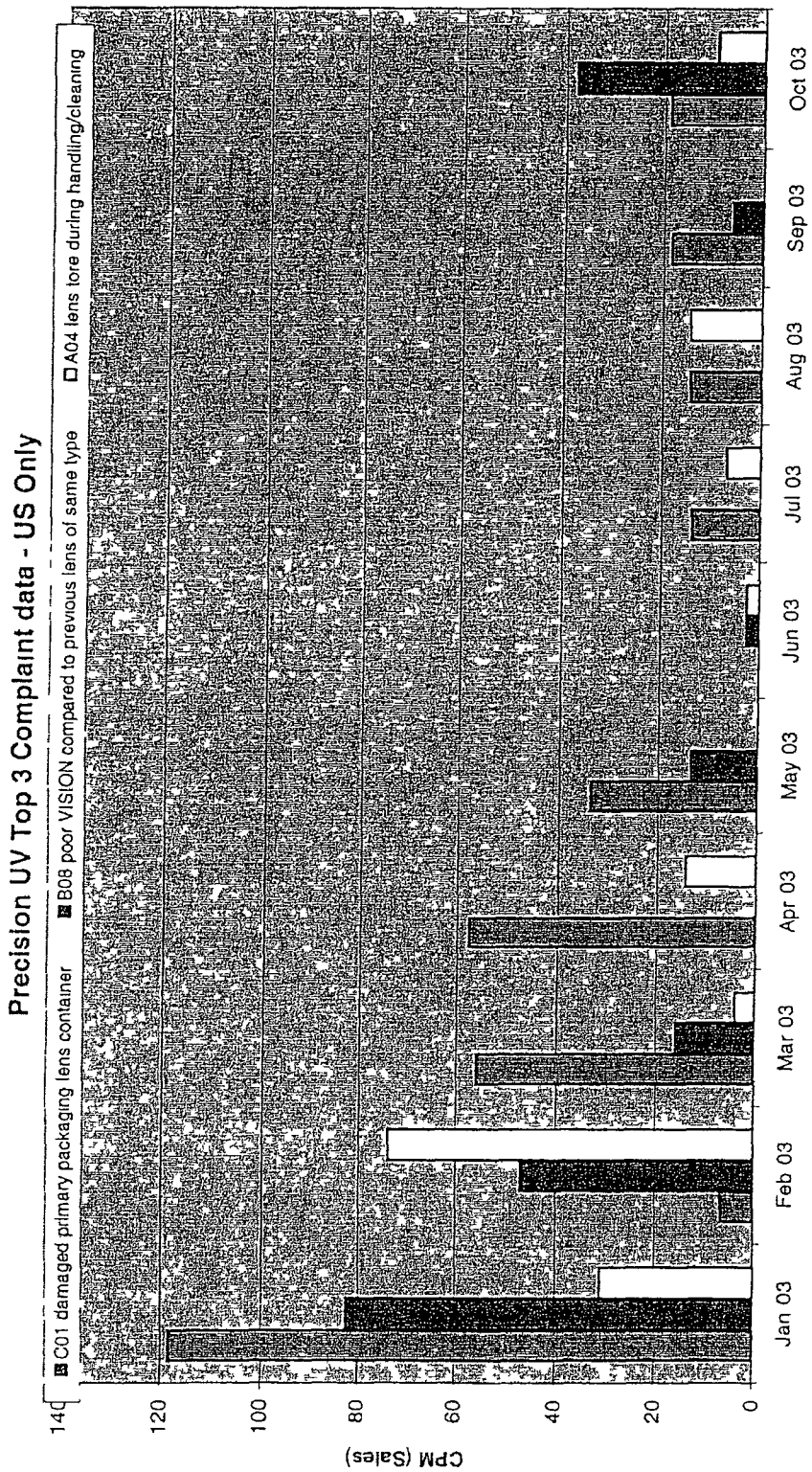

Focus Dailies Top 3 Complaint data - US Only
C01 damaged primary packaging lens container
B02 torn in pack/vial
A04 lens tore during handling/cleaning
CPM (Sales)
0
2
4
6
8
10
12
14
Jan 03
Feb 03
Mar 03
Apr 03
May 03
Jun 03
Jul 03
Aug 03
Sep 03
Oct 03


Focus Monthly Visitnt Top 3 Complaint data - US Only
A04 lens tore during handling/cleaning
C01 damaged primary packaging lens container
B02 torn in pack/vial
CPM (Sales)
0
10
20
30
40
50
60
70
80
90
Jan 03
Feb 03
Mar 03
Apr 03
May 03
Jun 03
Jul 03
Aug 03
Sep 03
Oct 03
Period


Focus Night & Day Top 3 Complaint data US Only
B08 poor VISION compared to previous lens of same type
C01 damaged primary packaging lens container
B99 other describe
CPM (Sales)
120
100
80
60
40
20
0
Jan 03
Feb 03
Mar 03
Apr 03
May 03
Jun 03
Jul 03
Aug 03
Sep 03
Oct 03
Period


Focus Progressives Top 3 Complaint data - US Only
C01 damaged primary packaging lens container
B08 poor VISION compared to previous lens of same type
A04 lens tore during handling/cleaning
CPM (Sales)
500
450
400
350
300
250
200
150
100
50
0
Jan 03
Feb 03
Mar 03
Apr 03
May 03
Jun 03
Jul 03
Aug 03
Sep 03
Oct 03
Period


Focus Toric Visitint Top 3 Complaint data - US Only
CPM (Sales)
250
200
150
100
50
0
Jan 03
Feb 03
Mar 03
Apr 03
May 03
Jun 03
Jul 03
Aug 03
Sep 03
Oct 03
Period
C01 damaged primary packaging lens container
B08 poor VISION compared to previous lens of same type
A04 lens tore during handling/cleaning


Precision UV Top 3 Complaint data - US Only
C01 damaged primary packaging lens container
B08 poor VISION compared to previous lens of same type
A04 lens tore during handling/cleaning
CPM (Sales)
0
20
40
60
80
100
120
140
Jan 03
Feb 03
Mar 03
Apr 03
May 03
Jun 03
Jul 03
Aug 03
Sep 03
Oct 03
Period

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

CIBA VISION CORPORATION, Plaintiff, v	)	
C & C TRADING COMPANY, INC , MICHELLE SINGH, MAS WHOLESALE & RETAIL, And JOHN DOES 1-50 Defendants	)	CIVIL ACTION NO 1 02-CV-245

CIBA VISION CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PRELIMINARY AND PERMANENT INJUNCTION

Plaintiff CIBA Vision Corporation (CIBA) respectfully submits this Memorandum of law in support of its Motion for Preliminary and Permanent Injunction [1]

STATEMENT OF FACTS

CIBA is one of the world s leading manufacturers of contact lenses including colored lenses that allow the wearer to enhance or change his or her eye color (Complaint ¶ 1) CIBA also manufactures a full line of eye-care products

[1] This is a preliminary brief which will be supplemented once an appropriate preliminary injunction record is compiled

including solutions and other products for the cleaning and storage of contact lenses (Complaint, ¶ 1)

CIBA owns a number of highly-recognized trademarks that it uses to identify the products in its highly successful line of colored contact lenses including, without limitation, Freshlook Colorblends, SoftColors and WildEyes (the "CIBA Marks") (Complaint ¶ 2) CIBA is also the owner of United States Trademark Registration Nos 1,357,825, 1,555,609, 2,123,193 2,182 347, 2,211,149, 2 251,945, and 2 340,808, *inter alia*, on the Principal Register maintained by the United States Patent and Trademark Office (Complaint, ¶ 13) Registration No 1,357,825 has become incontestable under 15 U S C § 1065 (Complaint, ¶ 13) All of the CIBA Marks are associated with CIBA's highly successful line of colored contact lenses (Complaint ¶ 13)

Beginning in 1982, CIBA has continuously used one or more of the CIBA Marks to identify its colored contact lenses (Complaint, ¶ 14) CIBA has spent at least $22,000,000 on the advertisement and promotion of the colored contact lenses that it sells under the CIBA Marks (Complaint, ¶ 15) As a result of such advertising and promotion, and as evidenced by the Registrations the CIBA Marks have become distinctive and well-known identifying goods emanating only from CIBA (Complaint, ¶ 15)

The CIBA Marks are recognized throughout the United States and the world and symbolize CIBA s reputation for producing safe and effective contact lenses of the highest quality (Complaint, ¶ 16) As a result of CIBA's reputation for producing safe and effective contact lenses and as a result of the visibility and success of the CIBA Marks, CIBA's sales of colored contact lenses last year equaled approximately $125,000,000 (Complaint ¶ 16)

Although some of CIBA's colored contact lenses are non-corrective lenses that are used for cosmetic rather than corrective purposes (plano lenses) federal law requires a written prescription from a licensed medical practitioner for the sale of all contact lenses including plano lenses which are considered by the Food and Drug Administration to be prescription medical devices within the meaning of 21 C F R ¶801 109 Georgia law also specifically prohibits the sale of any contact lenses without a prescription O C G A § 31-12-12

Contact lenses are required by law to be sold pursuant to a prescription in order to ensure that the patient is medically able to wear contact lenses that the patient receives lenses that fit the patient's eyes, and that the patient receives proper instruction and information on the care, cleaning sterilization and use of the contact lenses (Complaint, ¶ 17) Misuse of contact lenses can lead to serious and permanent injuries to the eyes including corneal abrasions, scarring of the eye

infections and loss of vision (Complaint ¶ 17) These risks are the same for corrective and plano lenses and for clear and colored lenses (Complaint, ¶ 17)

CIBA takes affirmative steps to prevent the misuse of its contact lenses and to ensure that its products are distributed, sold and used in the proper manner (Complaint, ¶ 18) CIBA sells its lenses only to licensed ophthalmologists, optometrists and opticians, to businesses licensed to dispense contact lenses and to authorized distributors that are permitted to re-sell lenses only to licensed eye-care professionals (Complaint, ¶ 18) To further ensure the safe use of its contact lenses, CIBA provides eye-care professionals with a fitting guide for practitioner use and a patient instruction booklet containing instructions and medical advisories to be given to patients (Complaint, ¶ 18) CIBA requires that all authorized distributors of CIBA lenses comply with all applicable federal, state and local laws and regulations (Complaint, ¶ 18)

In spite of CIBA s efforts to prevent the misuse of its lenses the Defendants are currently engaged in the widespread illegal distribution and sale of CIBA s contact lenses to consumers without prescriptions (Complaint ¶ 19) Defendant C & C Trading Company Inc ('C & C Trading') is selling CIBA s contact lenses to consumers without requiring prescriptions and without the instructions for use and medical advisories that are needed by consumers to properly use and care for the lenses (Complaint, ¶ 20) Defendant Michelle Singh (Ms Singh) and MAS

Wholesale & Retail (MAS Wholesale) have knowingly distributed and sold CIBA s lenses in interstate commerce throughout the United States to retailers who make it a practice to sell prescription medical devices without prescriptions (Complaint, ¶ 8) Ms Singh and MAS Wholesale have sold CIBA's contact lenses at a beauty products trade show in Las Vegas, Nevada, in addition to other locations throughout the country (Complaint, ¶ 21)

Because the purchase and use of CIBA's contact lenses by persons who have not been examined by a doctor and who have not received proper instructions and medical warnings could cause serious injury, including loss of vision, Defendants' conduct 1) threatens the assurance of quality represented by the CIBA Marks 2) exposes CIBA to potential liability and 3) damages CIBA's reputation

Because contact lenses are prescription medical devices, Defendants' conduct is analogous to the selling of potentially harmful prescription drugs on the street without a prescription Even if a prescription was not required Defendants reckless conduct would threaten not only the valuable goodwill and reputation associated with the CIBA Marks, but also the safety and welfare of the public CIBA seeks injunctive relief to stop Defendants' illegal and dangerous conduct and to protect the good reputation and valuable good will associated with the CIBA Marks CIBA also seeks to recover damages for the harm inflicted by Defendants' illegal conduct

ARGUMENT AND CITATION OF AUTHORITY

In order to obtain a preliminary injunction, CIBA must show

A) a substantial likelihood that CIBA will prevail on the merits,

B) a substantial threat that CIBA will suffer irreparable injury if injunctive relief is not granted,

C) that the threatened injury to CIBA outweighs any harm that the injunction may do to defendants and

D) that the granting of the injunction will not disserve the public interest

E Remy Martin & Co , S A v Shaw-Rose Int'l Imports, Inc , 756 F 2d 1525, 1530 (1985) As shown below each of these requirements is met in this case, and CIBA is entitled to injunctive relief

A CIBA IS SUBSTANTIALLY LIKELY TO PREVAIL ON THE MERITS

1 Defendants Conduct Constitutes Federal Trademark Infringement and Unfair Competition

In order to succeed on the merits of a trademark infringement claim the plaintiff must show that the defendant used the mark in commerce and that the unauthorized use was likely to deceive, cause confusion or result in mistake Davidoff & CIE, S A v PLD Int'l Corp , 263 F 3d 1297, 1300-01 (11th Cir 2001) The unauthorized resale of a trademarked product that is materially different from the genuine product constitutes trademark infringement because the sale of such

products ' may confuse consumers and erode consumer goodwill toward the mark ' Id at 1302

This particular form of trademark protection emerged from the courts recognition that a ' trademark owner has spent time, energy and money in presenting a product to the public and building a reputation for that product Id at 1301 Thus [o]ne of the most important protections afforded by the Lanham Act is the right to control the quality of the goods manufactured and sold under the holder's trademark El Greco Leather Prods Co v Shoe World, Inc 806 F 2d 392, 395 (2nd Cir 1986)

For example, in Warner-Lambert Co v Northside Dev Co , 86 F 3d 3 (2nd Cir 1996), the manufacturer of HALLS cough drops brought a trademark infringement suit against a distributor who had been purchasing large quantities of HALLS cough drops that were outdated and repackaging the product to conceal the fact that the cough drops were old Warner-Lambert 86 F 3d at 5 The distributor would sell the outdated product to retail outlets for sale to consumers Id

The court concluded that the distributor s conduct constituted trademark infringement because the purchase of stale HALLS cough drops by consumers could create negative impressions of the HALLS trademark and cause consumers and retailers to stop purchasing products associated with the mark Id at 8-9

Accordingly, the Second Circuit held that injunctive relief was warranted to halt the distribution of stale product Id

The Eleventh Circuit confronted a similar situation in Davidoff, where the owner of trademark for perfume brought suit against an unauthorized distributor who was removing the batch codes from perfume bottles with an etching tool Davidoff, 263 F 3d at 1299 The court noted that the etching degraded the appearance of the perfume bottles and suggested that the bottles had been subjected to tampering Id at 1303 Accordingly, the court found that the distributor s conduct constituted trademark infringement and affirmed the district court's grant of injunctive relief Id , see also Shell Oil Co v Commercial Petroleum, Inc 928 F 2d 104 107 (4th Cir 1991) (enjoining wholesaler from selling trademarked oil products without following manufacturer's quality control standards) , Clairol, Inc v Boston Discount Center of Berkley Inc , 608 F 2d 1114, 1120-21 (6th Cir 1979) (holding that unauthorized distributor s sale of hair care products without instructions and medical advisories constitutes unfair competition because such conduct increases the danger of customer dissatisfaction with products), Anthony Distrib , Inc v Miller Brewing Co 904 F Supp 1363 1367 (S D Fla 1995) (holding that authorized distributor s failure to prevent the sale of stale beer to consumers constitutes trademark infringement)

In this case, Defendants conduct constitutes trademark infringement because the unauthorized resale of CIBA s contact lenses without a prescription results in consumers receiving a materially different product

When used properly under the direction of a doctor and in conformance with the instructions and medical advisories, CIBA's colored lenses are a safe and effective way of correcting vision and/or enhancing or changing eye color However, Defendants have been selling and distributing CIBA's lenses without a prescription and without the instructions and medical advisories Under these circumstances, there is an enormous risk that consumers will purchase lenses that are the wrong size or that are otherwise not medically appropriate Also without the guidance of a doctor and without the instructions and medical advisories consumers may use the same lenses for a longer time than is safe and may not follow the proper cleaning and sterilization procedures Any of these misuses of CIBA's contact lenses could result in severe and permanent injury to the eyes of the users Thus Defendants conduct transforms a safe and effective product into a dangerous product with the potential to blind users

Defendants conduct is considerably more harmful than the conduct enjoined in the cases discussed above While the purchase of stale cough drops or flat beer could lead to consumer dissatisfaction with the product, the sale of a prescription medical device contrary to the manufacturer's instructions and without a

prescription could lead to serious injury, extremely negative associations with CIBA s valuable trademarks and complete consumer rejection of CIBA's products

Defendants' illegal conduct materially alters CIBA's trademarked products because it transforms a safe product into one with the potential to harm consumers Accordingly CIBA is substantially likely to prevail on its claim for trademark infringement

Additionally, because Defendants Singh and MAS Wholesale are supplying products to retailers that they know are engaging trademark infringement by selling CIBA s lenses without prescriptions and instructions CIBA is substantially likely to prevail on the merits of its claim for contributory infringement against those Defendants Polymer Technology Corp v Mimran Corp 975 F 2d 58, 64 (2nd Cir 1992) (a distributor who "continues to supply its product to one whom it knows or has reason to know is engaging in trademark infringement is contributorially liable for any injury)

Finally, because the test for establishing unfair competition under Section 43(a) of the Lanham Act is essentially the same as the test for trademark infringement CIBA is substantially likely to prevail on the merits of its claim for federal unfair competition Marathon Mfg Co v Enerlite Prods Corp , 767 F 2d 214, 217 (5th Cir 1985)

2 CIBA Is Substantially Likely To Prevail On Its Claim Under O C G A § 31-12-12 Against Defendants For Their Illegal Distribution and Sale of Contact Lenses

O C G A § 31-12-12 regulates the sale of contact of lenses in Georgia The statute prohibits any person from dispensing or adapting contact lenses without first receiving authorization to do so by a written prescription or when orally authorized to do so by a licensed medical practitioner O C G A § 31-12-12 (b) The statute also prohibits anyone from selling, dispensing or serving as a conduit for the selling or dispensing of the first set of contact lenses issued pursuant to a prescription except for persons who are licensed by the State of Georgia to engage in such activities O C G A § 31-12-12 (a) [2]

Finally O C G A § 31-12-12(j) specifically provides that proceedings to enforce the provisions of the statute may be brought by any state board created under certain provisions of Georgia law or by 'any other interested person through criminal prosecution, injunction, or other appropriate remedy O C G A § 31-12-12(j)

In this case, Defendants conduct violates O C G A § 31-12-12, and CIBA qualifies as an 'interested person' as its business and reputation are being damaged by Defendants illegal conduct Accordingly, CIBA is substantially

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A violation of this subsection constitutes a misdemeanor of a high and aggravated nature O C G A 31-12 13(i)

likely to prevail on the merits of its claim against Defendants based upon the statute

3 CIBA is substantially likely to prevail on the merits of its claims for deceptive trade practices under O C G A § 10-1-372 common law trademark infringement and common law unfair competition

The test for establishing a substantial likelihood of success on the merits on a claim for federal trademark infringement is 'essentially the same as the test for claims for deceptive trade practices under O C G A § 10-1-372 and for claims for trademark infringement and unfair competition under the common law of Georgia Gold Kist, Inc v ConAgra, Inc., 708 F Supp 1291, 1303 (N D Ga 1989) Because CIBA has demonstrated that it is likely to prevail on the merits of its claim for federal trademark infringement, it has also demonstrated that it is likely to prevail on those claims Id

B DEFENDANTS CONDUCT POSES A SUBSTANTIAL THREAT OF IRREPARABLE INJURY

Irreparable harm to a trademark owner is inherent in any situation involving the unauthorized use of its trademark Carling Brewing Co v Philip Morris, Inc 277 F Supp 326 335 (N D Ga 1967) (the infringement of a trademark is by its very nature, an activity which causes irreparable harm—irreparable in the sense that no final decree of a court can adequately compensate a plaintiff for the confusion that has already occurred)

Because of the nature of CIBA's business and the dangerous consequences of Defendants illegal conduct, the threat of irreparable harm is more acute in this case than in the ordinary trademark infringement case As with any manufacturer of drugs or medical devices like contact lenses, CIBA's reputation for producing a safe and effective product is its most valuable commodity There is no small degree of trust involved when a consumer selects a product that will be placed in his or her eyes Even one incident of a consumer suffering injury as a result of the use of CIBA s lenses could destroy the valuable goodwill associated with CIBA s trademarks and products It would be impossible to fully compensate CIBA for the damage that could be inflicted to its business by Defendants' conduct

Further, the Eleventh Circuit has held that a party seeking injunctive relief need only make a minimum showing of irreparable harm when the nonmovant has violated a statute that authorizes the issuance of an injunction See, e g Gresham v Windrush Partners Ltd 730 F 2d 1417, 1423 (11th Cir 1984) Defendants have violated O C G A § 31-12-12, a statute that specifically authorizes the issuance of an injunction CIBA has more than satisfied the irreparable harm ' requirement

C THE THREATENED INJURY TO CIBA OUTWEIGHS ANY HARM THAT THE INJUNCTION MAY DO TO DEFENDANTS

As discussed above CIBA faces possible catastrophic injury to its reputation and business as a result of Defendants conduct On the other hand, if enjoined Defendants will merely be prevented from engaging in illegal conduct that

threatens both CIBA and members of the public with injury See e g , Mediaone of Delaware, Inc v E&A Beepers and Cellulars, 43 F Supp 2d 1348, 1354 (S D Fla 1998) (observing that a defendant has no right to earn money by violating the law and will suffer no harm if an injunction is issued which simply requires defendant to obey the law) The balance of hardships overwhelmingly favors CIBA

D THE GRANTING OF THE INJUNCTION WILL NOT DISSERVE THE PUBLIC INTEREST

As discussed above, Defendants' conduct is illegal and poses a threat to the safety and welfare of the public An injunction against Defendants will serve the public interest by halting their illegal and dangerous conduct

CONCLUSION

For all of the foregoing reasons, CIBA respectfully requests that the Court GRANT its Motion for Preliminary and Permanent Injunction and enter an order prohibiting Defendants and those working with Defendants from selling or distributing CIBA products, otherwise infringing the CIBA Marks and competing unfairly with CIBA in any manner, and requiring Defendants to turn over all CIBA products in their possession to CIBA

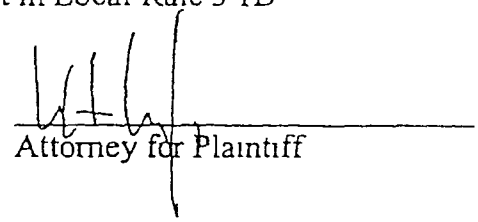
This 5th day of September, 2001

Respectfully submitted

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I certify that this brief has been prepared with one of the font and point selections approved by the court in Local Rule 5 1B



Attorney for Plaintiff

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By: Deputy Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

CIBA VISION CORPORATION,	)	
	)	
Plaintiff	)	
v	)	
	)	CIVIL ACTION NO
	)	
C & C TRADING COMPANY, INC ,	)	1 02-CV-2456
MICHELLE SINGH,	)	
MAS WHOLESALE & RETAIL,	)	
And JOHN DOES 1-50,	)	
	)	
Defendants	)	

COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES

COMES NOW Plaintiff CIBA Vision Corporation (CIBA) and respectfully shows the Court as follows

PARTIES

1 CIBA is a Delaware corporation that is licensed to do business in the State of Georgia CIBA is one of the world's leading manufacturers of contact lenses, including colored lenses that allow the wearer to enhance or change his or her eye color CIBA also manufactures a full line of eye-care products including cleaning and storage solutions for contact lenses

2 CIBA is the owner of various trademarks that are associated with its successful line of colored contact lenses including without limitation Freshlook Colorblends Softcolors and WildEyes (the "CIBA Marks)

3 Although some of CIBA s colored contact lenses are non-corrective lenses that are used for cosmetic rather than corrective purposes (plano lenses), federal law requires a written prescription from a licensed medical practitioner for the sale of all contacts lenses including plano lenses, which are considered by the Food and Drug Administration to be prescription medical devices within the meaning of 21 C F R § 801 109 Georgia law also specifically prohibits the sale of any contact lenses without a prescription O C G A § 31-12-12

4 Defendant C & C Trading Company, Inc ('C & C Trading') is a Georgia corporation that may be served by service upon its registered agent, Peter Chi at 3684 Stewart Road A-3 Doraville, Georgia 30340

5 Defendant C & C Trading is engaged in the illegal and unauthorized sale of CIBA s contact lenses to consumers at multiple locations without requiring a prescription

6 Defendant Michelle Singh is an individual who resides at Georgia 30296 Upon information and belief, Ms Singh does business as MAS Wholesale & Retail (' MAS Wholesale)

7 Although MAS Wholesale is not a legal corporation licensed with the Georgia Secretary of State it has acquired a business license issued by Clayton County

8 Ms Singh and MAS Wholesale, in concert with others, illegally and without authorization, have distributed and sold CIBA's contact lenses in interstate commerce throughout the United States to retailers who make it a practice to sell prescription medical devices without prescriptions

9 Ms Singh and MAS Wholesale have admitted that they have distributed and sold CIBA's contact lenses to retailers with the knowledge that the retailers were selling the contact lenses to consumers without prescriptions

10 Defendants John Does 1-50 are individuals and entities that are conspiring and acting in concert with the named Defendants and with each other in the illegal distribution and sale of CIBA's contact lenses to consumers without prescriptions and others unrelated to the named Defendants who are engaged in the illegal distribution and sale of CIBA s contact lenses

NATURE OF THE ACTION

11 This is an action for preliminary and permanent injunctive relief profits, damages and attorney's fees for Defendants infringement of CIBA s federally registered trademarks in violation of Section 32(1) of the Lanham Act 15 U S C § 1114(1) for Defendants unfair competition in violation of Section 43(a) of the Lanham Act 15 U S C § 1125(a), for Defendants unauthorized and illegal distribution and sale of contact lenses in violation of O C G A § 31-12-12, for Defendants' deceptive trade practices in violation of O C G A § 10-1-372, and for

Defendants trademark infringement and unfair competition in violation of the common law of Georgia

JURISDICTION AND VENUE

12 This Court has jurisdiction over the subject matter of this action pursuant to 15 U S C § 1121 and 28 U S C §§ 1331, 1338 and 1367 Venue is proper pursuant to 28 U S C § 1391(b)

FACTS COMMON TO ALL COUNTS

13 CIBA is the owner of United States Trademark Registration Nos 1 357,825 1,555,609, 2,123 193, 2,182,347, 2,211,149, 2,251,945, and 2,340,808 *inter alia*, on the Principal Register maintained by the United States Patent and Trademark Office for the CIBA Marks Registration No 1 357 825 has become incontestable under 15 U S C § 1065 All of the CIBA Marks are associated with CIBA's highly successful line of colored contact lenses

14 Beginning in 1982, CIBA has used one or more of the CIBA Marks to identify its colored contact lenses The rights supported by such use of the CIBA Marks and the goodwill associated therewith inure to the benefit of CIBA

15 CIBA has spent over $22,000,000 to advertise and promote the contact lenses that it sells under the CIBA Marks As a result of such advertising and promotion and as evidenced by the Registrations, the CIBA Marks have become distinctive and well-known identifying goods emanating only from CIBA

16 In 2001 CIBA's sales of colored contact lenses exceeded $125,000,000 The CIBA Marks are recognized throughout the United States and the world and symbolize CIBA s reputation for producing safe and effective contact lenses of the highest quality

17 All contact lenses manufactured by CIBA are required by federal and state law be sold pursuant to a valid prescription from a licensed medical practitioner The prescription is necessary to ensure that the patient is medically able to wear contact lenses that the patient receives lenses that fit the patient's eyes, and that the patient receives proper instruction and information on the care, cleaning sterilization and use of the contact lenses The sale of contact lenses without a prescription is illegal under federal and state law and could lead to serious and permanent injuries to the eyes of the user, including corneal abrasions scarring of the eye, infections and loss of vision These risks are the same for corrective and non-corrective lenses and for clear and colored lenses

18 CIBA takes affirmative steps to prevent the misuse of its contact lenses CIBA will sell its lenses only to licensed ophthalmologists, optometrists and opticians, to businesses that are licensed to dispense contact lenses and to authorized distributors who are permitted to re-sell lenses only to licensed eye-care professionals To further ensure the safe use of contact lenses CIBA provides eye-care professionals with a fitting guide for practitioner use and a patient instruction

booklet containing instructions and medical advisories to be given to patients CIBA requires that all distributors of CIBA lenses comply with all applicable federal, state and local laws and regulations CIBA has also actively sought to prevent the illegal and unauthorized sale of its contact lenses

19 Defendants are engaged in the widespread unauthorized and illegal distribution and sale of CIBA's colored contact lenses without a prescription on a national scale

20 C & C Trading is selling CIBA s contact lenses to consumers from at least three locations in Georgia without requiring prescriptions and without providing the instructions for use and medical advisories that are needed by consumers to properly use and care for the lenses

21 Ms Singh and MAS Wholesale have sold CIBA s contact lenses at a beauty products trade show in Las Vegas Nevada in addition to other locations throughout the country

22 Among the ways Ms Singh and MAS Wholesale implement their illegal scheme is a practice whereby the Defendants break down multiple sets of contact lenses that are marked not to be sold individually and sell the lenses individually without the instructions for use and medical advisories available from eye care professionals that are needed by consumers to properly use and care for the lenses

23 Ms Singh and MAS Wholesale have sold CIBA s contact lenses to retailers without the necessary instructions and medical advisories that CIBA provides to eye-care professionals However, Ms Singh and MAS Wholesale have provided their retail customers with a "COSMETIC CONTACT LENSES DISCLAIMER that falsely purports to absolve the unauthorized retail sellers of contact lenses of any responsibility to consumers Ms Singh and MAS Wholesale encourage their retail customers to distribute the COSMETIC CONTACT LENSES DISCLAIMER ' to consumers who purchase CIBA s contact lenses

24 Because the use of unfitted contact lenses by persons who have not been examined by a doctor and who have not received proper instructions could cause serious injury, Defendants conduct threatens the assurance of quality represented by the CIBA Marks and could expose CIBA to liability and damage CIBA's reputation Defendants' conduct results in consumers receiving a product that is materially different from the genuine product

25 Defendants' reckless conduct poses a threat to both the safety of the public and the valuable reputation and goodwill associated with the CIBA Marks

COUNT I

FEDERAL TRADEMARK INFRINGEMENT

26 CIBA incorporates by reference the allegations set forth in paragraphs 1-25

27 Defendants aforesaid acts constitute trademark infringement and contributory trademark infringement in violation of Section 32(1) of the Lanham Act 15 U S C § 1114(1)

28 Defendants' aforesaid acts of trademark infringement and contributory trademark infringement were committed knowingly, deliberately and willfully and are greatly and irreparably damaging to CIBA, and will continue to be greatly and irreparably damaging to CIBA unless enjoined by this Court, as a result of which CIBA is without an adequate remedy at law

COUNT II

VIOLATION OF SECTION 43(a) OF THE LANHAM ACT

29 CIBA incorporates by reference the allegations set forth in paragraphs 1-28

30 Defendants' aforesaid acts misrepresent the nature, characteristics and qualities of CIBA s contact lenses and are confusing and deceiving the public such that the public could hold CIBA responsible for any loss of quality or damages that

result from Defendants' distribution and sale of CIBA s contact lenses without a prescription

31 Defendants aforesaid acts constitute unfair competition under Section 43(a) of the Lanham Act and are greatly and irreparably damaging to CIBA and will continue to be greatly and irreparably damaging to CIBA unless enjoined by this Court, as a result of which CIBA is without an adequate remedy at law

COUNT III

ILLEGAL DISTRIBUTION AND SALE OF CONTACT LENSES IN VIOLATION O C G A § 31-12-12

32 CIBA incorporates by reference the allegations contained in paragraphs 1-31

33 Defendants have sold dispensed and served as a conduit for the sale and dispensing of contact lenses, including contact lenses manufactured by CIBA and sold under the CIBA Marks and continue to sell, dispense and serve as a conduit for the sale and dispensing of such contact lenses without having obtained the required licenses and authorization from the State of Georgia

34 Defendants have dispensed and continue to dispense contact lenses without first receiving authorization by written prescription

35 CIBA is an "interested person within the meaning of O C G A § 31 12-12(j)

36 Defendants' aforesaid acts constitute violations of O C G A § 31-12-12 and are greatly and irreparably damaging to CIBA and will continue to be greatly and irreparably damaging to CIBA unless enjoined by this Court, as a result of which CIBA is without an adequate remedy at law

COUNT IV

DECEPTIVE TRADE PRACTICES IN VIOLATION OF O C G A § 10-1-372

37 CIBA incorporates by reference the allegations contained in paragraphs 1-36

38 Defendants aforesaid acts constitute deceptive trade practices under O C G A § 10-1-372

39 Defendants aforesaid acts are greatly and irreparably damaging to CIBA and will continue to be greatly and irreparably damaging to CIBA unless enjoined by this Court as a result of which CIBA is without an adequate remedy at law

COUNT V

COMMON LAW TRADEMARK INFRINGEMENT

40 CIBA incorporates by reference the allegations contained in paragraphs 1-39

41 Defendants aforesaid acts constitute trademark infringement under the common law of Georgia

42 Defendants aforesaid acts are greatly and irreparably damaging to CIBA, and will continue to be greatly and irreparably damaging to CIBA unless enjoined by this Court as a result of which CIBA is without an adequate remedy at law

COUNT VI

COMMON LAW UNFAIR COMPETITION

43 CIBA incorporates by reference the allegations contained in paragraphs 1-42

44 Defendants' aforesaid acts constitute unfair competition under the common law of Georgia

45 Defendants' aforesaid acts are greatly and irreparably damaging to CIBA, and will continue to be greatly and irreparably damaging to CIBA unless enjoined by this Court as a result of which CIBA is without an adequate remedy at law

WHEREFORE, CIBA prays for the following relief

a) That Defendants their affiliated and/or related companies, and their officers, directors partners, agents servants and employees, their successors and assigns and all other persons working in active concert or participation with them or any of them, be temporarily and permanently enjoined and restrained from the following acts

1) selling or distributing CIBA products,

2) otherwise infringing the CIBA Marks, and

3) competing unfairly with CIBA in any manner

b) That Defendants be required to turn over all CIBA products in their possession to CIBA

c) That Defendants be required to account for and pay over to CIBA all damages suffered by CIBA and all profits wrongfully derived by Defendants

d) That CIBA receive from Defendants three times the actual damages caused by acts of Defendants

e) That Defendants be required to pay CIBA exemplary and punitive damages the costs of this action together with the reasonable attorneys fees and costs incurred by CIBA in the prosecution of this action

f) That CIBA receive such other and further relief as the Court deems just and proper

This 5th day of September, 2002

Respectfully submitted

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LIT/773897 1

Plaintiff's Exhibit

Alexander Gallo & Associates, Inc.

CIBA Vision — PACKAGE INSERT FreshLook Colors, FreshLook ColorBlends, FreshLook Color Enhancers, FreshLook Radiance and FreshLook Dimensions Soft Contact Lenses, including FreshLook Handling Tint FreshLook Colors FreshLook ColorBlends FreshLook Color Enhancers FreshLook Radiance and FreshLook Dimensions Spherical and Toric Soft Contact Lenses for Daily Wear or Extended Wear with Frequent Replacement or Disposable Wear

09852 10/2003

Important: This package insert is effective as of July 2003 and supersedes all prior inserts for the products described below Please read carefully and keep this information for future use This package insert is intended for the eye care professional but should be made available to patients upon request The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses Copies of this package insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service at 1 800-241-5999 or download from our web site at www.cibavision.com. CIBA Vision makes available a Patient Instruction Booklet that is recommended to be given to the patient

℞ only

CAUTION FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.

DESCRIPTION

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are available in Handling Tint, Colors Color Enhancers ColorBlends Radiance and Dimensions. FreshLook Toric soft contact lenses are available in Handling Tint and ColorBlends. The FreshLook soft contact lens family contains several products that incorporate a UV absorber Each of these products is identified appropriately on the product package. The lens wearing schedule may be prescribed for either Disposable Wear or Frequent Replacement. In the **Disposable Wear Program** the lens wearing time prescribed by the eye care professional is for either daily wear or extended wear from 1 to 7 days/6 nights. Patients should be instructed to dispose of the lenses at each removal and to use lens care products only on an emergency basis In the **Frequent Replacement Program** the lens wearing time prescribed by the eye care professional is for either daily wear or extended wear from 1 to 7 days/6 nights Each time the lens needs to be removed before the replacement time period has elapsed, the lens must be both cleaned and disinfected prior to placing it back on the eye. CIBA Vision recommends that the lens be discarded and replaced with a new lens every 2 weeks or as recommended by the eye care professional. The eye care professional is encouraged to determine the wearing schedule based on response of the patient.

PRODUCT DESCRIPTION Lens Material

The lens material phemfilcon A, is a hydrophilic copolymer of 2 hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate and methacrylic acid crosslinked with ethyleneglycol dimethacrylate FreshLook UV contact lenses contain a proprietary UV-absorbing monomer which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light.

FreshLook Colors, FreshLook ColorBlends FreshLook Color Enhancers and FreshLook Radiance soft contact lenses are made by modifying the clear FreshLook lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the iris FreshLook Dimensions soft contact lenses are made by modifying the tinted FreshLook lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the iris. Additionally a colored pigment is affixed to the front surface of the Toric lens to act as a unique orientation mark identified as (FreshMark) The colored pigments consist of the following color additives listed in the color additive provisions of 21 CFR. iron oxides, titanium dioxide [phthalocyaninato (2-)] copper chromium oxide, carbazole violet, mica coated with iron oxide and mica coated with titanium dioxide.

eshLook Spherical and Toric w th Handling T nt soft contact lenses are inted green with the color additive phthalocyanine green for easy visibility for handling Fr shLook Dimensions lenses are also tinted green with the color additive phthalocyanine green for a better contrast in the printed portion of the lens These color additives are not removed by lens handling or cleaning/disinfecting procedures The lens coloring process does not alter the opt cal and performance characteristics

Lens Properties

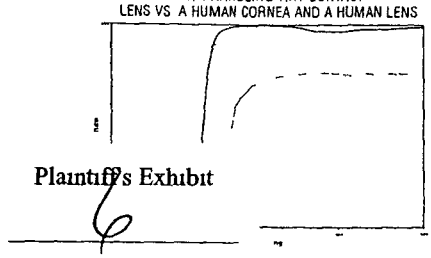
The physical properties of the lens are

Specific Gravity	1 152
Refract ve Index:	1 409
Light Transmittance	
FreshLook with Handling Tint with or without UV	95% m nimum
FreshLook Colors with or without UV	95% minimum
Surface Character	Hydrophilic
Water Content	55%
Optical Zone (FreshLook Colors)	5mm
Optical Zone (FreshLook with Handling Tint)	5mm to 9mm (varies with power)
UV Transmittance†	0-10 % in the ultraviolet portion of the spectrum (250 400nm) averaged across the spectrum
Oxygen Permeability (Dk)	16 1x10⁻ ml O₂cm /sec ml mmHg
Oxygen Transmissibility (Dk/L)	20x10 ml O cm/sec ml mmHg @ 35°C
(Dr Irving Fatt Method)	

†The referenced data was determined from Methods for Determining Ultraviolet Transmission of UV blocking Contact Lenses by Dr H Faubl International Contact Lens Clinic Vol 25 no 5 1998 Representative of the thinnest lens design

Figure 1 (below) illustrates the transmittance of a typical FreshLook UV and/or FreshLook Progressive Bifocal with Handling Tint lens (thinnest lens to be marketed) a human cornea and a human lens Curve 1 represents the transmittance of the thinnest (0 08mm nom nal center thickness) lens to be marketed

FIGURE 1 TYPICAL TRANSMITTANCE PROFILE OF A FRESHLOOK UV WITH HANDLING TINT CONTACT LENS VS A HUMAN CORNEA AND A HUMAN LENS



A small transmittance peak appears in Curve 1 in the 250 290 range The transmittance across this waveband is 0 12% average with a maximum of 29% This peak is located in the wavelength of ultraviolet radiation (250-290nm) which is not transmitted to the earth s surface Curves 2 and 3 represent the transmittance characteristics of a human cornea from a 24-year old person and a human lens from a 25-year-old person, respectively

1 Human cornea from a 24 year old person as described in Lerman, S Radiant Energy and the Eye, MacMillan, New York, 1980, p 58 figure 2 21
2 Human crystalline lens from a 25 year old person as described in Waxler M Hitchins V M Optical Radiation and Visual Health CRC Press Boca Raton Florida 1986 p 19 figure 5

ACTIONS

When placed on the cornea a hydrated FreshLook Spherical soft contact lens acts as a refracting medium to focus light rays on the retina. The FreshLook Toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina. The thinnest FreshLook UV lenses (3 50 diopters and lower) block 98% UVA radiation and 94 / UVB radiation averaged across the spectrum The degree of UV radiation blockage of FreshLook UV lenses will increase for thicker lenses FreshLook Spherical and Toric soft contact lenses with Handling Tint provide ease of patient handling and easy visibility but do not affect ins color The visibility tint allows the lens to become visible to wearers when not on the eye.

Patients should be advised of the following

Warning UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surround ng area You should continue to use UV absorbing eyewear as directed

NOTE. Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude geography cloud cover) and personal factors (extent and nature of outdoor activities) UV absorbing contact lenses help provide protection against harmful UV radiation However clinical studies have not been done to demonstrate that wearing UV absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care professional for more information

Available Lens Parameters

FreshLook soft contact lenses are hemispherical shells of the following dimensions:

Spherical Lens Parameters

Chord Diameter:	12.0 to 15 0 mm	
Center Thickness:	Extended Wear and (Varies with power)	Daily Wear 0 08 to 0 56mm (Varies with power)
	0 08 to 0 19mm	
Base Curves:	7 80 to 9 00 mm	
Powers:	20.00 Diopters to +20.00 Diopters for Daily Wear 20.00 Diopters to +4.50 Diopters for Extended Wear	

Toric Lens Parameters

Chord Diameter:	12 0 to 15 0 mm	
Center Thickness	Extended Wear and (Varies with power)	Daily Wear 0 08 to 0 56mm (Varies with power)
	0 08 to 0 19mm	
Base Curve	7 80 to 9 00 mm	
Powers:	20.00 Diopters to +20 00 Diopters for Daily Wear 20.00 Diopters to +4.50 Diopters for Extended Wear	
Cylinder:	-0 75 Diopters to -6 00 Diopters	
Prism Ballasted	0 25 Diopters	
Axis	0 to 180 in 1 steps	

INDICATIONS (USES)

Vision Correction

Spherical

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2 0 diopters that does not interfere with visual acuity The FreshLook Spherical Colors Color Enhancers ColorBlends Radiance and Dimensions lenses act to enhance or alter the apparent color of the eye

Toric

FreshLook Toric (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6 0 diopters The FreshLook Toric ColorBlends lenses act to enhance or alter the apparent color of the eye

The lenses may be prescribed for Daily Wear or Extended Wear in not-aphakic persons from 1 to 7 days between removal for cleaning and disinfection or disposal as recommended by the eye care professional or for Daily Wear in aphakic persons The eye care professional may prescribe the lens in either the single use disposable wear or for frequent replacement with cleaning disinfection and scheduled replacement When prescribed for frequent replacement the lens may be disinfected using a chemical disinfection system FreshLook soft contact lenses with UV absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye

CONTRAINDICATIONS (REASONS NOT TO USE)

FreshLook soft contact lenses are contraindicated when any of the following conditions exist:

Acute and subacute inflammation or infection of the anterior chamber of the eye
Active disease injury or abnormality affecting the cornea conjunctiva or eyelids
Microbial infection
Insufficiency of lacrimal secretion (dry eyes)
Corneal hypoesthesia (reduced corneal sensitivity if not aphakic)
Use of medication that is contraindicated including eye medications
Patient history of recurring eye or eyelid infections including styes or of adverse effects associated with contact lens wear or of intolerance or abnormal ocular response to contact lens wear
History of patient non-compliance with contact lens care and disinfection regimens wearing restrictions wearing schedule or follow-up visit schedule
Patient's inability or unwillingness because of age infirmity or other mental or physical conditions or an adverse working or living environment, to understand or comply with any lens care requirements warnings precautions restrictions or directions
Allergy to any ingredient such as mercury or Thimerosal in a solution which must be used to care for the lens
Patients who require only vision correction and who would not, or could not, adhere to a recommended care system for lenses or who are unable to place and remove lenses should not be provided with them
Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
If eyes become red or irritated.
Any active corneal infection (bacterial fungal or viral) Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products Therefore after a thorough eye examination including appropriate medical background patients must be fully apprised by the prescribing professional of all the risks associated with contact lens wear To minimize these risks the need for strict compliance with the care regimen including cleaning of the lens case if the patient is on the Frequent Replacement Program wearing restrictions, wearing schedules and follow-up visit schedule must be emphasized to the patient (see considerations listed in CONTRAINDICATIONS and PRECAUTIONS Sections)

Since eye injury can develop rapidly it is most important that patients be instructed in the possible signs or symptoms of problems and the need to remove the lenses and be examined by the prescribing eye care professional or a corneal specialist immediately if they experience any symptoms such as those listed below under the ADVERSE EFFECTS Section (Professionals examining patients presenting such symptoms should refer to the Professional Fitting Guide and Patient Instruction Booklet)

Extended Wear The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals beginning with the first overnight use Some researchers believe that these complications are caused by one or more of the following a weakening of the cornea s resistance to infections particularly during a closed-eye condition as a result of hypoxia an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms particularly when a regular periodic lens removal and disinfection or disposal schedule has not been adhered to by the patient; contamination of lens and/or lens care products poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule accumulation of lens deposits damage to the lens improper fitting length of wearing time and the presence of ocular debris or environmental contaminants Additionally smoking increases the risk of ulcerative keratitis in contact lens users While the great majority of patients successfully wear contact lenses extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates and endothelial polymegathism which require consideration of discontinuation or restriction of extended wear The epithelial conditions are reversible upon discontinuation of lens wear The reversibility of endothelial effects of contact lens wear has not yet been established As a result professionals views of extended wearing times vary some do not prescribe extended wear at all others prescribe flexible wearing times with occasional overnight wear and others prescribe extended wearing periods from 1 to 7 days/6 nights with specified intervals of no lens wear for certain patients with follow-up visits as in the case of the Frequent Replacement Program with a proper care regimen Some professionals also recommend frequent replacement of lenses at intervals such as one to two weeks

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear

Serious eye injury scarring of the cornea and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products To reduce these risks emphasize to the patient the need for strict compliance with the lens care regimen including hand washing proper lens disinfection cleaning of the lens case wearing restrictions wearing schedules and follow-up visit schedules

Eye problems including corneal ulcers can develop rapidly and if left untreated lead to loss of vision Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and promptly contact their eye care professional if they should experience eye discomfort foreign body sensation excessive tearing vision changes redness of the eye or other problems with their eyes

Non-compliance with the manufacturer's labeled lens care instruction may put the patient at significant risk of developing a serious eye infection Tap water distilled water or homemade saline solution should NOT be used as a substitute for any component in the lens care process The use of tap and distilled water has been associated with Acanthamoeba keratitis a corneal infection that is resistant to treatment and cure

Smoking increases the risk of corneal ulcers for contact lens users especially when lenses are worn overnight or while sleeping

PRECAUTIONS

In prescribing contact lenses the Precautions should be carefully observed It is also strongly recommended that the professional review with the patient the appropriate Patient Instruction Booklet (describing either the Frequent Replacement Program or the Disposable Wear Program) available from CIBA Vision prior to dispensing the lenses and ensure that the patient understands the contents

Plaintiff's Exhibit 6

Alexander Gallo & Associates, Inc. COURT REPORTING VIDEO SERVICES TRIAL PRESENTATIONS

CIBA000153

Due to the small number of patients enrolled in clinical investigation of lenses not all refractive powers design configurations or lens parameters available in the lens material are evaluated in significant numbers Consequently when selecting an appropriate lens design and parameters the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health including oxygen permeability wettability central and peripheral thickness and optic zone diameter

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient s need for refractive correction therefore the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care professional

In the Disposable Wear Program the FreshLook soft contact lenses are intended to be disposed of once they are removed from the patient's eye Therefore it is important that patients be instructed to always have available a pair of new sterile lenses In the event that a lens must be removed from the eye because of dust a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry) the lens should be removed and replaced with a new sterile replacement lens If replacement lenses are not available the patient should follow emergency lens care directions

In the Frequent Replacement Program in the even that a lens must be removed from the eye because of dust a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry) the lens should be removed cleaned and disinfected before reinsertion. If the lens becomes dehydrated the patient should follow the lens care directions for CARE FOR A DEHYDRATED LENS In the Frequent Replacement Program or in the event of Emergency Lens Care in the Disposable Wear Program chemical disinfection solution may not be used with heat unless specifically indicated in the labeling for heat and chemical disinfection

In the Frequent Replacement Program or in the event of Emergency Lens Care CIBA Vision recommends use of sterile solutions Sterile non preserved solutions should be used if the patient is allergic to preservatives such solutions must be discarded after the time specified in their label directions

Contact lens wear may not be suitable for certain occupations or in other instances may require eye protection equipment. Therefore the patient should always inform his/her employer that contact lenses are being worn Environmental fumes smoke dust vapors and windy conditions must be avoided in order to minimize the chances of lens contamination or physical trauma to the cornea

Eye injury from irritation or infection and damage to lenses may result from lens contamination The patient should be instructed to refrain from using saliva or anything other than the recommended solution for lubricating or wetting lenses The patient should also be informed to wash and rinse hands before handling contact lenses at all times

Eye care professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated

The patient should be informed that contact lenses should not come into contact with any cosmetics lotions soaps creams hairsprays or deodorants that it is best to put on lenses before putting on makeup and that water based cosmetics are less likely to damage lenses than oil based products

The patient should be informed not to use aerosol or pump products such as hairspray while the lenses are worn since liquid and vapors may damage the lens

The patient should be instructed to handle the lenses carefully and avoid dropping or touching them with fingernails which can cause contamination or damage of the lens The patient should also be told that if the lens becomes nicked or torn it should not be worn

Tweezers or other tools should not be used by patients to remove a lens from the lens container The lens should be poured into the hand Lenses should be cleaned in the palm of the hand rather than between thumb and finger

Patients should be instructed on and be able to demonstrate prompt removal of the lenses

Fluorescein should not be used while the lenses are on the patient s eye The lenses absorb this dye and become discolored Fluorescein in the eye should be thoroughly flushed with a sterile saline solution recommended for in-eye use and a new lens should be re nserted only after at least one hour

A lens must move freely on the eye for a proper fit For further information refer to the appropriate FreshLook soft contact lens Professional Fitting Guide

Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a da ly wear basis Patients should be carefully evaluated for extended wear prior to prescription and dispensing and professionals should conduct early and frequent follow up examinations to determine ocular response to extended wear

To prevent contamination and avoid serious eye injury the patient should be instructed to empty and rinse the lens case with fresh rinsing solution and allow the lens case to air dry between each lens disinfection cycle as in the Frequent Replacement Program or in the event of Emergency Lens Care

The patient should be instructed to inform his or her physician that contact lenses are worn and to consult his or her eye care professional before using any medication in the eye

Exposure to water while wearing contact lenses in activities such as swimming water skiing and hot tubs may increase the risk of ocular infection including but not limited to Acanthamoeba keratitis

Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly

Certain medications such as antihistamines decongestants diuretics muscle relaxants tranquilizers and those for motion sickness may cause dryness of the eye increased lens awareness or blurred vision Should these conditions exist proper remedial measures should be prescribed

Depending on the severity this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used

A patient who has been prescribed FreshLook contact lenses on a daily wear schedule should be cautioned to remove the lenses before sleeping

ADVERSE EFFECTS

otentially serious complications are usually accompanied by one or ore of the following signs and symptoms

- Foreign body sensation
- Excessive watering (tearing) of the eyes or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning st nging itching or other pain associated with the eyes
- Comfort is less compared to when lens was first placed on eye
- Poor visual acuity
- Blurred vision rainbows or halos around objects
- Feeling of dryness

If the patient notices any of the above signs or symptoms he or she should be instructed to **IMMEDIATELY REMOVE THE LENSES**

- If the discomfort or problem stops look closely at the lens
  - If the lens is in any way damaged DO NOT put the lens back in the eye Discard the lens.
  - If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops clean disinfect and reinsert the lens If in the Frequent Replacement Program or discard the lens and replace it with a new sterile replacement lens if in the Disposable Wear Program
- If the discomfort or problem continues after removal of the lens or upon reinsertion immediately remove lenses and promptly contact his or her eye care professional The eye care professional must determine the need for examination treatment or referral without delay

Patients should be informed that a serious condition such as infection corneal ulcer corneal vascularization or iritis may be present and may progress rapidly Less serious reactions such as abrasions epithelial staining and bacterial conjunctivitis should be treated appropriately to avoid complications Additionally contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear These include but are not limited to local or generalized corneal edema epithelial microcysts epithelial staining infiltrations, neovascularization endothelial polymegathism tarsal papillary changes conjunctival infection or iritis

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of FreshLook (phemfilcon A) contact lenses eye care professionals please notify CIBA Vision Corporation technical consultation at 1 800-241 7468

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS

The lens must move adequately on the eye for a proper fit and continued health of the eye When prescribing FreshLook lenses for extended wear it is important to reevaluate the lens fit for adequate movement at various times after the patient sleeps while wearing lenses This reevaluation should include a follow-up visit as soon as possible after the patient awakens as well as at other times of the day If the fit is judged to be too tight or steep the patient must be refit into a lens that provides the criteria of a well fitted lens

Conventional methods of fitting contact lenses apply to FreshLook soft contact lenses. For a detailed description of the fitting technique refer to the appropriate CIBA Vision *Professional Fitting Guide*

It is strongly recommended that the patient be provided appropriate *Patient Information Booklet* available from CIBA Vision and understands its contents prior to dispensing the lenses.

Copies of **Fitting Guides** and **Patient Information Booklets** for FreshLook lenses are available without charge from CIBA Vision Corporation Duluth Georgia USA 30097 or by calling a CIBA Vision customer service representative at 1-800-241 5999

LENS REPLACEMENT SCHEDULES

In a **planned replacement program** the replacement schedule is determined by the eye care professional based upon the patient's physiological condition CIBA Vision recommends frequent replacement of FreshLook lenses at intervals of every two weeks The eye care professional may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient, professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary When FreshLook lenses are prescribed for **disposable wear** the contact lens is considered a single use medical device in which the lenses are worn from 1 to 7 days and **discarded upon removal** from the eye

WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional

CIBA Vision recommends that contact lens wearers see their eye care professional twice each year or if directed more frequently The maximum suggested wearing time each day should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary The eye care professional may prescribe the lens for frequent replacement with cleaning disinfection and scheduled replacement. When prescribed for frequent replacement the lens may be d s nfected sing a chemical (not heat) disinfection system

DAILY WEAR There may be a tendency for the daily wear patient to over-wear the lenses initially Therefore the importance of adhering to a proper initial daily wearing schedule should be stressed to these patients The wearing schedule should be determined by the eye care professional and provided to the patient. These lenses may be worn in the Frequent Replacement Program

EXTENDED WEAR (Greater than 24 hours or while asleep) The wearing schedule should be determined by the prescribing eye care professional for each individual patient, based upon a full examination and patient history as well as the professional s experience and professional judgment

CIBA Vision recommends beginning extended wear patients with the recommended initial daily wear schedule followed by a period of daily wear and then the gradual introduction of extended wear one night at a time unless individual considerations indicate otherwise The eye care professional should examine the patient in the early stages of extended wear in order to determine corneal response The lens must be removed cleaned and disinfected or disposed of and replaced with a new lens as determined by the prescribing eye care professional (See the factors discussed in WARNING Section) Once removed a lens should remain out of the eye for a period of rest overnight or longer as determined by the prescribing eye care professional.

LENS CARE DIRECTIONS

Disposable Wear (Emergency Lens Care)

No lens care is indicated as lenses are discarded upon removal from the eye Lenses should only be cleaned rinsed and disinfected on an emergency basis when replacement lenses are not available (See BASIC INSTRUCTIONS FOR LENS CLEANING RINSING AND DISINFECTION below)

Planned Replacement

Patients must adhere to a recommended care regimen Lenses must be cleaned rinsed and disinfected after removal and prior to reinsertion on the eye according to the package inserts and patient instructions provided with the lens care products recommended by the eye care professional Fa lure to follow the complete regimen in accordance with the manufacturer's package inserts and patient instructions may contribute to problems (see ADVERSE EFFECTS) and/or result in the development of serious ocular complications as discussed in WARNINGS

Basic Instructions for Lens Cleaning and Disinfection

When lenses are dispensed the patient must be provided with appropriate and adequate instructions and warnings for lens care handling The eye care professional should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system The specific instructions for such products and the particular characteristics of the patient should also be taken into consideration.

The basic general instructions for general lens care are as provided below

- Always wash and rinse your hands before handling your contact lenses
- The lenses should be cleaned and disinfected before reinsertion into the eye. Use a suggested chemical (not heat) lens care system recommended by the professional since heat may cause discoloration
- Use and follow the instructions of lens care products intended for use with soft (hydrophilic) contact lenses.
- Always use lens care solutions before they reach the expiration date
- Always keep the lenses completely immersed in the recommended storage solution when they are not being worn (stored)
- In the Frequent Replacement Program CIBA Vision recommends that sterile solutions be used in the soft lens care system Sterile non-preserved solutions should be used only if the patient is allergic to preservatives. When used sterile non preserved solutions must be discarded after the time specified in their label directions

Refer to the PRECAUTION Section for further information on lens care and handling.

CARE FOR A DEHYDRATED LENS

Disposable Wear Program If a soft (hydrophilic) contact lens is exposed to air while off the eye it may become dry and brittle Dehydrated lenses should be disposed of Therefore it is important that the patient always have a pair of new sterile replacement lenses available

Frequent Wear Program If a soft (hydrophilic) contact lens is exposed to air while off the eye it may become dry and brittle and need to be rehydrated If the lens is adhering to a surface, such as a counter top apply sterile saline solution before handling

Eye care professionals should review the following information on rehydrating the lens with the patient:

- Handle the lens carefully
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state.
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking the lens does not become soft, the lens should not be used until examined by the eye care professional

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye the patient should be instructed to apply several drops of the recommended lubricating or rewetting solution directly to the eye and wa t until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after several minutes the patient should be instructed to immediately consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.

Each contact lens is shipped sterile in a sealed blister pack containing borate buffered saline Hands should be thoroughly washed rinsed and dried with a lint free towel prior to handling a lens In order to insure sterility the blister pack should not be opened until immediately prior to use For fitting and diagnostic purposes, the lenses should be disposed of after a single use and not be re used from patient to patient

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions laboratory chemicals etc.) are splashed into the eyes, the patient should flush eyes immediately with tap water and call or visit the eye care professional or a hospital emergency room without delay

HOW SUPPLIED

Each sterile lens is packaged in a foil sealed plastic container contain ng a borate buffered saline solution with 0 005% poloxamer and is steam sterilized The package is marked with the lens power diameter base curve cylinder and axis (if applicable) expiration date manufacturing lot number and if applicable UV absorber lens t nt and opaque color

ADDITIONAL INFORMATION

For answers to your questions about FreshLook soft contact lenses or to report any adverse reactions contact our Professional Consultation Services at 1-800-241 7468 during regular business hours

For additional copies of the Eye Care Professional Package Insert Professional Fitting Guide and Patient Instruction Booklets contact our Customer Service Department at 1 800-241 5999

PATENT PROTECTED

U S Patents. 4 976 533 5 062 701 5 020 898 5 936 705 4 668 240 4 720 188 4 704 017 4 582 402, 4 668 240 5 414 477 5 637 726

Patents Pending for FreshLook Progressive Bifocal

GB Patents. 0346032, 0498835 0158999 0187137 0440107

FR Patents 0346032 0498835 0158999 0187137 0440107

AUS Patents 620886 636679 569649 634624

CN Patents 26003 4158 4136 3788 4157

PH Patents 26412 29984 23319

SG Patents 9790790 1 9790791 9 9090530-8 9290545 4

TW Patents NI 42746 NI 63667 NI 26506 NI 51612

BR Patents. P18600017 9 P190078012 P18600017 9

HK Paten

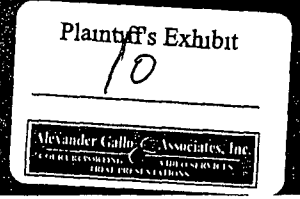
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth Georgia USA 30097
Date/Part No July 2003
D7400B/096137

CIBA Vision

CIBA000154

CIBA Vision Corporation Meeting with FDA:

Advertising and Promotion of Contact Lenses
21 November 2003



CIBA Vision
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Agenda

- Introductions
- Presentations & Discussion
  - Opening Remarks: Consumer Advertising
  - Orientation: Current Situation
  - Fashion Category: FreshLook Ads & Commercialization
  - Regulatory Framework: Device Advertising & Promotion
  - Continuous Wear Category: NIGHT & DAY Advertising
- Meeting Close - Summary & Follow-up

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Introductions – CIBA Vision Attendees

- Andrea Saia, President Lens Business Franchise
- Joseph Foos, Vice President Scientific Affairs
- Richard Weisbarth, OD, Vice President NA Professional Services
- Alicia Plesnarski, Director Global Regulatory Affairs
- Thomas Henteleff, Esq., Kleinfeld, Kaplan and Becker

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CIBA Vision - Vision Statement

Our Purpose

- *Better eyes for a better life.*

Our Vision

- *A billion eyes around the world will benefit from our innovation.*

- *We will be:*
  - *recognized by consumers worldwide as the best eye care company. We deliver compelling brands built upon breakthrough innovation and world-class marketing.*
  - *trusted by customers for our competence, service and a following of consumers excited by our brands.*
  - *the fastest growing, most profitable company in eye care - staffed by people who care passionately about their work.*

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CIBA Vision – Strategic Imperatives

- External Focus – Consumer & Practitioner Needs Satisfaction
- Innovation – Lead the discovery and delivery of new benefit solutions
- Strategic Discipline – Key consumer needs segments, leading global brands, top geographical markets, and priority customers
- Operational Excellence – Superior quality products at reasonable prices to right places at right times
- Brand Building - Our principle assets and relationship vehicles

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U.S. Lens Market Share - %

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Slide 6

"Including the Consumer"

- Only 8% of consumers request a contact lens by name
- Only 29% of consumers are given a brand choice by their practitioner
- 92% of potential users have no brand preference
- The patient/practitioner dialogue has yet to begin
- Demonstrates the importance of educating and informing consumers about unique and meaningful brand benefits

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Ciba Vision
"Including the Consumer"

Metric	Rx Meds	Contact Lens
• Consumers who spoke to physician/ practitioner re: a specific Rx brand	32%	8%
• Consumers who asked physician to prescribe a specific Rx brand	29%	N/A
• Consumers receiving a specific Rx brand requested	77%	75%

Opportunity exists to grow the 8% CL Rx brand requests!

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CIBA Vision

Build Benefit Oriented Relationships:
Practitioner + Consumer

FUNCTION

Does the brand provide a solution to my problem; my patient's problem?

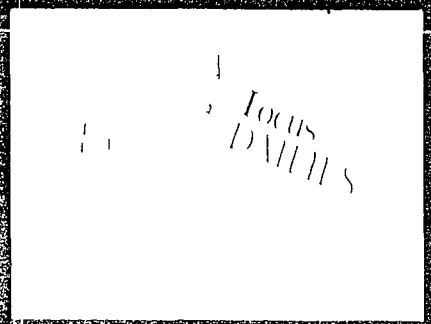
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EMOTION

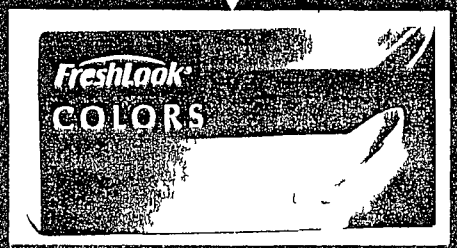
Why is that solution important to me; to my patient?

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Ciba Vision Lens Business: Brand Benefits Portfolio







Establish that Focus Dailies hygienic lens provides the clearest vision possible

- Non-ionic material
- 10 X less build up than ordinary SCLs
- Single Use

Establish that eyes can be their most beautiful w/FreshLook

- Widest most natural color pallet
- Customize to needs
- Enhance & change
- With or without vision correction

Establish that FND is the best lens you can wear because:

- 6X more oxygen to the eye; breathable lens
- Provides continuous vision for up to 30 days & nights, if desired
- In US, FDA Approved

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Slide 10

Our Commitments

- Honest, ethical and responsible business practices
- Responsible for safe, effective and efficient use of products and services
- Deliver the highest quality standards of performance for all products, services and functions
- Partner with key constituents to ensure the advancement of important new benefit solutions (FDA, AAO, AOA, etc)
- Seek improvements in all we do

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Current Situation

- 2002/2003 Ads developed in consideration of :
  - FDC Act: Device class & approval letters
  - Looked to available drug DTC guidance/model
  - Historical CV experience/competitor examples
  - Expert consultants
  - Where possible, proactive review by FDA
- 2002/2003 Office of Compliance Letters
  - NIGHT & DAY TV Ad
  - FreshLook Print & TV Ad

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Fashion Category: Freshlook Advertising

FDA Letter

- FDA Concerns
  - FL Advertising
    - o Lacks UV statements
    - o Lacks brief statement of intended use
    - o Lacks fair balance
  - Illegal Sale of Cosmetic Lenses
    - o Freshlook reported complaints and product availability

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Freshlook Advertising: Print Ads

- Print Ads contain:
  - Rx Only
  - General Risk Statement :

    Contact lenses, even if worn for cosmetic reasons, are medical devices that require a valid prescription and should only be worn under the supervision of an eye care professional.

- Print Ads do not contain:
  - UV Claims



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Freshlook Advertising: TV Ad

- CV TV Ad removed from website and TV shortly after receipt of letter
- No interruption of competitor color lens (UV containing) TV Ads

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FreshLook Print & Broadcast Ads

Proposal

- UV risk disclaimer is appropriate when UV claims included in Ads
- For Ads Lacking UV claim, include general balancing risk statement in both print & broadcast Ads

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FreshLook Print & Broadcast Ads

- Example of general risk statement:

  Contact lenses, even when used to change eye color, should only be worn under supervision of an eye care professional.

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Regulatory Framework

- Contact Lenses
  - Prescription Required
  - Historically Class II and III Devices
- Plano Colored Lenses
  - Prescription Required
  - Recent Cosmetic Designation

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Regulatory Framework: Advertising & Promotion

- All Devices Subject to General Restrictions
  - Fair balance, can not be false or misleading
- Advertising Oversight
  - FTC - OTC and prescription devices
  - FDA - Restricted devices
- Contact Lens Distinction
  - While all contacts require a prescription, not all contacts are restricted devices

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Regulatory Framework: Advertising & Promotion

- Restricted Device Status (RDS)
  - Designation by FDA regulation or approval order
  - Are Class II/daily wear contact lenses containing UV designated as restricted?
  - Historical experience establishes distinction for RDS practices per language in approval letters & advertising practices
    - Recent UV 510k clearance letters don't indicate restricted device status
    - Different language used in PMA approval letters for lenses with restrictions (6N UV vs. 30N)
    - Historically, Ads with UV claims contain UV FDA statements but do not contain a brief summary

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Regulatory Framework: Advertising & Promotion

- UV Warning restrictions
  - Underlying purpose to control advertising so that Ads do not imply a misleading interpretation of a public health benefit
    - UV PMA Approval letters - Possible original assumption that all ads would include UV claim
    - Consider adopting a policy of not requiring restricted device information regarding UV warning & brief summary when Ad is silent
- Consider Drug DTC Advertising
  - If choose to advertise for limited indication, not required to reveal complete risk information.

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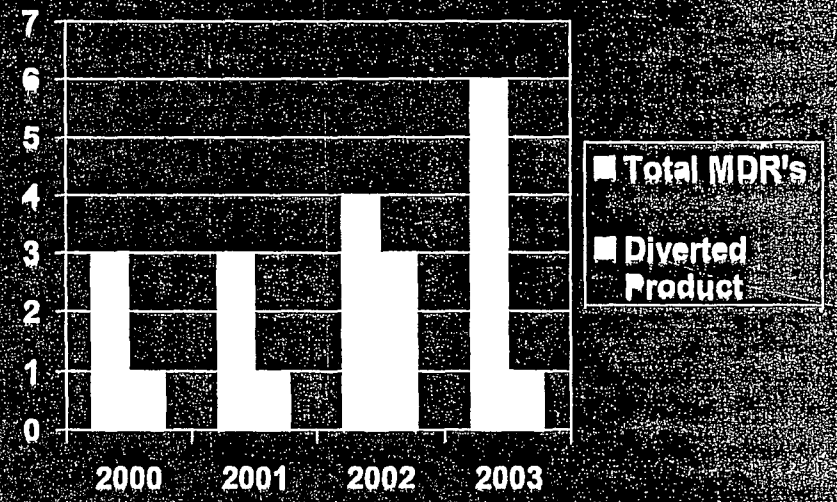
Market Environment for Cosmetic Contacts

- FreshLook Complaint Information
- Operation Healthy Eyes to address illegal sales

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FreshLook Complaint Information

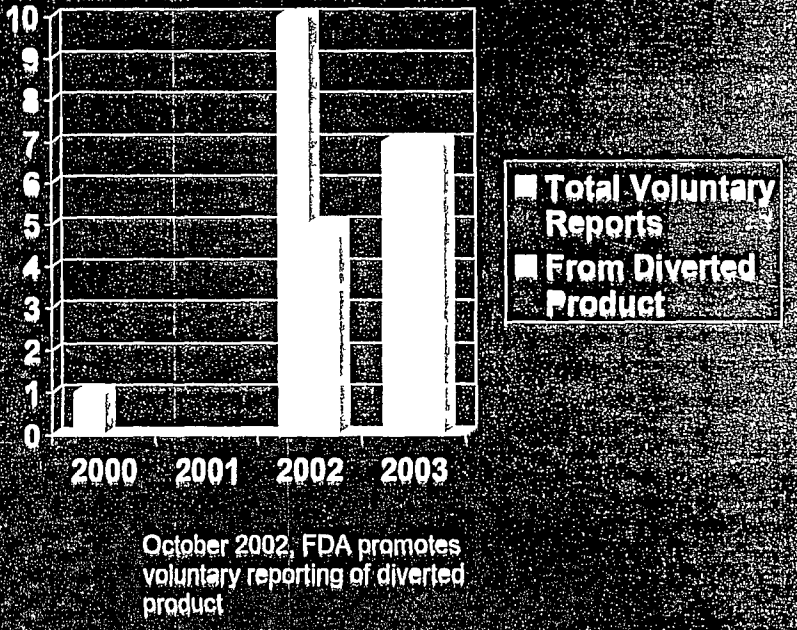
- FreshLook/Durasoft Manufacturer Reports
  - Overall, numbers are similar to non-cosmetic products
  - No negative trend relative to diverted product



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Voluntary Reports from Diverted Product

- Conclusion
  - Increase coincides with increased FDA activity regarding public announcement on health risks.



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Slide 24

Market Environment Cosmetic Contacts

- Public statements of support about concern over continued regulation of non-prescription color lenses as medical devices
  - CLI involvement
  - Professional organizations
  - Legislative initiatives
  - ARBO Registry
- Source of product is difficult to trace

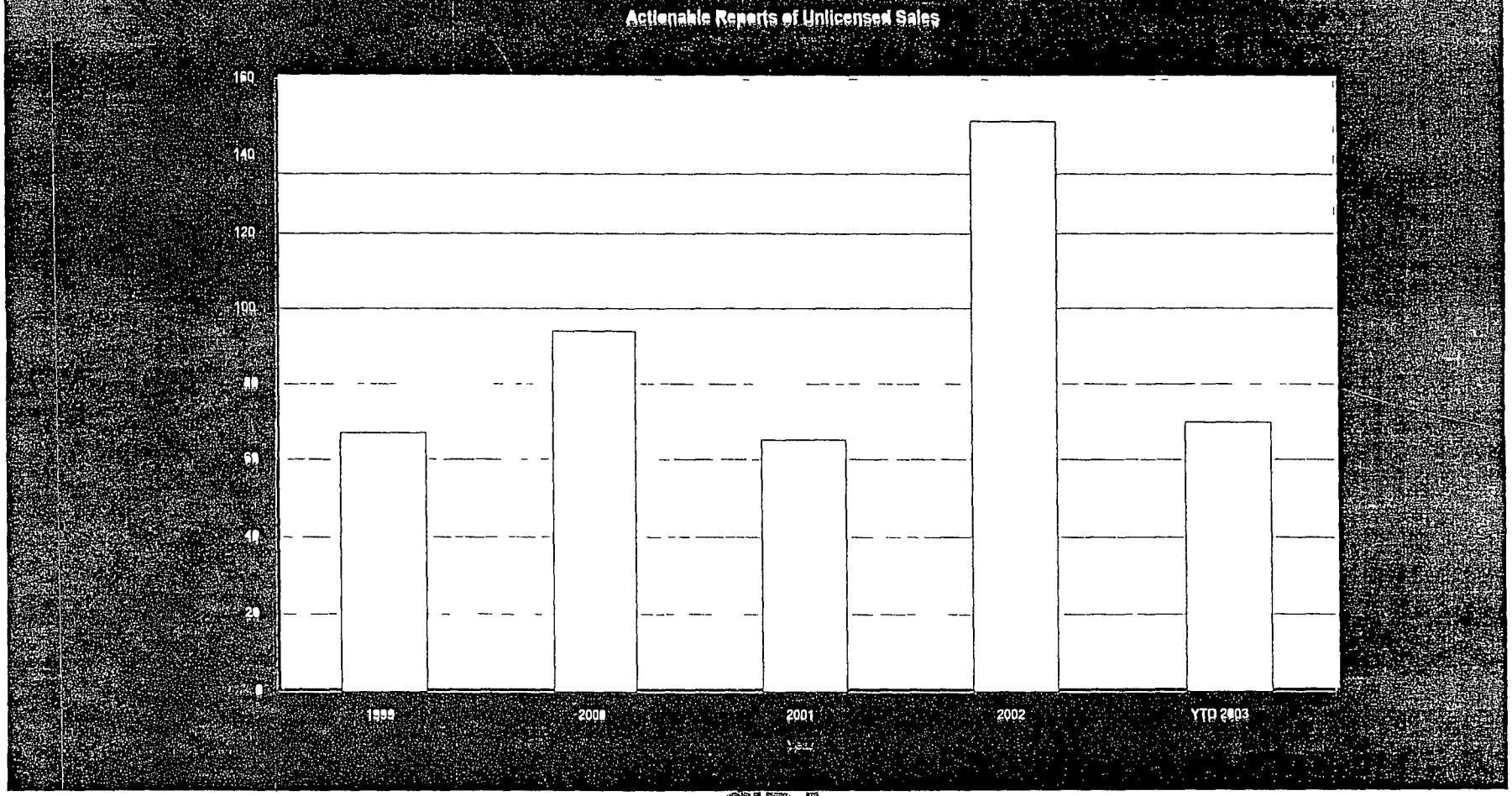
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Management of Cosmetic Contact Lenses

- Operation Healthy Eyes
  - CIBA Vision Cross Functional Team (professional services, legal, corporate communications, regulatory, quality, security, marketing)
  - Active and ongoing initiatives to ensure control of CIBA Vision products to licensed and authorized vendors and to investigate and restrict reported cases of illegal sale of CIBA Vision products

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Management of Cosmetic Contact Lenses



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Management of Cosmetic Contact Lenses

- Internal Checks
  - New Account Set-up: Professional license number is required on new customer applications.
  - Verification of license number whenever possible against publicly available professional databases.
  - Regular review our direct & indirect customer databases to ensure proper credentials

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Management of Cosmetic Contact Lenses

- Internal Checks
  - Monitor our sales reports for unusual activity
  - Semi-annual review of both direct and indirect customers.
  - Verify credentials of all significant new or rapidly growing customers, particularly those with significant FreshLook purchases.
  - Trace lenses when lot numbers are available to determine probable source

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Management of Cosmetic Contact Lenses

- U.S. based sites that offer cosmetic lenses without a prescription or practitioner information do not sell CIBA Vision products.

These sites include:

www.optiwild.com

www.bwild.com

http://store.yahoo.com/cosmetic-contacts/

www.clsdistributing.com (wholesale only)

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Management of Cosmetic Contact Lenses

- Actions
  - Issue cease & desist letters whenever we learn about our lenses being sold by an unlicensed seller without professional involvement
  - Notify state authorities
  - Instrumental in getting internet auction sites to prohibit the sale of contact lenses
  - Work with local agencies to eliminate improper sales in their areas

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Management of Cosmetic Contact Lenses

- Reporting to State Agencies:
  - California Medical Board
  - Florida Department of Health
  - Texas Department of Health
  - Illinois Department of Professional Regulation
  - Ohio Optical Dispensers Board
  - South Carolina Board of Examiners in Optometry
  - Washington State Department of Health
  - Arizona Board of Optometry

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Management of Cosmetic Contact Lenses

- Reporting to the FDA:
  - Medwatch
  - Consumer Coordinators
  - Compliance Officers

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Management of Cosmetic Contact Lenses

- Actions taken against known violators
  - Frank discussions with accounts when issues are discovered (i.e. chain activity)
  - Shut down accounts
  - Take legal action against unlicensed sellers

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Continuous Wear Category: NIGHT & DAY

- Consumer strategy currently supported by breathable statement appearing in print & TV Ad
- To support a branding strategy for High Dk lenses, would like to include breathable on product labeling
- Recent request to reconsider *Breathable Contact Lenses* as descriptor on NIGHT & DAY product packaging

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Summary

CIBA Vision is requesting concurrence that:

- UV warnings are not required when UV claims are not made
- A general risk statement is appropriate in TV and print media for cosmetic lenses
- The use of the term *breathable* is an appropriate descriptor for high Dk lens labeling
- CV efforts regarding illegal sales of cosmetic lenses are effective

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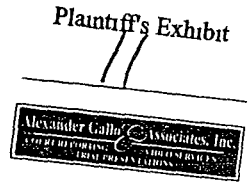
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Angela L Bunn, RAC
Global Regulatory Affairs Specialist
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097-1556

AUG 22 2003



Re P830037/S46
FreshLook® COLORBLENDS® (phemfilcon A) UV Soft Contact Lenses

P830037/S39
FreshLook® Colors UV and FreshLook® LiteTint UV (phemfilcon A) UV Soft (hydrophilic) Contact Lenses

Dear Ms Bunn

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your premarket approval application (PMA) supplements referenced above and issued approval orders on September 4, 2002 for Supplement 46 and January 25 1996 for Supplement 39 We inadvertently made an error by not including the appropriate restricted device conditions of approval that apply to all UV absorbing contact lenses

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801 109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act

As a condition of this restriction all advertisements and other descriptive matter issued by the manufacturer, packer or distributor with regard to this device will include the following warning and precaution (note) statements

"WARNING UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area You should continue to use UV-absorbing eyewear as directed "

"NOTE Long term exposure to UV radiation is one of the risk factors associated with cataracts Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extend and nature of outdoor activities) UV-absorbing contact

lenses help provide protection against harmful UV radiation However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders Consult your eyecare practitioner for more information "

We hope that this omission has not inconvenienced you If you have any questions about this corrective action, please contact James F Saviola, O D at (301) 564-1744

Sincerely yours,

A Ralph Rosenthal M D
Director
Division of Ophthalmic, Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

STATE OF SOUTH CAROLINA

IN THE COURT OF COMMON PLEAS

COUNTY OF RICHLAND

Monica Weston, Plaintiff, vs Kims Dollar Store and CIBA Vision a division of Novartis Company, Defendants	Civil Action No 05-CP-40-0655

DEPOSITION OF SUZANNE PARISIAN, M D

Phoenix, Arizona
August 18, 2006

CD ENCLOSED

ARIZONA REPORTING SERVICE, INC
Court Reporting
Suite Three
2627 North Third Street
Phoenix Arizona 85004-1126

By JODY L LENSCHOW, RMR CRR
Certified Reporter
Certificate No 50192

Prepared for

Mr A Victor Rawl Jr
Attorney at Law

CERTIFIED COPY
(When in red)

A Because she would have disposed of them
Q Do you know that for a fact, or was that a question?
A I believe that -- I have not heard that they're available, and I would assume that she would have disposed of them, since they've not been addressed anywhere Plus, they were soft contact lenses, weren't they, and after a while they deteriorate
Q So do you have any actual knowledge as to what happened to the contact lenses?
A No
Q Have you had an opportunity to review the contact lens packaging for the contact lenses that she allegedly wore?
A I've been told that this packaging -- this represents what was on her package
Q And the --
A This isn't her package, but this is a similar contact lens I think it's been used as Exhibit 4
MR RAWL That was in the 30(b)(6) deposition of CIBA Vision
MR MUNSON Well let's go ahead and mark it Can I mark this one?
MR RAWL I have another copy if you would like to do that

Q In your opinion, in 1995 did the FDA consider cosmetic -- let me start again

In your opinion, in 1995 did the FDA consider zero-powered plano color lenses capable of extended wear to be Class III medical devices?

A You threw in -- wait a second There are no plano lenses that have been cleared for changing the eyes that are capable of extended wear The minute you throw in extended wear, you've changed it to something different This is just a purely cosmetic device that its only purpose is to change the color of the eye We're not talking extended wear And so that one cite that they are referring to was a specific case by the FDA in order to address a manufacturer who was making a lens We don't know what kind of lenses he was going to make So it's specific to that one litigation

Q I don't want to talk about that litigation anymore

A Right

Q So let's break it down

In 1995 is it your opinion that the FDA's position would have been that a plano contact lens, color contact lens used to enhance the color of the eye was not a medical device?

A I don't believe they would have said that and

it's a cosmetic because there is no medical indication for this product at all

Q So your answer is, no, that you don't -- you don't believe that the FDA's position in '95 was that a plano color contact lens used to enhance the color of the eye was a medical device?

A I think in 1995 there really wasn't a market for what we're talking about The market for the plano lenses just for changing eye color came after '95 So I don't think the FDA even really focused specifically on the plano lens But by definition it is a cosmetic device

But we were talking about that one paragraph where they were trying to take -- a manufacturer had come into the United States and was going to make contact lenses

Q You say is a cosmetic device, but "is" is -- you're using that inappropriately, because it is today a medical device, correct?

A Well, no it's deemed a medical device, which is different

Q It's not a medical device?

A It's deemed a medical device

Q In your opinion, it's not a medical device today?

A In terms of where it's regulated by the FDA it

is deemed a medical device

Q In your opinion, is it a medical device or not?

A It's deemed a medical device, which is --

Q But you just said there's a difference between that, and so my question is, is it a medical device?

A I'll tell you what the difference is In terms of the word deem, when the Medical Device Act came through, products were eventually deemed as safe and effective because they were on the market They were deemed by Congress, and it's because you could bring -- you know you bring them into the system and so when FDA says or Congress says something is deemed it didn't say it is It said it's deemed a medical device

Therefore the oversight is going to be through medical devices because there is no premarket oversight of a cosmetic, and so there is no regulation that would really get into the premarket review of a cosmetic device, and so therefore, they deem it as a medical device, so that it is now covered under medical device regulations

Early medical devices were deemed as drugs so that they could be covered under drug regulations before there were device regulations

Q Including contact lenses?

A Right

Q Is it your position -- is it your opinion that

the FDA does not today consider plano colored contact lenses used to enhance the eye to actually be medical devices?

A They're deemed medical devices, but there's been no 510(k) or no PMA ever cleared or approved that I've seen yet that is just for color enhancement for CIBA

Q That's not my question My question is --

A Well, no, that's --

Q -- in your opinion --

A It would be --

Q Let me ask you this In your opinion today, is it the FDA's position that a plano color contact lens used to enhance the color of the eye is deemed a medical device?

A It is deemed, yes, and therefore --

Q But the answer to my question is yes?

A Yes and if I was a manufacturer and I wanted to market one then I would have to go and submit a PMA or a 510(k) in order to bring the product on the market with that indication

Q In your opinion today, is it the FDA's position that a plano zero-powered color contact lens intended to enhance the color of the eye is, in fact a medical device?

A It would be regulated under medical devices

Q Is it your opinion that it is -- that FDA's position is that it is a medical device?

A It's deemed a medical device and regulated under the regulation It doesn't --

Q But you seem to make a distinction between being deemed a medical device and actually being a medical device You agree that it is deemed a medical device I want to know if you agree that the FDA thinks that it is a medical device yes or no?

A I'm trying to explain It is a -- it doesn't have -- it doesn't meet the definition of a medical device It meets the definition of a cosmetic But there is no premarket oversight over cosmetics Ten years from now there may be and this would be a transition device, a cosmetic, that would go over to cosmetics but at this point in time there is no premarket oversight of cosmetics

Now if you go to Canada, this is a cosmetic in Canada what we're talking about a plano device A plano lens that's only for color is a cosmetic and it is regulated in Canada as a cosmetic It has to get licensed as a cosmetic it has to fill out forms as a cosmetic But in this United -- and that's because they have a process for looking at cosmetics We don't

So at this point in time the regulation of this

cosmetic device is under medical devices because the regulations are stronger So, therefore, that's where it sits But you don't know, ten years from now Congress may change the act and there may be regulation and premarket review of cosmetics

So the regulations -- and this is typically what FDA does, like you said before These were regulated as drugs initially because there weren't regulations for premarket oversight of devices So right now these cosmetic devices sit in CDRH, and you would have to have some kind of a premarket clearance, either a 510(k) or a PMA, to market a product that would be intended as just a cosmetic device But that's where you would go

Q In 1975 a plano color contact lens would have been considered by the FDA as a Class III drug requiring PMA approval correct?

A Well, contact lenses were considered drugs because of the concern about the dyes

Q So the answer to my question is, yes, a zero-powered contact lens then in 1975 would have been considered a drug by the FDA and regulated as a Class III premarket approval device?

A Not necessarily I don't think they were making -- they weren't selling -- in 1975 they weren't selling plano lenses just to enhance vision in 1975 But

it still doesn't meet the definition of a device
Q In your opinion in 1975 nobody made a color contact lens at zero power?
A Well, actually, in 1975 we didn't have the marketing that we have now in terms of the internet and availability of things
Q My question is, was anybody making it?
A They could be making it, because there are medical devices that would be planos that you would actually prescribe They could be -- they're usually clear and it would be for a medical indication, and that would be a device But if you're talking about a contact lens and the only reason it's being marketed is to change the color of your eyes that still doesn't constitute a device, and so if I was a manufacturer in 1975 and I had cosmetic lenses --
Q There are no devices in '75 It's got to be a drug in '75
A If I made lenses and I'm talking about generically and I wanted to do it you would have fought not to be a device because a --
Q A drug in '75
A I know that I know that But I'm talking about when the Medical Device Acts came through if there had been a market of plano lenses for cosmetic they would

have fought not to be brought over into devices because they want -- they were cosmetic enhancement

Q Let's add the extended wear complication to this discussion

A Well, that's different

Q If a plano today -- well, let me go back and ask you this Today, do you have an opinion as to whether or not the FDA considers plano color contact lenses used to enhance vision to be a medical device yes or no, do you have an opinion about whether the FDA takes that position?

MR RAWL Object to the form

THE WITNESS The plano, we just talked about that

BY MR MUNSON

Q I know Yes or no, do you have an opinion?

A Yes I did and I've talked about it It's deemed a medical device

Q And you make a distinction between something being a medical device and something being deemed a medical device correct?

A Correct

Q So I want to take those one at a time Let's just talk about something being a medical device and maybe you don't have an opinion But my question is do you have an opinion as to what FDA's position is as to

whether or not a plano color contact lens used to enhance the color of the eye is a medical device?

A It's regulated under medical device regulations

Q Do you have an opinion as to whether the FDA takes a position as to whether or not it is a medical device?

A And I've explained over and over, it is regulated under medical devices Say ten years --

Q But that's not answering my question as to whether or not --

A It is answering the question, because I can't answer it any other way

Q You may not have an opinion as to whether FDA has a position

A There is a definition of what a medical device is and there's a definition of a cosmetic and the FDA has said that the plano lenses just to change the color of the eye is cosmetic by definition, and it is going to be a cosmetic by definition Just because they put it under the device regulations doesn't change that it's still a cosmetic

Q So in your opinion the FDA currently would not consider a plano color contact lens used to enhance the eye to be a medical device?

A Correct

Q Okay
A It's a cosmetic, but it's being regulated under medical device regulations
Q Now, if it's authorized for extended wear, does that make it a medical device?
A And you're making claims that -- in terms of oxygen, you know, that you're -- once you start making medical claims about that you can wear it safely you're not going to have oxygen depravation, then you start going into medical device because you're actually making claims about what it can do in terms of your anatomy and your eye and so forth So you've walked over The minute you start getting into extended wear and all these other things you're starting to walk into making medical claims
Q Okay So let me ask you this If the FDA approved a plano color contact lens intended to enhance the color of the eye for extended wear, would FDA consider that to be a medical device?
A They could depending on the claims
Q Do you have an opinion as to whether or not they would or not?
A They could Any manufacturer of a plano lens could submit a marketing application for that and they could potentially be approved or cleared under the medical

that?

A No But I think that that is appropriate for a prescription device, and so we're talking about something that the FDA was not designing this label for, a cosmetic device So this label has -- it identifies the color It can also have other things on the label, but, you know, these are the basic requirements for a label for a contact lens

Q So in your opinion, if the FDA approved that labeling, it thought that was a medical device?

A Well, this is the -- this is if you go into the PMA application you'll see their draft labeling, that this is what they're proposing This is in there, as well as prescription device, that it will only be offered as a prescription device

The other information that's in the PMA is the patient manual that's going to go with this device So the FDA, in their PMA application, looked at a whole bunch of issues, and this was one component in terms of the PMA product that they approved

Q I don't know if this is a term that makes any sense to you or not but do you have -- looking at this FreshLook Colors lens which was apparently manufactured in 2003 from your review of the FDA documents related to FreshLook Colors and predecessor products, do you have a

sense of what the product genealogy of this product is? You mentioned that a 1983 PMA I think

A Right, the PMA is an 83 number, and the history, I mean you're talking about the history of this product in terms of its original approval and its --

Q (Nodded)

A Yes, various documents that I've gone through in terms of, you know, this FreshLook line, as opposed to other things that are under this PMA

Q The original 1983 PMA never mentions FreshLook, right?

A Right This came later

Q And so it's like the great-great-grandfather of this product?

A Correct, and FDA has allowed companies just to piggyback in terms of the information Some of this product was actually broken off after 1994 and cleared as 510(k)s, the daily wears, nonextended wears Same device but only with a different intended use

Q So you would have a daily wear product that would trace its genealogy back to this 1983 PMA you would have an extended wear product that would trace its genealogy back and they may come into existence from different PMA supplements, is that kind of how it --

MR RAWL Objection, form

THE WITNESS Right, and they also cite, in terms of they're citing the predicates, you'll see that they're citing predicates that may have been a PMA or a 510(k) so you have a various genealogy

Before user fees, that was probably more common, that FDA would go back and forth between 510(k)s and PMAs User fees now have made it so that there's more standardization of PMAs versus 510(k)s But at the FDA you typically looked at PMAs, 510(k)s, same family, same genealogy, they're just in different covers Some are -- the PMAs were orange and the 510(k)s were blue But you thought nothing of going back and forth between them

BY MR MUNSON

Q So you would agree that the genealogy for that FreshLook Color product begins with the 1983 PMA?

MR RAWL Object to the form

THE WITNESS Correct, and I believe that that also had went back to the NDAs Wasn't there an NDA before?

BY MR MUNSON

Q There may have been a -- well, are you aware of an IDE that may have preceded the --

A Right I saw a mention for an IDE but I also saw a reference back to an NDA So the genealogy actually extends back to drugs

approved by the FDA through a 510(k) process?
A Not until --
MR RAWL Object to the form
THE WITNESS Not until 2005
BY MR MUNSON
Q Okay So in 2003 you would agree that that product would have been approved by the FDA through a PMA, PMA supplement process?
MR RAWL Same objection
THE WITNESS Only because they're wanting -- there was no reason why they couldn't market a FreshLook Colors under a 510(k) if they wanted to It was just a marketing choice that kept this as a PMA product
BY MR MUNSON
Q And we agree that prior to 2005 the choice they made was PMA supplement process?
MR RAWL Same objection
THE WITNESS That's what the company did
BY MR MUNSON
Q Yes
A But the labeling would be just appropriate for a 510(k) product
Q Okay
A For a medical device not for --
Q I understand that

is not something that the FDA would take on lightly to do, but, yes, there technically would be authority But is it done? Never done And is it easily done? Very hard to have done and they would have to have a really good reason to do something like that, and I know of no process where FDA retrospectively goes back and looks at a PMA supplement

BY MR MUNSON

Q Do you agree in 1983 the FDA affirmatively determined that soft contact lenses were safe and effective?

A They approved that PMA No one is disagreeing They said it was safe and effective, for the contact lens that was available in 1983

Q Do you have any reason to believe that the FDA would not consider soft contact lenses today to be safe and effective?

A No

Q Okay

A And that is a prescription device with a patient manual and you have a physician interacting and giving all the warnings and labelings

Q The premarket approval process requires that the manufacturer submit specimens of labeling proposed to be used for the device right?

forget They have two of these One is for people who throw them away immediately and then they have one that they wear them for a while and then they throw them away later on, and so there's two versions of this, and the difference is just which one it's intended for But this is -- again, this is generic It could go with the 510(k) or the PMA

(Deposition Exhibit No 6 was marked for identification)

MR RAWL Go ahead and read that while he's looking for another one

BY MR MUNSON

Q Dr Parisian, what do you understand Exhibit 6 to be?

A This is in reference -- this is a Wesley-Jessen submission looks like to the FDA for an amendment to its PMA P830037 which is Supplement 33 and it's dated September 12th 1994

Q And is there a brief explanation of what the purpose of that PMA is?

A It says that the purpose of this amendment is to submit approved labeling in final printed form inclusive of the primary package unit labels secondary package labeling package insert professional fitting and information guide and patient instructions

Q Okay And what's the next page there?
A Is the list of attachments
Q Are those generally the kinds of things you would find as the labeling for a medical device?
A Yes, except not all medical devices have a fitting guide
Q Okay And what's the next page?
A And the next page it looks like it's flipped over the labeling The package insert and it would start over here on 27 and then it goes to 26 So it's kind of backwards
Q And what's the last page there, 28 628?
A And last page looks like it's proposed draft labeling of what they're going to have for FreshLook Colors and the different colors green, hazel, violet and blue, and then the LiteTint
Q And what's the date of this PMA supplement?
A This PMA supplement is 1994
Q Okay On Page 626, under the heading of Actions on the package insert, would you read the second paragraph?
A "The FreshLook Colors Soft Contact Lenses act to enhance or alter the apparent color of the eye or for use in ocular masking "
Q Okay And the enhance or alter the apparent

color of the eye, that's a decorative purpose?
A Correct, but it's also involved with a prescription lens, the Spherical and the Toric
Q And what is ocular masking?
A Ocular masking would be a medical indication, in that if you have like an abnormality of your iris, you know, like a scar or some people have had injuries, it would make a color so that it would correct the defect in your eye
Q Under Indications on Page 626 the last paragraph, would you read the first sentence there?
A The first paragraph?
Q The first sentence -- I'm sorry, the first sentence of the last paragraph
A Okay "The lenses may be prescribed for either Daily Wear or Extended Wear for 1 to 7 days between removal for cleaning and disinfection or disposal, as recommended by the eye care practitioner "
Q Okay So these are more than daily wear, could be used for extended wear?
A Yes, it could be used for any -- you know, in terms of the PMA submission, they're listing that it could be for any of those you know, one to seven days So it could be -- and there's nothing here that would prohibit this from being on the 510(k) product either if they --

for marketing the 510(k) product for daily
Q Okay But because it's authorized for extended wear, it would be a Class III medical device?
A The device you're talking about? When they market their lens for extended wear, then it's a Class III
Q Okay
A But the same lens could be perhaps marketed just for a single day, and then it's a daily and then it would be a 510(k) Class II
Q But if it came with this package insert, it would be a Class III medical device?
A Not necessarily, no, in the labeling because they just happen to choose not to market one for FreshLook but there's nothing here that would -- this is the type of labeling you see for a 510(k) product, too I mean the 510(k) lenses have products like this, I mean their labeling looks just like this
Q But isn't it going to say -- if it's a 510(k) product that's only allowed to be used for daily wear, it won't have an indication that it could be prescribed for extended wear?
A Extended wear right Right So the only reason this would be -- this is one to seven But in that they put one to seven and they said it's recommended by

the physician, that you could almost use this for a 510(k), as long as you don't use this as promoting it for seven days

Q Okay The FreshLook labels on the last page, 28, these appear to be draft labeling for the blister packs?

A Correct

Q And all these examples are 0 00, right?

A Correct

Q Which would be plano zero-powered lenses?

A Correct and this would be draft labeling, so these are not -- sometimes they even just say XX

Q On Exhibit 4, the blister pack, there's a symbol there with a letter capital U capital V and a dotted circle around it

What does that mean to you?

A That would be the ultraviolet component They have a product that they've added to the lenses to reduce ultraviolet, you know, the sun, sun effect on the contacts

Q So that symbol to you suggests that these contacts contain that ultraviolet ray protection ingredient?

A Right They're supposed to have an effect for ultraviolet blocking

(Deposition Exhibit No 7 was marked for identification)

BY MR MUNSON

Q I'm showing you what's been marked as Exhibit No 7 Will you glance at that and tell me what it appears to be to you?

A It's a letter from the FDA dated May 7th, 1999 to Mr Joseph Foos of Wesley-Jessen Corporation, who I know also worked for CIBA when CIBA took over, regarding the ultraviolet-absorbing monomer that was added to contact lenses, and it talks about the device will be modified and have this marketed under this trade name

Q And would that be PMA Supplement 42?

A Yes, and it was received April 7th, 1999 and approved shortly after, May 4th 1999 less than a month Pretty good turnaround

Q On the second page --

A Okay

Q -- there's a paragraph that begins "FreshLook Lenses with UV-absorbing monomer "

A Okay

Q That says "FreshLook Lenses with UV-absorbing monomer help protect against the transmission of harmful UV radiation to the cornea and into the eye," is that right?

A Right
Q And is that what they were -- this PMA is to allow them to add that monomer and make that -- for the purpose of protecting against the transmission of harmful UV radiation?
MR RAWL Object to the form
THE WITNESS Well, that was one of the things, to add that claim, but then if you look at the first page they were doing some other changes to the design of the lenses, and so adding that statement was just one of the issues
BY MR MUNSON
Q And do you agree that UV radiation can be harmful to the human eye?
A Well yes
Where are you reading, specifically, from somewhere?
Q No, no
A You don't want to sit there and look at the sun
(Deposition Exhibit No 8 was marked for identification)
BY MR MUNSON
Q Dr Parisian I'm handing you what's been marked as Exhibit 8 Would you glance at that?
MR MUNSON That's the only one I have but

that relates to the same thing
BY MR MUNSON
Q Is that PMA Supplement 33?
A 39
Q I'm sorry, 39?
A Yes, approved January 25th, 1996 And, again, it's the ultraviolet absorber, and there have been discussion with the FDA about whether the company was going to make claims or not about the UV, and so a lot of this in the PMA deals with whether the company was going to make advertising claims
Q And this one deals with FreshLook Colors?
A FreshLook LiteTint UV Soft Contact Lenses
Q FreshLook Colors UV and FreshLook LiteTint?
A Correct
Q And is it your understanding that after this was approved, that the symbol UV could appear on the labeling?
A Yes
Q Okay
A Because it says on here with UV-absorbing chromophores So again, a physician would know what that means A consumer wouldn't have a clue And I meant health care provider not just physician
(Deposition Exhibit No 9 was marked for identification)

the guidance and then the significance of the guidance
So typically they will do an import alert and it won't have a whole background This one is unusual in that it has the whole background as to the law and what the status of these products are and then the guidance Normally they just say, you know, detain them or, you know, they make an alert for a specific manufacturer This one they just made across the board
Q So it's your understanding that after issuing this alert, no zero-powered colored contact lenses were allowed into the United States?
A No No product that is intended to be marketed as a cosmetic, because you could have, like you brought up a minute ago, about the ocular defects You could use a plano lens for a person that may have a birth defect on their lens
So there are times when a plano lens can be prescribed and it's being used as a medical device This is saying that you cannot let any product in that the only purpose is to change the color of the eye, and it says Import Alert 86-10 applies to contact lenses that are intended to change the appearance of the normal eye in a decorative fashion and, two, intended for distribution directly to the wearer without the involvement of a qualified eye care professional

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Precision
8-18-06
Jodi L Lenschow RMR CRR

EXHIBIT 4

Alexander Gelfand & Associates, Inc.

Plaintiff's Exhibit

FreshLook®

Patient Instruction Manual

For Wearers of FreshLook (phemfilcon A) Soft Contact Lenses with or without UV Absorber

Frequent Replacement Wear Program

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CIBA000072

Parisian EXHIBIT 5
DATE 8-18-06
Jody L. Lenschow RMR CRR

1/55 FWI P t Instruc 2/16/99 11 17 AM Page 2

IMPORTANT

This Patient Information Booklet contains important information and instructions about FreshLook® Spherical Handling Tint Colors Color Enhancers and ColorBlends, FreshLook® Toric Handling Tint and Colors soft (hydrophilic) contact lenses

IMPORTANT· PLEASE READ CAREFULLY AND KEEP THIS INFORMATION FOR FUTURE USE

Personal Property of _____

Name _____

Street _____

City _____ State _____ Zip _____

Date Lenses Received _____

Eye Care Specialist _____

Street _____

City _____ State _____ Zip _____

Telephone _____

Emergency Number _____

How Lenses are Supplied _____

Your prescription power _____

Right Eye Power _____

Left Eye Power _____

Lens Color _____

Lens Replacement Schedule _____

Appointment Schedule for Check up Exam _____

ADDITIONAL INSTRUCTIONS _____

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CIBA000073

SOME TERMS USED IN THESE INSTRUCTIONS

Cornea	Transparent part of the eye covering iris and pupil
Sclera	The white part of the eye
Dehydrate	To dry out
Hydrophilic	Water-loving
Saline Solution	A 0 9-% solution of sodium chloride in water similar in many respects to human tears

INTRODUCTION

Welcome to the FreshLook® (phemfilcon A) Soft (Hydrophilic) family of frequent replacement contact lenses This handbook contains instructions in the proper method of handling and caring for your FreshLook lenses for Frequent Replacement Wear

In the Frequent Replacement Program, the lens wearing time prescribed by your eye care practitioner is from 1 to 7 days Every time the lens needs to be removed before the replacement time period has elapsed, the lens must be both cleaned and disinfected prior to placing it back on the eye Wesley Jessen recommends that the lens be discarded and replaced with a new lens every 2 weeks or as recommended by your eye care practitioner

To maintain optimal eye health it is important that you use FreshLook lenses for the wearing period prescribed by your eye care practitioner Your eye care practitioner will prescribe a program of care based on your specific needs which includes wearing time follow up visits and replacement schedules

Wesley Jessen recommends that contact lens wearers see their eye care practioner at least twice each year, or if directed, more frequently

Your eye care practitioner will review with you all instructions for lens handling and care, including how to properly insert and remove the lenses At the end of your wearing regimen which has been prescribed by your eye care practitioner lenses should be removed cleaned and disinfected prior to placing the lenses back on your eyes If you have any questions always ask your eye care practitioner

CIBA000074

INDICATIONS

FreshLook® lenses are indicated for the correction of visual acuity in non aphakic persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit astigmatism of up to 2 00 Diopters that does not interfere with visual acuity

The lenses may be prescribed for either Daily Wear or Extended Wear from 1 to 7 days between removal for cleaning and disinfection or disposal as recommended by the eye care practitioner See WARNINGS Section with reference to the relationship between the lens wearing schedule and corneal complications

Instructions for the Monovision Wearer

You should be aware that as with any type of lens correction there are advantages and compromises to monovision contact lens therapy The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks Some patients have experienced difficulty adapting to it Symptoms such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance may last for a brief minute or for several weeks as adaptation takes place

The longer these symptoms persist, the poorer your prognosis for successful adaptation You should avoid visually demanding situations during the initial adaptation period It is recommended that you first wear these contact lenses in familiar situations which are not visually demanding For example it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction

Some monovision patients will never be fully comfortable functioning under low levels of illumination such as driving at night If this happens you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required

If you require very sharp near vision during prolonged close work you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required

Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks You should discuss this with your eye care practitioner

It is important that you follow your eye care practitioner s suggestions for adaptation to monovision contact lens therapy You should discuss any concerns that you may have during and after the adaptation period

The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs

CONTRAINDICATIONS (REASONS NOT TO USE)

FreshLook® Lenses are contraindicated when any of the following conditions exist

- Inflammation in the anterior chamber of the eyes

  Active disease injury or abnormality affecting the cornea conjunctiva or eyelids
- Microbial infection of the eye

  Insufficiency of lacrimal secretion
- Corneal hypesthesia
- Use of medication that is contraindicated, including eye medications

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- Patient history of recurring eye or eyelid infections including sties or of adverse effects associated with contact lens wear or of intolerance or abnormal ocular response to contact lens wear

  History of patient noncompliance with contact lens care and disinfection regimens wearing restrictions wearing schedule or follow-up visit schedule

- Patient s inability or unwillingness because of age infirmity or other mental or physical conditions or an adverse working or living environment, to understand or comply with any warnings, precautions restrictions or directions

  Allergy to any ingredient such as mercury or thimerosal in a solution which must be used to care for the lens

- Patients who require only vision correction and who would not, or could not adhere to a recommended care system for lenses or who are unable to place and remove lenses should not be provided with them

  Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses

WARNINGS

Prior to purchasing contact lenses you should discuss fully with your practitioner the effect of contact lenses on your eyes, and all risks associated with contact lens wear in addition to receiving a thorough eye examination While the great majority of people successfully wear contact lenses without problems, a small percentage of wearers have experienced adverse effects with contact lens wear and usage of lens care solutions, resulting in serious eye problems such as infections, ulcers and other damage to the cornea (the front layer of the eye) In some cases these problems can lead to serious eye injury and loss of vision particularly if prompt and effective medical treatment is not obtained Additionally smoking increases the risk of ulcerative keratitis for contact lens users

FreshLook® lenses should be regularly removed, cleaned and disinfected, and regularly replaced on the schedule prescribed by your eye care practitioner The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals beginning with the first overnight use As a result eye care practitioners have differing views concerning the maximum wearing time of lenses Some eye care practitioners do not prescribe extended wear at all while others prescribe flexible wearing time of occasional overnight wear and still others prescribe wearing times from 1 to 7 days/6 nights for certain patients

To minimize the risks of contact lens wear, it is essential that you follow your eyecare practitioner s directions and all instruction in this booklet for proper care and handling of our lenses, use of solutions and other lens care products wearing restrictions and schedule lens replacement and check-up visits

If a problem should occur you may require immediate medical attention because some eye problems such as infections and corneal ulcers can develop rapidly and unexpectedly lead to loss of vision Prompt professional attention to these problems is essential If you have any pain eye discomfort, tearing sensitivity to light, vision changes redness of the eye or any other symptoms or unusual feeling in your eye, follow the steps in the 'Adverse Effects Section

UV absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses Persons should continue to use their protective UV absorbing eyewear as directed

Note The effectiveness of wearing UV absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time

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PRECAUTIONS AND WEARING RESTRICTIONS

The safe wear of contact lenses requires you to observe certain precautions and wearing restrictions designed to reduce the possibility of problems and eye injuries Your eye care practitioner may prescribe additional precautions and restrictions for you to follow and you should ask your eye care practitioner to explain anything that you do not understand

At Your Initial Visit to Your Eye Care Practitioner

- Be sure that you read and understand the full context of this booklet, and discuss it with your eye care practitioner
- Give your eye care practitioner a complete history of your eye health including any eye injuries diseases, conditions or other problems you have had with your eyes even if they seem unimportant to you

  Also tell your eye care practitioner about your general health any medicines you are taking current treatment by a physician, any disease you had or now have and any prior surgery

  Before leaving your eye care practitioner's office make sure that you are able to place and promptly remove your lenses

Lens Handling

FreshLook® lenses prescribed for Frequent Replacement Wear are intended to be disposed of at the end of the prescribed period (1 week, 2 weeks, etc) Therefore, it is important to always have available a pair of new sterile replacement lenses In the event that a lens must be removed from your eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated (dry) the lens should be removed cleaned and disinfected in the recommended manner Refer to the Section of this entitled Lens Care Directions" If the lens becomes dehydrated refer to "Care for a Dehydrated Lens"

- Do not touch your eyes or contact lenses until after you have washed and rinsed your hands thoroughly Failure to wash your hands before handling may result in eye infections
- Do not allow any cosmetics lotion, soaps, creams or deodorants to come into contact with lenses which also can cause eye infections or irritations
- Do not touch the lenses with your fingernail which can cause contamination or damage of the lens If a lens becomes nicked or torn do not wear it because damaged lenses can cause injury
- Before placing lenses on your eyes examine the lenses to assure they are moist, clean, clear, and free of any nicks or tears
- Do not place a dry or brittle lens on your eye
- Do not use saliva tap water, distilled water or anything other than a recommended sterile solution labeled for the care of your soft lenses
- Do not use tweezers or other tools to remove your lens from the lens package Pour the lens into your hand
- Soft contact lenses occasionally fold on the eye and do not remain on the cornea (front portion) This is no cause for alarm Although the contact lens can never be lost in the eye it may become lodged under the eyelids without irritation (usually the upper lid) In this case, the lens should be located and removed by yourself or if you cannot find it, by your eye care practitioner Once removed dispose of the lens and replace it with a new lens
- It is important to the health of your eyes that your contact lenses move freely If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution or drops recommended by your eye care practitioner into your eye In this case do not use plain water or anything other than the recommended solutions Do not attempt to remove a lens that is sticking which could damage your eye If the lens does not begin to move when you blink after several applications of the solution or drops contact your eye care practitioner immediately
- If you are on a daily wear schedule do not sleep with the lenses on If you forget, however check to see immediately upon awakening if the lenses will move on the eyes If they do not move readily do not attempt to remove them Place several drops of a recommended lubricating or rewetting solution in the eyes and try moving them again If after several applications of solution the lenses still do not move, contact your eye care practitioner immediately

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Wearing Restrictions

- Always keep a pair of new sterile replacement lenses with you when you wear your lenses in case you have to remove the lenses immediately upon the appearance of a problem or symptom

  Do not use aerosol products, such as hair spray while wearing your lenses The lenses may absorb the spray resulting in injury to the eye and damage to the lens
- Avoid wearing the lenses around fumes irritating vapors or smokey or dusty conditions The lenses may absorb the chemicals or particles, resulting in injury to the eye
- Avoid rubbing your eyes with the lenses in which can irritate the eye or dislodge the lens
- Keep your eyes closed tightly when washing or showering to keep water and soaps out of the eyes which can cause loss of the lenses, contamination or injury to the eye

  Do not wear your lenses while in a hot tub or steam room or while swimming

  If you get something in your eye remove the lens immediately and dispose of the lens Do not reinsert the lens until your eye feels normal

  Tell your employer that you wear contact lenses Some jobs may require use of eye protection equipment or that you not wear contact lenses

  Tell your regular physician and every other doctor that you visit that you wear contact lenses and the type of lenses that you wear If you are admitted to a hospital also tell your nurses that you wear contact lenses
- Do not use any eye drops, ointments or medicines in your eye unless they are specifically approved by your eye care practitioner or physician Some drops, ointments or medicines will cause injury to the eye if used by a contact lens wearer

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On Check Up Visits To Your Eye Care Practitioner

- When you return for check up visits be sure to tell your eye care practitioner if your eyes have felt dry irritated or anything other than completely comfortable while wearing your contact lenses
- If there is any question in your mind about your wearing schedule and restrictions lens handling procedures, lens replacement program the condition of your lenses your follow-up visit schedule emergency cleaning and disinfection procedures or anything else about contact lens wear be sure to discuss the subject with your eye care practitioner who is there to help you use your contact lenses safely and properly The use of most dyes or drops will require a waiting period before new lenses may be reinserted

EMERGENCY LENS CARE DIRECTIONS

When new sterile replacement lenses are not available and it becomes necessary to remove the lens follow the instructions below

- Always wash and rinse your hands before handling your contact lenses
- The lenses should be cleaned and disinfected before reinsertion into the eye Use a suggested chemical (not heat) lens care system since heat may cause discoloration
- Use and follow the instructions of lens care products intended for use with soft (hydrophilic) contact lenses

Emergency lens care does not apply to lenses worn on a daily wear basis

BEFORE HANDLING LENSES

It is essential to follow good practices in the care and the handling of your lenses Get into the habit of using proper procedures every time so that they become automatic Cleanliness is the first and most important principle of proper contact lens care Before touching lenses, always wash hands with neutral unmedicated soap, rinse thoroughly, and dry with a

lint free towel Avoid using oils hand creams, lotions or any medications on hands before handling lenses Such materials may get on lenses and interfere with successful wear Make certain your fingernails are well trimmed and smooth so they do not damage lenses

CARE FOR DEHYDRATED LENS

If a lens is exposed to air while off the eye it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface such as a counter top apply sterile saline solution before handling Place the lens in a storage case and soak the lens in a recommended rinsing and storage solution for at least one hour until it returns to a soft state Then, clean and disinfect the rehydrated lens using a recommended lens care system If after soaking the lens does not become soft, it should not be worn until examined by your eye care practitioner

THE LENS PACKAGE

Your lens prescription may not be the same for both eyes, so it's important that your eye care practitioner tells you which lenses are for your right eye and which lenses are for your left You should indicate in the space given on the box whether the lenses are for right or left eyes

OPENING THE LENS PACKAGE

To open the lens package, first shake the lens package to correctly position the lens in the solution Place the lens package on a flat surface, then slowly and carefully peel back the foil where indicated on the label

PREPARING LENS FOR WEAR

1 Carefully remove the right lens from the plastic package Avoid mix ups, work with one lens at a time Get into the habit of starting with the right lens

2 To correctly position the lens for insertion, place the lens on the tip of a finger When looking down upon the lens, a W J logo should be seen at the bottom edge of the lens If the W J logo is inverted then the lens is inverted Reposition the lens so that the W-J reads correctly

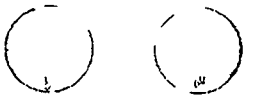
Figure 1



Correct Inside Out

FreshLook® Colors UV

Figure 2



Correct Inside Out

FreshLook® UV with Handling Tint

LENS INSERTION

Fingers should never touch the eye during lens insertion or removal Two lens insertion methods A and B are described use the one most comfortable for you



Figure 3

METHOD A One Hand Method

1 Place right lens on index finger of dominant hand (Fig 3)



Figure 4

2 Hold down lower lid with middle finger of dominant hand and look up (Fig 4)



Figure 5

3 Place lens on lower portion of the white part of the eye (Fig 5) Apply gentle pressure to expel any air under lens Use of a mirror may help place lens correctly



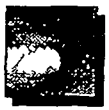
Figure 6

4 Continue to hold lens against eye while releasing the lower lid (Fig 6)

5 Look down and remove finger from lens Lens should immediately center

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Figure 7

6 To help center lens, close eye momentarily and lightly massage the closed lid (Fig 7) It may take a few minutes for the lens to center


Figure 8

7 Insert left lens following the same procedure

METHOD B Two Hand Method

1 Place right lens on index finger of dominant hand (Fig 8)


Figure 9

2. With your other hand separate and pull open your upper and lower eyelids using thumb and index finger (Fig 9)


Figure 10

3 While looking in a mirror or straight ahead, gently place lens on eye (Fig 10)


Figure 11

4 Slowly release lids, then blink Lens should immediately center

5 To help center lens close eye and lightly massage lid (Fig 11)

6 Insert left lens, following the same procedure

Within a very brief time after insertion lenses should be comfortable and vision should be clear

Any discomfort may be caused by the presence of a foreign body or incorrect insertion. Poor vision may be caused by mixing right and left lenses or by a lens which has been displaced off center If you cannot find cause and correct the situation discontinue wear and consult your eye care practitioner

LENS REMOVAL


Figure 12

1 Pull down lower lid with the finger of non dominant hand (Fig 12)


Figure 13

2 Look up and lightly place tip of index finger of dominant hand on the lens (Fig 13)


Figure 14

3 Slowly slide lens down onto white of eye Keep finger on lens and compress lens between thumb and finger (Fig 14) Remove the lens

4 After lens removal, follow your eye care practitioner s instructions for lens care and replacement

GENERAL TIPS

Hands must be washed rinsed thoroughly and dried with a lint free towel before handling the lenses

Cosmetics, lotions, soaps and creams must not come in contact with the lenses since eye irritation or infection may result Do not use aerosol or pump products, such as hair spray, while the lenses are being worn, since liquids and vapors may damage the lens Care for a dehydrated lens with the Frequent Replacement Program If your contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated

For Frequent Replacement Lens Wear, lenses must be cleaned and disinfected as often as recommended by the eye care practitioner Use a suggested chemical (not heat) system of lens care, since heat may cause discoloration Use and follow instructions of lens care products intended for use with soft (hydrophilic) contact lenses recommended by your eye care practitioner

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ADVERSE EFFECTS

Problems and What to Do

The following problems may occur

Eye discomfort

- Eye pain

Eyes sting burn or itch (irritation)

Comfort is less than when lens was first placed on eye

- Feeling of something in the eye (foreign body scratched area)
- Watering (tearing) of the eyes
- Eye secretions or discharge of matter
- Redness of the eyes

Reduced sharpness or decrease in vision

- Blurred vision rainbows or halos around objects
- Sensitivity to light
- Feeling of dryness

If any of the above symptoms occur

Immediately remove the lenses

- If the discomfort or problem stops, then look closely at the lens
- If the lens is in any way damaged has dirt an eyelash or any other foreign body on it, or the problem stops discard the lens and replace it with a new sterile replacement lens as directed by your eye care practitioner
- If the above symptoms continue after removal of the lens or upon insertion of a new lens, the lens should be removed immediately and you should immediately contact your eye care practitioner or a physician, who will determine the need for examination treatment or referral without delay

Chemicals in Eyes

If chemicals of any kind (household products, gardening solutions, or laboratory chemicals) are splashed onto the eyes do the following

- Immediately remove your lenses and flush your eyes with water

If unable to remove lenses immediately flush your eyes with water

- Seek immediate medical eye care treatment

IMPORTANT In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you DO NOT WAIT for your next appointment TELEPHONE YOUR EYE CARE PRACTITIONER IMMEDIATELY

IF IN DOUBT, TAKE THE LENS OUT!

Problems with contact lenses may lead to a medical emergency because a serious condition such as infection corneal ulcer, neovascularization (small blood vessels growing into the cornea) or iritis (inflammation in the eye) may be present, and may progress rapidly and lead to loss of vision unless treated promptly When you go for treatment bring your lenses lens case and care products The doctor may want to examine test or analyze these items to help in your treatment If your eye care practitioner or physician is not available, go to the nearest emergency room

The safe wear of contact lenses requires you to observe certain precautions and wearing restrictions designed to reduce the possibility of problems and eye injuries Your eye care practitioner may prescribe additional precautions and restrictions for you to follow, and you should ask your eye care practitioner to explain anything that you do not understand

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September 12, 1994

Food and Drug Administration
Center for Device and Radiological Health
PMA Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

RE PMA P830037/33
Amendment

PRODUCT Wesley-Jessen/FreshLook™ Colors & LiteTint Spherical Hydrophilic Contact Lens
Final Printed Labeling

Dear Sir/Madam

Pursuant to Section 515 of the Federal Food, Drug and Cosmetic Act and 21 CFR Part 814 for Pre-market Approval of Medical Devices and in accordance to the Conditions of Approval, Wesley-Jessen herewith submits the required copies (3) of an Amendment to PMA P830037/33 for the Wesley-Jessen FreshLook™ Colors & LiteTint Spherical Hydrophilic Contact Lens

The purpose of this amendment is to submit approved labeling in final printed form, inclusive of the primary package unit labels, secondary package labeling, package insert, professional fitting and information guide and patient instruction manual

Wesley-Jessen considers the pages marked "Confidential Company Secret" within this submission to be proprietary Requests for any of this information under Freedom of Information must not be honored without permission from the sponsor

Sincerely,

Rick Main

Rick Main
Regulatory Affairs

Parisien EXHIBIT 6
DATE 8-18-06
Jody L Lenschow RMR CRR

CIBA PMA
00624

LIST OF ATTACHMENTS

Attachments	Description
A	Secondary Package
B	Primary Package Unit Labels
C	Package Insert
D	Instruction Manual
E	Fitting Guide

co nds to the Iris The colored pigments consist of the fc olor additives listed in the color additive provisions of 21 C olored lenses contain iron oxides titanium dioxide and [(pl cyaninato (2 1)] copper In addition the green lens contains chromium ox de and the violet lens contains carbazole violet The FreshLook Colors (phemfilcon A) Soft (Hydrophilic) Contact Lenses are available in the following opaque colors Blue Green Hazel and Violet See you Wesley Jessen Representative for availability The FreshLook LiteTint (phemfilcon A) Soft (Hydrophilic) Contact Lens is tinted green with the color additive phthalocyanine green for easy visibility for handling

These color additives are not removed by lens handling and cleaning/disinfecting procedures The optical and performance characteristics are not altered by the lens coloring process

The physical properties of the lens are

Specific Gravity	1 152
Refractive Index	1 412
Light Transmittance	
FreshLook LiteTint	95 / minimum
FreshLook Colors	97 / minimum
Surface Character	Hydrophilic
Water Content	55 /
Optical Zone (FreshLook Colors)	5 mm
Optical Zone (FreshLook LiteTint)	9 mm
Oxygen Transmissibility (Dr Irving Fatt Method)	Dk/L $\frac{32 \times 10^{-9} \text{ ml } O_2 \text{ cm at } 35\ C}{\text{sec ml mm Hg}}$

ACTIONS

In its hydrated state when placed on the cornea the FreshLook Colors (phemfilcon A) Soft (Hydrophilic) Contact Lenses and FreshLook LiteTint (phemfilcon A) Soft (Hydrophilic) Contact Lenses act as a refracting medium to focus light on the retina

The FreshLook Colors (phemfilcon A) Soft (Hydrophilic) Contact Lenses act to enhance or alter the apparent color of the eye or for use in ocular masking

The FreshLook LiteTint (phemfilcon A) Soft (Hydrophilic) Contact Lenses provides for ease of patient handling for easy visibility and does not affect iris color The visibility tint allows the lens to become visible to wearers when not on the eye

INDICATIONS

The FreshLook Colors (phemfilcon A) Soft (hydrophilic) Contact Lenses and the FreshLook LiteTint (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in not aphakic persons with non diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit ast gmatism of up to 2 00 Diopters (D) that does not interfere with visual acuity

The lenses may be prescribed for either Daily Wear or Extended Wear from 1 to 7 days between removal for cleaning and disinfection or disposal as recommended by the eye care practitioner (for available powers see Lens Description Section) Eye care practitioner may prescribe the lens for either single use **disposable wear** or for **frequent replacement wear** with cleaning disinfection and scheduled replacement (see Wear Schedule S ction for additional information) When prescribed for **frequent ment wear** the lens may be disinfected using a chemical disinfe em

CONTRAINDICATIONS (REASONS NOT TO USE)

The FreshLook Colors (phemfilcon A) Soft (Hydrophilic) Contact Lenses and FreshLook LiteTint (phemfilcon A) Soft (Hydrophilic) Contact Lenses are contraindicated when any of the following conditions exist

Inflammation in the anterior chamber of the eye

Active disease injury or abnormality affecting the cornea conjunctiva or eyelids

Microbial infection

Insufficiency of lacrimal secretion

Corneal hypoesthesia

Use of medication that is contraindicated including eye medications

Patient history of recurring eye or eyelid infections including styes or of adverse effects associated with contact lens wear or of intolerance or abnormal ocular response to contact lens wear

History of patient non compliance with contact lens care and disinfection regimens wearing restrictions wearing schedule or follow up visit schedule

Patient s inability or unwillingness because of age infirmity or other mental or physical conditions or an adverse working or living environment to understand or comply with any warnings precautions restrictions or directions

Allergy to any ingredient such as mercury or thimerosal in a solution which must be used to care for the lens

Patients who require only vision correction and who would not or could not adhere to a recommended care system for lenses or who are unable to place and remove lenses should not be provided with them

WARNINGS

Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products Therefore after a thorough eye examination including appropriate medical background patients must be fully apprised by the prescribing practitioner of all the risks associated with contact lens wear To minimize these risks the need for strict compliance with the care regimen including cleaning of the lens case if the patient is on the Frequent Replacement Program wearing restrictions wearing schedules and follow up visit schedule must be emphasized to the patient (see considerations listed under Contraindications and Precautions)

Since eye injury can develop rapidly it is most important that patients be instructed in the possible signs or symptoms of problems and the need to remove the lenses and be examined by the prescribing eye care practitioner or a corneal specialist immediately if they experience any symptoms such as those listed below under Adverse Effects (Practitioners examining patients presenting such symptoms should see F tting Guide and Patient Instruction Manuals)

Extended Wear The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals beginning with the first overnight use

Some researchers believe that these complications are caused by one or more of the following a weakening of the cornea s resistance to infections particularly during a closed eye condition as a result of hypoxia an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms particularly when a regular periodic lens removal and disinfection or disposal schedule has not been adhered to by the patient contamination of lens care products poor personal hygiene by the patient patient unsuitability to the particular lens or wearing schedule accumulation of lens deposits damage to the lens improper fitting length of wearing time and the presence of ocular debris or environmental contaminants Additionally smoking increases the risk of ulcerative keratitis in contact lens users

While the great majority of patients successfully wear contact lenses extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates and endothelial polymegathism which require consideration of discontinuation or restriction of extended wear The epithelial conditions are reversible upon discontinuation of lens wear The reversibility of endothelial effects of contact lens wear has not yet been established As a result practitioner s views of extended wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional o e night wear to prescribing extended wearing periods from 1 to 7 days/6 nights with specified intervals of no lens wear for certain patients with follow up visits and in the case of the **Frequent Replacement Program** with a proper care regimen Some practitioners also recommend frequent replacement of lenses at intervals such as one to two weeks

PRECAUTIONS

In prescribing contact lenses the **Precautions** should be carefully observed It is also strongly recommended that the practitioner review with the patient the appropriate Patient Instruction Manual (either the Frequent Replacement or Disposable Patient Instruction Manual) available from Wesley Jessen prior to dispensing the lenses and ensure that the patient understands its contents

In the **Disposable Program** the FreshLook Colors (phemfilcon A) Soft (Hydrophilic) Contact Lenses and FreshLook LiteTint (phemfilcon A) Soft (Hydrophilic) Contact Lenses are intended to be disposed of once they are removed from the patient s eye Therefore it is important that patients be instructed to always have available a pair of replacement lenses In the event that a lens must be removed from the eye because of dust a foreign body or other contaminant gets on the lens or the lens becomes dehydrated the lens should be removed and replaced with a replacement lens If replacement lenses are not available the patient should refer to the emergency lens care directions

In the **Frequent Replacement Program** in the event that a lens must be removed from the eye because of dust a foreign body or other contaminant gets on the lens or the lens becomes dehydrated the lens should be removed and cleaned and disinfected before reinsertion If the lens becomes dehydrated follow the lens care directions for Care for a Dehydrated Lens

Contact lens wear may not be suitable for certain occupations or in other instances may require eye protection equipment

Environmental fumes smoke dust vapors and windy conditions must be avoided in order to minimize the chances of lens contamination or physical trauma to the cornea

In the Frequent Replacement Program or in the event of Emergency Lens Care in the Disposable Program chemical disinfection solution may not be used with heat unless specifically indicated in the labeling for heat and chemical disinfection

In the Frequent Replacement Program or in the event of Emergency Lens Care Program sley Jessen recommends that sterile solutions be usr soft lens care system Sterile non preserved solutio l be used if the patient is allergic to preservatives Wt d sterile non preserved solutions must be discarded after the time specified in their label directions

Eye injury from irritation or infection and damage to lenses may result if cosmetics lotions soaps creams hairsprays or deodorants come in contact with lenses

Eye injury from irritation or infection may result from lens contamination

Tweezers or other tools should not be used by patients to remove a lens from the lens container The lens should be poured into the hand

Patients should be instructed on and demonstrate the ability of prompt removal of the lenses

Fluorescein should not be used while the lenses are on the patient s eye The lenses absorb this dye and become discolored Fluorescein in the eye should be thoroughly flushed with a sterile saline solution recommended for in eye use and a new lens should be reinserted only after at least one hour

A lens must move freely on the eye for a proper fit For further information see the FreshLook Colors (phemfilcon A) Soft (Hydrophilic) Contact Lenses and FreshLook LiteTint (phemfilcon A) Soft (Hydrophilic) Contact Lenses Fitting Guide

Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis Patients should be carefully evaluated for extended wear prior to prescription and dispensing and practitioners should conduct early and frequent follow up examinations to determine ocular response to extended wear

In the Frequent Replacement Program or in the event of Emergency Lens Care in the Disposable Program after removal of the lenses from the lens case to prevent contamination and to help avoid serious eye injury always empty and rinse lens case with fresh rinsing solution and allow to air dry between each lens disinfection cycle

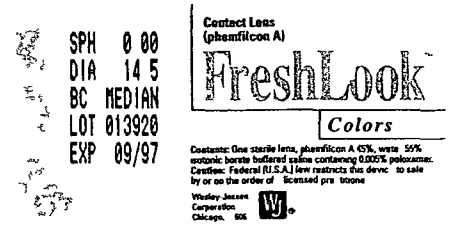
Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses Patients should be cautioned accordingly

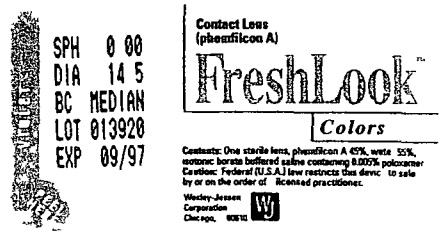
The patient should be instructed to inform his or her physician that contact lenses are worn and to consult his or her eye care practitioner before using any medication in the eye

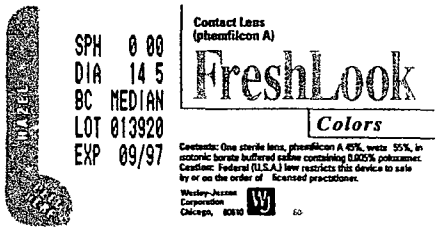
Certain medications such as antihistamines decongestants diuretics muscle relaxants tranquilizers and those for motion sickness may cause dryness of the eye increased lens awareness or blurred vision Should these conditions exist proper remedial measures should be prescribed Depending on the severity this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used

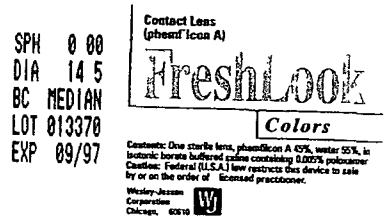
The patient who has been prescribed FreshLook Colors (phemfilcon A) Soft (Hydrophilic) Contact Lenses and FreshLook LiteTint (phemfilcon A) Soft (Hydrophilic) Contact

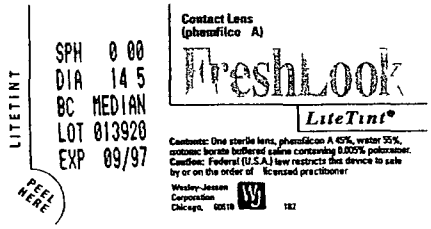
CIBA PMA
00626











CIBA PMA
00628

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr Joseph Foos
Vice President, Scientific Affairs
Wesley Jessen Corporation
333 East Howard Avenue
Des Plaines IL 60018 5903

MAY - 7 1999

Re P830037/S42
FreshLook® Bifocal UV absorbing Spherical (phemfilcon A) Handling Tint and Colors Soft (Hydrophilic) Contact Lenses for Extended Wear
Received. April 7, 1999
Amended. April 26 and May 4 1999

Dear Mr Foos

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement which qualified for review under the Real Time Review Program We have reviewed your application at a teleconference on April 19, 1999, with subsequent labeling discussions on April 28, 1999

Your supplement requested approval for the following

a minor modification of the polymer formulation to include changes in the ratio of ingredients

configuration change to include a bifocal design for the referenced device,

modifications to the labeling to include the presbyopic indication and add the sentence FreshLook® Lenses with UV absorbing monomer help protect against the transmission of harmful UV radiation to the cornea and into the eye",

- modification of the NOTE and Warning as stated below;

combining the package inserts for the bifocal, spherical and toric configurations and,

minor editorial changes to the spherical and toric indications

The device, as modified, will be marketed under the trade name referenced above with the following indication

FreshLook® Spherical (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2 0 diopters that does not interfere with visual acuity

Parisian EXHIBIT 1
DATE 8 18 06
Indy L Lenschow RMR CRR

CIBA000044

FreshLook® Tonic (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6 0 diopters

FreshLook®Bifocal UV absorbing Spherical (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity and presbyopia in persons with non diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 0 75 diopters that does not interfere with visual acuity

The lens may be prescribed for Extended Wear in not aphakic persons from 1 to 7 days between removal for cleaning and disinfection or disposal, as recommended by the eye care practitioner The eye care practitioner may prescribe the lens in either a single use disposable program or in a frequent replacement program with cleaning disinfection and scheduled replacement When prescribed in a frequent replacement program, the lens may be disinfected using a chemical disinfection system

FreshLook Lenses with UV absorbing monomer help protect against the transmission of harmful UV radiation to the cornea and into the eye

Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval (enclosed) You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter

The sale distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801 109 within the meaning of section 520(e) of the Federal Food, Drug and Cosmetic Act (the act) under authority of section 515(d)(1)(B)(ii) of the act

As a condition of this restriction, all advertisements and other descriptive matter issued by the manufacturer, packer or distributor with regard to this device will include the following warning and precaution (note) statements

"WARNING UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed."

"NOTE Long term exposure to UV radiation is one of the risk factors associated with cataracts Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities) UV absorbing contact lenses help provide protection against harmful UV radiation However, clinical studies have not been done to demonstrate that wearing UV absorbing contact lenses reduces the risk of developing cataracts or other eye disorders Consult your eyecare practitioner for more information.

Expiration dating for this device has been established and approved at the prevailing shelf life This is to advise you that the protocol used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814 39(a)(8)

Failure to comply with the conditions of approval as attached invalidates this approval order Commercial distribution of a device that is not in compliance with these conditions is a violation the act

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA supplement submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling The labeling will not routinely be reviewed by FDA staff when PMA

applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment Please see the CDRH Pilot for Review of Final Printed Labeling document at http //www fda gov/cdrh/pmat/pilotpmat.html for further details

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

We are interested in continuing to improve the Real Time PMA Program If you have any suggestions for how we can modify it, please send a facsimile to Bonnie Markovitz at (301) 827 2930 or an electronic message to her at BAM@CDRH.FDA.GOV at CDRH.

If you have questions concerning this approval order please contact Ms Eleanor M Felton at (301) 594-1744

Sincerely yours

A. Ralph Rosenthal, M.D
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr Rick Main
Regulatory Affairs
Wesley-Jessen
333 East Howard Avenue
Des Plaines, IL 60018-5903

JAN 25 1996

RECEIVED
JAN 31 1996
REG. AFFAIRS

RE P830037/S39
FreshLook® Colors UV and FreshLook® LiteTint UV
(phemfilcon A) Soft (Hydrophilic) Contact Lenses
Filed October 2, 1995
Amended January 11, 1996

Dear Mr Main

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for incorporating an ultra-violet absorber into the above referenced lenses Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed) You may begin commercial distribution of the devices as modified by your PMA supplement upon receipt of this letter

The sale, distribution and use of these devices are restricted to prescription use in accordance with 21 CFR 801 109 Expiration dating for this device has been established and approved at 8 months This is to advise you that the protocol used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814 39(a)(8)

Failure to comply with the conditions of approval as enclosed invalidates this approval order Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act

You are reminded that as soon as possible, and before commercial distribution of your devices, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing

Parisian EXHIBIT 8
DATE 8-18-06
Jody L Lenschow RMR CRR

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Ms Eleanor M Felton or James F Saviola, O D at (301) 594-1744

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Interim Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

RECEIVED
JAN 31 1996
REG. AFFAIRS

Enclosure

Issued 5-2-95

CONDITIONS OF APPROVAL

APPROVED LABELING As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd , Rockville, Maryland 20850

ADVERTISEMENT No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801 109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814 39(d) or an alternate submission is permitted in accordance with 21 CFR 814 39(e) A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814 39 of the final rule for Premarket Approval of Medical Devices

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance The guidance provided below is only for several key instances

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814 39(d)(2) It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected " This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814 39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used

POSTAPPROVAL REPORTS Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814 84 at intervals of 1 year from the date of approval of the original PMA Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd , Rockville, Maryland 20850 The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814 84

(1) Identification of changes described in 21 CFR 814 39(a) and changes required to be reported to FDA under 21 CFR 814 39(b)

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant

    (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device), and

(b) reports in the scientific literature concerning the device

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA

ADVERSE REACTION AND DEVICE DEFECT REPORTING As provided by 21 CFR 814 82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd , Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning

(1) A mixup of the device or its labeling with another article

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use

CIBA Vision

PACKAGE INSERT for FreshLook (phemfilcon A) Spherical and Toric Soft Contact Lenses including FreshLook Handling Tint FreshLook Colors FreshLook ColorBlends FreshLook Color Enhancers and FreshLook Radiance (phemfilcon A) Soft Contact Lenses
When Prescribed for Frequent Replacement or Disposable Wear

D9652Z/D7400A

Importa t. This p kage insert is effect ve as of Decemb r 2002 and supersedes all p or i serts for the produ ts d sc b d below Please read a efully d keep th s fo mat on for futu e use Th pa k ge rt is l t ded f r the eye c p ofessional but should be made available to patients upon equest Th eye care p ofess onal should provide the pat ent with appropriat inst ctions that p rt in to the pat ents p escr b d lenses Cop es of this package nsert are a a lable without charge f om CIBA Vision Corporation by c lli g CIBA V sion Customer Service at 1 800 241 5999 or download from our web site at www.cibavision.com CIBA V sion makes a ailable Patient I struction Booklet that is ec mmended to be g ven to the pat e t

Rx only

CAUTION FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSE EYE CARE PROFESSIONAL

DESCRIPTION

F eshLook Sphencal (phemfilcon A) soft (hydrophil c) contact lenses re available in Handl ng T t, Colors Color Enhancers ColorBl nds and Radianc F eshLook Tonc soft contact lenses are available in Handl g tint and ColorBlend The F eshLook soft contact lens family contains se eral products that I corporate a UV ab rbe Each of these p oducts is identified appropriately on the product packag Th le s weaning schedule may be prescribed for either D sposable Wear or Frequent Replacement I the **Disposable Wear Program** the lens weanng time prescnbed by the eye care professional is for either daily wear or extended wea from 1 t 7 days/6 nights Patients should be instructed to dispose of the lenses t each rem val and to use lens care products only n an mergency basis In the **Freq e t R placement Program** th lens weanng time presc bed by th eye care p fessional is for either daily wear or extended wear from 1 t 7 days/6 ghts Each time the lens needs to be removed before the replacement time period has elapsed the lens must be both cleaned and d sinfected prior to placi g it back on the eye. CIBA V sion recomme ds that th lens be discarded and repl ced with a new lens every 2 weeks or as recommended by the eye ca e prof ssional The eye care prof ss o al is couraged to d t rm e the wearing schedul based on esponse of the patient.

PRODUCT DESCRIPTION Lens Material

The lens material ph mf lcon A is hydrophilic copolymer of 2 hydroxyethyl m thacrylat d 2 th xyethyl m thacrylate F eshLook UV contact lenses co ta proprietary UV abs rbi g mo mer wh ch has bee I corporated to th polymer matrix f th l s t bsorb ultraviolet (UV) l ght.

FreshLook colored soft contact lenses are made by modifying the clear FreshLook lens by affixing a colored pigment o that portion of the front surface f th lens wh ch corre pond t th ins Additionally lored pigment is affixed to the front rface of the Toric lens t cl as unique orientation mark id tif d as (FreshMark) The colo ed pigments co s st of the following colo dditives listed the color additive provisions of 21 CFR o des titan m d oxid {phthalocy ninato (2)} copper chromi m oxide carbazole violet, mica coated with fro oxide and mica coated with tita ium dioxide

F shLo k Sphencal d T with Handl g T t oft co tact le ses re t t d gr with the col r dd t phth l cy nine g f a y v sib l ty for handling The colo additi es are t remo ed by f s ha dl ng or cleaning/d s fect g proced r The lens colors g process do s not alte the opt cal a d performa ce ch racte st cs

Le s P op rti s

The phy cal p pertı s f th l a e

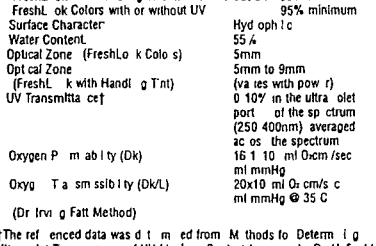
Specific Gravity	1 152
Refract e Inde	1 409
Light Tra sm tta ce	
FreshL ok with Ha dl g Ti t w th o without UV	95% mi mum
FreshL ok Colors with or without UV	95% minimum
Surface Character	Hyd oph l c
Water Content	55 %
Optical Zone (FreshLo k Colo s)	5mm
Opt cal Zone (FreshL k with Handl g Tnt)	5mm to 9mm (va ies with pow r)
UV Transmitta ce†	0 10% in the ultra olet port of the sp ctrum (250 400nm) averaged ac os the spectrum
Oxygen P m ab l ty (Dk)	16 1 10 ml O2cm /sec ml mmHg
Oxyg T a sm ssib l ty (Dk/L) (Dr Irvi g Fatt Method)	20x10 ml O2 cm/s c ml mmHg @ 35 C

†The ref enced data was d t m ed from M thods fo Determ i g Ultraviolet Tra m ss on of UV blocki g Co tact L nses by D H Fa bl Intern t o al Co tact Le s Cl Vol 25 no 5 1998

Repr sentat of the thinn st lens d sig

Fg re 1 (b low) ll st ates the t smitt c f typ cal F hLook UV a d/or F eshLook Prog essi e Bifocal with Handling Tnt le s (th e t le s to be ma keted) a hum corn a and a hum le s Curve 1 rep e ts the t ansmittanc of the th n t (0 08mm nomi al c te th ckn ss) l ns to be mark ted

FIGURE 1 TYPICAL TRANSMITTANCE PROFILE OF A FRESHLOOK UV WITH HANDLING TINT CONTACT LENS VS A HUMAN CORNEA AND A HUMAN LENS



A small t a m tt ce peak app rs i Curv 1 f th 250 290 g Th t mitta ce across this wa eba d is 0 12 / a ag w th ma mum f 29 / Th s peak is fo t d l th wa l gth f lt let d to (250 290nm) wh ch is t t smitted to the arth s su face Curves 2 and 3 rep ese t the transm ttance ch actenst cs of a human cornea from a 24 ye r old perso a d a human l s f m 25 yea old person espectively

1 H ma cornea f m 24 year old p rs described Lerma S Radia t E e gy d th Ey M cMil New York, 1980 p 58 fg 2 21

2 Hum crystall e lens from a 25 ye old perso as described n W le M H tch s VM Optical Radiat and V sual He th CRC Press Boc Rato Flo d 1986 p 19 f gur 5

ACTIONS

Wh pl ced the cornea a hyd ated F e hLook Sphe cal soft c ta t lens acts as a refracting med um to f cus l ght rays on the et na. The Fr hLo k T nc f ns p o des a more even surface over the highly une n stigmat cornea a d thus helps t fo l ght y o the et na The thinn st FreshLo k UV le ses (3 50 d opt rs d lowe) block 98 % UVA radiat on and 94% UVB radiation veraged a oss the spectrum The degree of UV rad tion blockage of FreshLook UV lenses will increase f r thicker lenses FreshLook Sphe al a d Toric soft conta t le es w th Ha dl g Ti t prov de f p t e t handl ng d y vis bil ty but do ot affect i f Th vi b l ty t nt all w th l to b m vi bl to wearers wh to the eye

Your patients should be advised of the follow g W rning UV abso b g conta t le e NOT substitut s f p t t UV b rb g y w s ch s UV b b g goggl gl beca th y d t c mpl t ly e th y d surr u d g Y h ld c nt n to use UV absorbi g y w as d ected

NOTE Long term exposure to UV rad ation s one of the risk fa t s a sociated with cataracts Exp e l based on a numbe f a t rs such as env nmental co dit n (altit de geography cl ud er) and p rs l factors (exte ta d natur of td t t) UV abso b g co tact le es help p de protecti gai t harmf l UV rad t H w clinical st d h ve ot bee done to demonstrat th t w g UV bsorbing contact lenses red ces the ri k of develop ng cata acts or oth eye d rders Consult yo r ey ca e p ctit o er for more inf rm ti

A llabl F P ram t rs

FreshLook soft contact lenses are h mu ph ncal shells of the following dimens on

Spherical Le s P r m t rs

Ch d D m t	12 0 to 15 0 mm	
Cente Thick ess	Exte ded Wea a d 0 08 to 0 19mm (Vanes with pow)	Da ly Wea 0 08 to 0 56mm (Vanes with powe)
Base Curve	7 80 to 9 00 mm	
Powers*	20 00 Diopters to 20 00 Diopters for Daily Wear 20.00 Diopters to +4.50 Diopters for Extended Wear	

T ric Lens Param t rs

Chord D ameter	12 0 to 15 0 mm	
Ce ter Thick ess	Exte ded Wear a d 0 08 t 0 19mm (Vanes with powe)	Daily Wea 0 08 to 0 56mm (Va es with power)
Base Curve	7 80 to 9 00 mm	
Powers	20 00 Diopters to +20 00 Diopters for Daily Wear 20.00 Diopters to +4.50 Diopters for Extended Wear	
Cylinde	0 75 Diopters to 6 00 Diopters	
Prism Ball sted	0 25 D opt rs	
Axis	0 to 180 1 steps	

INDICATIONS (USES)

V i C t on

Spherical

FreshLo k Sph f (ph mf l o A) soft (hyd oph l) c t t l nses a e nd cated for the co rect o f su l ulty persons with on- d seased eyes that a myopic (s ghted) or hyperopi (i rs ght d) a d may exh b t refractive a t gm t sm of up to 2 0 d opters that does n t te fe e w th visual acu ty Th F hLo k Spherical Colo s Colo E ha cers ColorBlends a d Rad le ses act to e ha ce or lt th pp e t colo of the ey

To ic

F hLook To ic (phemf lco A) soft (hyd phil c) contact lens s a l d cated for the correction of sual acuity i p o s with o d seased eyes that are myopi (nea s ghted) or hyperopic (fars ghted) a d may xhib t f ti astigmatism of p to 6 0 d opte s The F eshLook Tonc olorBlends le ses act to nha ce o alte the appa e t color of the eye

The lenses may be p scribed for Da ly Wea or Extended Wea ot ph k c p s f om 1 to 7 d ys b tw en mo al for ct an ng d d i lection or d sposal as re ommende d by the eye car p fess o al or for D ily Wea ph kic pe so s The y p ofess o al may prescr be the len either the s ngl use d sposable we r o for f equ nt epl cem nt w th clea g d sl fe t on and s h d l d eplaceme t Wh p esc ibed fo f q t epla ement the l m y be d sl fect d us ng a chem cal dis nf ct o sy tem F eshL k oft co tact l s with UV bso b ng monomer help prot ct ag l st tra smiss on of h mf l UV rad t o t the m d i to the ey

CONTRAINDICATIONS (REASONS NOT TO USE)

F eshLook s ft tact le ses are co t d cat d wh y of th f ll wi g ndit o s exist

Acute and subacute inflamm tion or infection f th anteno chambe f the eye

Active d sease jury or abnormality affecting the cornea, conjunctiva o eyelid M c obl f f t

I suff cie y of lac m l sec et o (dry yes)

C hypo sthesia (duced c rne l se s t y f ot phak)

Use of med cat th t s o tra dicat d i cl d g y m d cat o s

P te th story of e g eye o eyel d i f t lud g styes o of d ers eff ts ssoc ated with co tact le s wear or of t l c o ab orm l oc t spo e to o tact le w

H story of patie t o complia ce with co tact l s ca e a d d si fect o regime s w a g rest ct ons wea ing sched le o foll w up visit s h d le

P t t b l ty or u w ll g b cause f g t f m ty th m t f o phy cal c dit o a d e ework g f g n iro me t to und rst d or comply w th y l s r q l eme ts warni gs precauti o s r strict ons d ect on All gy to any i gr d e t such m cu y r Th m l a l t whi h mu t be u d to fo the le

P t ts who r qur ly visl rr ct o d who w uld ot, could n t dhe e to a ecomme ded ca syst m f r f ses or wh unable to pl ce a d remo lenses sh ld ot be p ovided with th m Any syst mic d sease that may affect the eye or be exagge ated by weari g contact lens

If yes become r d rrtat d

A y active orn al f ct (ba te l f gal viral) Se s y nj ry and loss of sion may esult from p oblems s ated with w ing contact len es a d using contact lens ca e p oducts Therefore after thorough ye e amination ncluding appropnate medical backg ound patie ts m st be fully appri ed by th prescnb g practitione f t l the ks assoc t d with o tact l w a T m mize th s ks th eed for strict compl a ce with th care regim including lea ing of the l ns case if the pat ent is o the Frequ t Repl cement P ogram wea ng restnctions wean g schedules and foll w up vi nt sch d le must be mpha zed to the pat ent (see c d at o s t st d

CONTRAINDICATIONS d PRECAUTIONS Sect)

S y l j ry de elop ap dly rt ls m t mp rtant th t p t ts b nstruct d r the po sible s g s or sympt ms of p oblems and the ed t m e th l s a d be exami ed by the prescnb ng ye ca e p act o or corneal sp l f st mmed ately If they xpen e a y symptoms s ch s th e ll ted bel w u d th ADVERSE EFFECTS S ct (Practi rs exami g p ts ts p t g ch ympt ms should f t the P of al Fitting Gu d d Pati t l tructon B kl t)

Exte ded Wea The sk f l at ke t ts has b h wn to b g eat among users of extend d wea contact l ses tha am g use s of d ily wea c tact le es Th k mo g xt ded wea l rs ea es w th th mb f co ut ve days th t the f e worn betw m val beg ng with the first ght s S me res rch s b le that these compl t a e cau ed by on r more of th f ll wi g a weaken g of the cornea sista ce to fecti particularly d g a closed-eye co dition as a res lt of hypox a, a eye environme t wh ch s omewhat more co ducive to th g owth of bact ria and oth m croorganism p rticularly whe a egular p dc lens rem al d d s nf ct n o d sposal schedule has not b en adhered t by the pat t contami t of lens d/o le s ca p oducts poor p rs al hygi by the patient patie t unsuritability to the particular lens or wea l g schedule accumul t of le s deposits d m ge to th lens mprope fitting l ngth f wea ing t m and th presen f ocular deb s o en iro m tal contam ants Additionally smoki g ncrea es th sk of ulc rati e keratitis in contact lens users While the great m j rity of pat e ts successfully wear contact le ses extended wear of lenses also is eported to be assoc ated with a higher incidence and deg ee of epithel al microcysts a d f ltrates and endothelial polymegathism whlch equ re considerat o of d continuation or restrict on of xte ded wear The p thelial ond t o s are eversible upon d c t uat on of le s wear The e ersibil ty f e d th f f effects of contact le s wear has not yet been established As a res lt, practit oners v ws of exte ded wea g t mes vary s me do not p s b exte ded wea t ll others pre c ibe fle ible wea g t mes with oc asio al overn ght wear and ther p esc be extend d wear g p ods f m t l 7 days/6 ights with pecified intervals of no le s wea fo certa n pat ts with follow up visits as in th c se of the F eque t Repl cem t Prog am with a p pe ca e reg m Some practit ers lso ecomme d f equent epl cement f lens s at ntervals such as one to two weeks

WARNINGS

Ad ise p t ts of the foll w g war ngs p rt ing to o t ct l s w ar Serious eye j ry sca ng of the cornea d loss of vis o m y res lt from p oblems associated with we g o tact lenses d usl g ontact lens care p oducts To reduce the e nsks emph s ze t th pat e t the need for st t compl ce w th th le s care reg ment includ ng h d wa h g prope lens d sinfect on cle n g of th le s case we g est ction w g s hed l s d follow p visit sched les Ey p oblems l cl d g corne l ice s can de el p rapidly nd if left untreat d lead to loss of vision I st ct patients t the disp s g visit nd subsequ nt vi its to fmm d ately m their lenses a d promptly co tact their eye ca e pra tit o er if they should experience eye di c mfort, fo e gn body se sato excessive tea g vi o changes red ess of the eye or other pr blems with their ey s Non compl ance with th rna uf ct r l beled le s care nst ucto m y put the pabe t t g ficant sk of de el p g as no s eye fection Tap water d st lled w te homemad s l e solut on hould NOT be sed as a substt t f a y comp ent th l s c re proce s The use of tap a d d st lled wate h s b ass t d w th Aca tham eb ke att s a orn al f fect th t is esista t to treatme l d cu e Smok g i s the risk f or eal ul fo contact le s sers sp ally whe l ses wo n ght o wh l p g

PRECAUTIONS

I pr bng o t ct l ses the P e aut s h uld b ca ef lly ob erv d ll s ls t gly omm d d th t th p a tt l w w th the p t t the app opn t Pat e t l t uct o Bookl t (desc bi g e the th F eque t R pl ment P og am o the D p bl W P og am) available f om CIBA V sl p o to d'sp s g the l es d u e that the p t t u d t ds it co t ts

Du to th sm ll umber f patie ts olled i cl l l est g to of t s s tall f t pow rs d lg co f g t s o l p amet s labl th le s m t la ev l t d s g fi t

Parisian EXHIBIT 9
DATE 8-18-06
Jody L Lenschow RMR CRR

CIBA000058

numbe s Consequ ntly when sele ti g a app opri te le s des gn a d pa ameters the eye car professional sh uld co sider aff ch racteristcs of the lens th t ca aff ct lens perfo mance and ocular health includi g oxygen permeabil ty wettability ce tral and p riph ral th ck ss and opt c zo e d mete

The pot tial impact of these fa to s on the pat ents ocular health sh ld be carefully we ghed aga st the patie nt s need for refractive correctio ther fo e the continuing ocular health f the patient a d lens perf rmance on the ye should be ca efully monitored by the p escribing ye care pr fes io al.

I the D spos ble Wear P gram the Fr shL ok soft contact l are intended to be dispos d of o e they a e rem d f m the pat t s ye The efor t mp rta t that pat ents b i tr cted to afw ys h t ble a pa f w st l l s l th e ent th t lens must be rem v d f m the eye bec u e of dust, a f g body or other co tam t the le s the l s bec m s dehydrated (dry) the lens sho ld be remo ed d eplac d w th ew st nl repl cem t lens If pl cem t le se ot a it bl th p tent should foll w me gency l s ca d r ct o s

In the F quent Replaceme t Program t the ve that a lens must be em ed f om th y beca f dust, a f re g body o oth co tamina t on the lens th le s becomes dehydrated (dry) the lens should be mo ed lea ed and dis fected befor sert o If the l ns b com s dehyd at d th pate t h ld f llow the l s ca e directions for CARE FOR A DEHYDRATED LENS In the Fr q t Repla eme t Program m the event f Emerg cy Lens Ca in th D spo bl Wear P ogram, chemical d s fection solut on may t be used with heat unless sp cif cally ind cat d the label ng for heat d chemical d sl f ction In the Frequent Repl cement Prog m or n the e nt f Emerge cy Lens C re CIBA Vi ion c mme ds use of steril solutio s Steril non p eserved solut o s should be used f th p tent is all rg c to p eservativ s such solut s must be d sca ded aft th t me specif ed in their l bel d ect o s

Cont t lens wear may ot be s table for certa occupat other l stances m y equire eye p tect on equipm t Therefore the patient should always inform h s/he empl yer that cont ct l es are being worn Enviro m tal fumes smoke dust, vapors d windy condit ons must be a o ded in o der to minimize the chances f le s co t mination o phys cal trauma to th or ea

Eye inj ry from m tal i fect n d d mage to l s s may r lt f om lens co tam atio Th p tl t should be l structed to ref ain from usi g sal va or nyth g ther than th e omm d d luti for lub cat ng or wett ng l s s The pat t should also be fo med to wash and se hand bef re ha dl g co tact le ses t all t mes Eye care pra t t on rs h uld struct th p t t to m the len e mmed at ly if th eyes b com r d o rmtat d

The pati t should be i formed th t tact lens s should not c me int co tact with a y cosmet cs l t o s soaps eams hairsprays or deodo a ts that t s best to put o lenses bef putting makeup and th t wate b ed cosm t cs a e less likely t d mage l nse th oil b d p odu t

The pat ent sh ld be form d t to use a sol o pump p od cts such s ha rsp y wh le the len a e worn s ce l quid a d vapo s may d mage th l

Th p te t should b instruct d t h dle the le ca efully and avoid d opp g or t h g th m with f gernails wh h ca caus contaminat on or dam g f the l s The pat ent sho ld also be told that if the l s be mes ck d torn ft sh uld ot be worn Tweezers o ther tools sho ld ot be sed by pat ent t em e a lens from the le s c ta The le should be pou ed into the hand Le ses should be clea ed in the p lm of the hand rather then between thumb and fing

Patients sh uld be i struct d o and be ble to d mo strate prompt removal of th le ses

Fluoresce should t b used wh l the lenses are on the patie t s eye The le ses ab orb this dy a d become d scolo ed Fluor c n in the eye should be thoro ghly flushed with ster le sali e solution recommend d i eye use and a ew le s should be r sert d o ly fte at lea t e ho r

A le s must move f ly the ey f ap op r fit Fo further l formati n r f r to the pp pnate F hLook soft co tact le s Profession l Fitt ng G de

Some patients will not b abl to tolerate exte ded wear e en if able to tolerate the sam or a othe len a daily w a basis Pati t should be ca efully valu t d fo extended wea pn r t pr s lptio a d dispen l g d pract t rs hould o d ct e rly d f q e t f llow up e am t s to dete mi e oc lar po se to xt d d wear To preve t contamination and avoid serious eye injury the patie t should be instructed to mpty nd n the l ns case with fresh ns ng solution and allow the len case to air dry between each lens disinfection cycle as in the Freq ent Repl cem nt P ogram, In the event f Emerg ncy Le Care The p te t should b i stru ted to nf rm h s or h phys c an th t contact l s are worn d t cons lt his or he y ca e pract ti bef re u i g a y m d c to l the eye

Exp su e to wat while w an g contact le ses in activit s such as swimm g water ki g a d hot t bs may i cr se the risk of ocular i fect on Incl d g but not limited to A a thamo ba kerat tis

Oral co t a ept ve users could de elop visual cha ges or cha ges le s tolerance wh us ng c t ct l ses P t ents should be cautio ed accord gly

Certain medications such as a th stam es d g sta ts d tcs muscle relaxants tra quil zers and those fo m bo s ckness may cause dryness of the eye creased lens awa e ess or blurred vision. Should thes cond tions e st, proper r med al meas res should be p escribed Depend g on th s ty th s co ld in lude th use of lub cati g drops that are l d caled for use with soft contact lense o the temporary d sco tinu ce of co tact le s wea whil such med catio is being used A patient who has been p sc b d FreshLook co tact le ses o a daily wear s h dule sh ld be auto ed to r mo th le ses b fo sleep ng

ADVERSE EFFECTS

Pot t lly seno ompl cat o s e usu lly ccompan d by o e r more of the follow g g s a d sympt ms

For g body se s t

E cess v wate g (t l g) f th y s o oth y s c t includ g m cop f t d h g

R d of th y

Ph toph b a (l ght s t vity)

B m ng t g g lt h g oth p as o at d w th th ye

C mf rt s t s c mp ed to wh le s w f t pla d y

Poor v sual acuity

Blurred vi ion rainbow o halos a ound obj cts

Feel g of dry ess

If the patient notice a y of th ab e s g s o sympt ms he or sh should be instructed to **IMMEDIATELY REMOVE THE LENSES**

If the d scomfort r p oblem st ps look closely at the lens

If the lens is l any way damaged DO NOT put the le s back i the eye D sca d the lens

If th lens has dirt a eyelash or other fo eign body o it, or the pr blem stops cle d s nfect and r nsert the lens If in the F q ent Repl c ment Pr gr m or d ca d the le s a d replace it with a new ste le replaceme t le s ril the D sposable W a P gram If the d scomfort or p blem cont nues afte emoval f the le s or up e s rt immed at ly emov l ses and p mptly contact his or her y ca e profe st l The eye car p f fional m st dete m e th n ed for e m at on treatment or efe al without delay

P te ts sh ld be l form d that a rious cond tion uch as i fect o co neal ulcer corneal vas lanzatio rn s may b p s ta d may progress rap dly L ss se ous rea bo s ch as abra ns ep thelial sta n g and b cte ial co j ct vitis should be tr ted appropri tely to a o d compl at ons Addt onally contact le s wear may be assoc ted w th o ula chang s that requ e considerat on of d sco tinu t on o rest ict on of w Thes ncl de b t e not l mited to loc l o gen l ed o eal edem pithel l m crocyst pithel al st ng l filtrations eovascul zatio doth t l p lym g thl m tars l pap llary h g s c junctival fection o rn s

ADVERSE EFFECT REPORTING

If a pat ent e pe ien es any s o s adver e effects sociat d w th the us of F shLook (ph mFlcon A) co tact le ses y ca e profess nals please otify CIBA V sion Co porat o t chn c l co sultat t 1 800-241 7468

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS

The le s must m v adequately on the ye for a pp ope f t a d co t ued h alth of the eye Whe p escribi g F eshLook l nses for xtended w a rt is imp rtant to r evaluate th lens fit for adequate mov ment at ous times after the pat ent sle ps whil w ring le ses This ree lu tio sho ld i clud a f ll w up s t as soon as pos bl after th p te t awakens as well as at th r t mes of the day If the fit is judged to be too t ght or st ep the p tient mu t be efit nt l s that p ov des the tera of a well f tt d le s

Conventional m thod f fitting tact l nses pply to F shLook oft co tact lenses Fo a d tail d des ptio f th fitt g t chniq e r f t the approp t CIBA V *Prof onal Fitt g Guide*

It is trongly rec mm nd d that the p t nt be p vided app op te *P t rl form ll Booklt* vailabl f om CIBA V s on a d unde stands its contents p o to dispensing th lenses

Cop es of **Fitting G lde and Patl t l lo mation Booklets** for F eshLook lens s vailabl without h ge from CIBA V sio Co po ti Duluth Georgia USA 30097 o by calling CIBA V customer ervice r p tat v t 1 800 241 5999

LENS REPLACEMENT SCHEDULES

In a pla ned repla ement program th r placement ch dule is d t rm ned by the eye car p of ss on f based upo the patient physiological cond ti CIBA V s on rec mmends f equent repl cement f Fr shLook le ses t nt rvals of every two weeks The eye care professional may determ ne a repl cement schedule g eater or less tha these suggested nterval b ed upon clinical examination of the patient, profes onal judgment, and cl mical experience with th len es becaus individual esponses to contact len es vary When FreshLook lenses are p escribed for d sposable wear the contact lens is con sidered a s gl use medical device in which the lenses are worn from 1 to 7 days and dis arded upo remo l from the eye.

WEARING SCHEDULES

The wearl g schedul should be det rmi d by the ey care professio al CIBA Vision ecommend that contact le s w rs see their eye care professional twice each year or if d rected more frequently The maximum ggested we g t me each day hould be determined by th eye care professional ba d po th p ti t's physiol g cal ye co dit o beca e i d vidu l re ponses t co tact lenses vary The eye care profes lonal may prescribe the lens f frequent replacement with cleaning disinfect n and scheduled replacement. When prescribed f freque t replacement, the le s may be disinfected using a chemical (ot heat) d sl fection system

DAILY WEAR There may be a tend ncy for the da ly wear pat nt t over wea the lenses init lly Ther fore the importa ce of adhering t pr per initial daily wearing schedule should be stressed to these patients The wea ng schedule should be determined by the eye care profess onal and provided to the patient. Th s lense may be worn in th Freque t R placement Pr gram

EXTENDED WEAR (G e te th n 24 h whil asleep) Th wea ing s h dule sh uld be d termi ed by th p e cnbi g eye care pra titio er f rea h i d vid l pat ent, bas d upon f ll examl ti n a d p te t h story s well as the practit er's experience and p ofessional j dgme t

CIBA V sion recommends beginning extended wea pat nts with the recomme ded initial daily wear sched le followed by a period of daily wear and then the gradual introduction of xtended wea one night at a time u less ndividu l considerations ndicate otherwise The eye care professional should examine the pat ent in the early stages of extended wear i order to determine corneal resp nse The le s must be removed cleaned and d s nfected or d sposed of and replaced w th a new lens as determi ed by the prescribing eye care professional (See the factors discussed in WARNING Sectio) On remo ed a lens should remain out of the ey fo a period f rest overn ght o longer as determ ed by the p escrib g eye care professional

LENS CARE DIRECTIONS

Dispo able Wear (Emerg cy Lens Care)

No lens care is ind cated as lenses are discarded upon removal from the ey Lenses should only be cleaned sed and d s fected an em rge cy basis when replacement lenses are ot available (See BASIC INSTRUCTIONS FOR LENS CLEANING, RINSING AND DISINFECTION below)

Pla ed Repla ement.

P te ts mu t adhe e t c mmend d c e gim n Le ses must be cleaned n sed and d s nfected ft r em val a d pn f el sert the ey acco di g to th p k g i serts d pall t tructions p ovid d with the l e p od ct comm ded by the y ca pr f sso l Fail to follow the compl t g me l acco da w th th m f tu e p kage rts d p te t struct s m y contribute t p bl ms (e ADVERSE EFFECTS) d/ ftl th d l pme t of se o ul compl c tio s as d cuss d l WARNINGS

Basic Instructions fo Lens Cleaning and Disinfection

When lenses are d spensed the patient must be provided with app opriate and adeq ate instructions and warnings for lens care handl ng The eye care p ofessio l sho ld recomme d appropriate a d adequate procedures a d p oducts for each ind vidual pat ent in acco dance with the part cular l ns wean g sch dule and care system The specific instruct ons for such products a d the part cular charact rist cs of the patie t should also be take into consideration.

Th bas c g ral instructions for ge e al lens care ar as provided below

Always w h d rinse your ha ds before handli g your co tact lenses.

The le s should be clean d a d d sinfect d befo e ei sertio nto the eye Us a suggested chem cal (not heat) le s ca e sy tem ecomme ded by the pract t on r si ce heat may cause d scolorat n

Use and follow the nstructions of le s care p oducts t nded f r use with soft (hyd oph l c) tact lenses

Always lens solut s b fo e th y ach the e p ation dat

Always keep the le ses ompletely immersed in the recomm ded to ag s l t o whe they a e not be ng wo n (stored)

I the F equ nt Replac me t P ogram CIBA Vis on c mme d th t sterile solutio s be us d t th soft le s ca e system Ster l non p s rved olut hould b used only if the pati nt is alle g c to pres rvat es Whe us d st nle non p e erv d olutions must be d sca ded aft the t me specif ed in their label directi ns

Refer to the PRECAUTION Section for further information on lens care and handling

CARE FOR A DEHYDRATED LENS

Di posable Wear Program If a soft (hydroph lic) contact le s is expos d to air whil ff the eye it may b come dry nd b ttl Dehydrated l es sh uld b d sposed of The efore it is importa t that the patie t always hav pa of w sterile eplacement l ses available

F eq nt W Program If a soft (hydrophil c) contact le s s exp d to r while off the eye it may become dry and brittle and eed to be rehyd at d If the l s s adhere g t a surface such s a counter top pply st le salin olution b fo handl g

Eye ca e pract tion r hould re ew the follow g informatio on rehydrati g the lens w th the patient

H dle the le s caref lly

Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state.

Clean and dis nfect the rehydrated lens u ing a recommended lens care system. If fter so ki g the l s does not become soft the lens should not be used u til xam d by the eye care prof ssi al

CARE FOR A STICKING LENS

If the le s sticks (stops mo g) o begins to dry on th eye the pat ent h ld be i structed to apply se al drops of the recommend d lubricat g rew tt g solut on di ectly to the eye and wait until the le s beg s t mo e f ly on th eye b fore removing it If non movement of the le s t ues aft se eral minutes the pat ent should be instructed t immedi t ly o s lt the ey care p ofess onal

IN OFFICE USE OF TRIAL LENSES

Ey ca e p fe s ons is should ducate contact l s tech s cerning pr p us f t al l nses

Each ontact l s is shipp d ste le i a eated bl ster p ck conta ning borat buff r d In H d sh uld be thoroughly washed rinsed and dried with a l t free towel prior to handl g a l s In orde to i su e ste l ty th bl ster pa k should ot be ope ed u t l immed ately prior to use For fitting d diag tic pu pos s the lenses should be d sposed of aft r a single use and ot be r used f om pati nt to pat e t.

EMERGENCIES

The pat ent should be i formed that d chemicals of any kind (household p oducts garden g solutions laboratory chemicals etc) are splashed into the eyes the patient should flush eyes **immediately with tap water and call or visit the eye care prof ssio al or a hospital emergency room without delay**

HOW SUPPLIED

E ch st le lens is p ckaged a fo l led pl tic co tai er containi g a borate buffe ed sal e solutio with 0 005% poloxamer and is steam sterilized The p ckage is marked with the l ns power diameter base curve cylinder and axis (if applicable) expi ation date ma factu ing lot numbe d If appl cable UV bsorber lens t nt and op q e color

ADDITIONAL INFORMATION

For answ rs to y que t o s about Fre hLook soft ontact lenses o t report any adverse eactio s contact our P ofessional Consult tion S rvic s at 1 800 241 7468 du g regul r bu ness h u s F add t o al copi s f th Eye Car P ofe s l Package In ert, P of l nal Fitt g G d d P t t l structo B klets o tact C t m r S rvice D p rtm t t 1 800 241 5999

PATENT PROTECTED

U S Pate ts 4 976 533 5 062 701 5 020 898 5 936 705 4 668 240 4 720 188 4 704 017 4 582 402 4 668 240 5 414 477 5 637 726

Patents Pe d ng for Fr shLook P og ive B focal

GB Patents 0346032 0498835 0158999 0187137 0440107

FR Pat nts 0346032 0498835 0158999 0187137 0440107

AUS Patents 620886 636679 569649 634624

CN P tents 26003 4158 4136 3788 4157

PH Patents 26412 29984 23319

SG Pate ts 9790790 1 9790791 9 9090530 8 9290545 4

TW Patents NI 42746 NI 63667 NI 26506 NI 51612

BR Patents P18600017 9 P190078012 P18600017 9

HK Paten

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Date/Part N Decembe 2002
D7400A/096137s

CIBA Vision

dsma/pmaman/front html This guid ance document is also available upon request from the Center for Devices and Radiological Health Division of Small Manufacturers Assistance (HFZ-220) 1350 Piccard Dr Rockville MD 20850 FAX 301-443-8818

(h) If you are sending a PMA PMA amendment PMA supplement or cor respondence with respect to a PMA you must send it to the Document Mail Center (HFZ-401) Center for Devices and Radiological Health Food and Drug Administration 9200 Corporate Blvd Rockville MD 20850

[51 FR 26364 July 22 1986 51 FR 40415 Nov 7 1986 as amended at 51 FR 43344 Dec 2 1986 55 FR 11169 Mar 27 1990 62 FR 40600 July 29 1997 63 FR 5253 Feb 2 1998 65 FR 17137 Mar 31 2000 65 FR 56480 Sept 19 2000 67 FR 9587 Mar 4 2002]

§ 814 37 PMA amendments and resub mitted PMA s

(a) An applicant may amend a pend ing PMA or PMA supplement to revise existing information or provide addi tional information

(b) FDA may request the applicant to amend a PMA or PMA supplement with any information regarding the device that is necessary for FDA or the appro priate advisory committee to complete the review of the PMA or PMA supple ment

(c) A PMA amendment submitted to FDA shall include the PMA or PMA supplement number assigned to the original submission and if submitted on the applicant s own initiative the reason for submitting the amendment FDA may extend the time required for its review of the PMA or PMA supple ment as follows

(1) If the applicant on its own initia tive or at FDA s request submits a major PMA amendment (e g an amendment that contains significant new data from a previously unreported study significant updated data from a previously reported study detailed new analyses of previously submitted data or significant required information previously omitted) the review period may be extended up to 180 days

(2) If an applicant declines to submit a major amendment requested by FDA the review period may be extended for the number of days that elapse between the date of such request and the date that FDA receives the written response declining to submit the requested amendment

(d) An applicant may on its own ini tiative withdraw a PMA or PMA sup plement If FDA requests an applicant to submit a PMA amendment and a written response to FDA s request is not received within 180 days of the date of the request FDA will consider the pending PMA or PMA supplement to be withdrawn voluntarily by the appli cant

(e) An applicant may resubmit a PMA or PMA supplement after with drawing it or after it is considered withdrawn under paragraph (d) of this section or after FDA has refused to ac cept it for filing or has denied ap proval of the PMA or PMA supplement A resubmitted PMA or PMA supple ment shall comply with the require ments of § 814 20 or § 814 39 respec tively and shall include the PMA num ber assigned to the original submission and the applicant s reasons for resub mission of the PMA or PMA supple ment

§ 814 39 PMA supplements

(a) After FDA s approval of a PMA an applicant shall submit a PMA sup plement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an ap proved PMA unless the change is of a type for which FDA under paragraph (e) of this section has advised that an alternate submission is permitted or is of a type which under section 515(d)(6)(A) of the act and paragraph (f) of this section does not require a PMA supplement under this paragraph While the burden for determining whether a supplement is required is primarily on the PMA holder changes for which an applicant shall submit a PMA supplement include but are not limited to the following types of changes if they affect the safety or ef fectiveness of the device

(1) New indications for use of the de vice

(2) Labeling changes

(3) The use of a different facility or establishment to manufacture process or package the device

123

Parsian EXHIBIT 12
DATE 8-18-06
Jody L Lenschow RMR CRR

(4) Changes in sterilization proce dures

(5) Changes in packaging

(6) Changes in the performance or de sign specifications circuits compo nents ingredients principle of oper ation or physical layout of the device

(7) Extension of the expiration date of the device based on data obtained under a new or revised stability or ste rility testing protocol that has not been approved by FDA If the protocol has been approved the change shall be reported to FDA under paragraph (b) of this section

(b) An applicant may make a change in a device after FDA s approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device s safety or effec tiveness and the change is reported to FDA in postapproval periodic reports required as a condition to approval of the device e g an editorial change in labeling which does not affect the safe ty or effectiveness of the device

(c) All procedures and actions that apply to an application under § 814 20 also apply to PMA supplements except that the information required in a sup plement is limited to that needed to support the change A summary under § 814 20(b)(3) is required for only a sup plement submitted for new indications for use of the device significant changes in the performance or design specifications circuits components ingredients principles of operation or physical layout of the device or when otherwise required by FDA The appli cant shall submit three copies of a PMA supplement and shall include in formation relevant to the proposed changes in the device A PMA supple ment shall include a separate section that identifies each change for which approval is being requested and ex plains the reason for each such change The applicant shall submit additional copies and additional information if re quested by FDA The time frames for review of and FDA action on a PMA supplement are the same as those pro vided in § 814 40 for a PMA

(d)(1) After FDA approves a PMA any change described in paragraph (d)(2) of this section that enhances the safety of the device or the safety in the use of the device may be placed into ef fect by the applicant prior to the re ceipt under § 814 17 of a written FDA order approving the PMA supplement provided that

(i) The PMA supplement and its mail ing cover are plainly marked Special PMA ' Supplement—Changes Being Ef fected

(ii) The PMA supplement provides a full explanation of the basis for the changes

(iii) The applicant has received ac knowledgement from FDA of receipt of the supplement and

(iv) The PMA supplement specifically identifies the date that such changes are being effected

(2) The following changes are per mitted by paragraph (d)(1) of this sec tion

(i) Labeling changes that add or strengthen a contraindication warn ing precaution or information about an adverse reaction

(ii) Labeling changes that add or strengthen an instruction that is in tended to enhance the safe use of the device

(iii) Labeling changes that delete misleading false or unsupported indi cations

(iv) Changes in quality controls or manufacturing process that add a new specification or test method or other wise provide additional assurance of purity identity strength or reli ability of the device

(e) FDA will identify a change to a device for which an applicant has an approved PMA and for which a PMA supplement under paragraph (a) is not required FDA will identify such a change in an advisory opinion under § 10 85 if the change applies to a ge neric type of device or in correspond ence to the applicant if the change ap plies only to the applicant s device FDA will require that a change for which a PMA supplement under para graph (a) is not required be reported to FDA in—

(1) A periodic report under § 814 84 or

(2) A 30 day PMA supplement under this paragraph

(f) Under section 515(d) of the act modifications to manufacturing proce dures or methods of manufacture that affect the safety and effectiveness of a device ' subject to an approved PMA do

RECORDED IN LAW ORDER
BOOK 35 PAGE 000450

VIRGINIA

IN THE CIRCUIT COURT FOR SPOTSYLVANIA COUNTY

ANNA BARNES,	)	
	)	
Plaintiff,	)	
	)	
v	)	AT LAW NO 98-439
	)	
EBI MEDICAL SYSTEMS, INC , et al ,	)	
	)	
Defendants	)	

ORDER

THIS MATTER is before the Court upon the Motion to Exclude the Expert Testimony of Dr Suzanne Parisian filed by Defendants EBI Medical Systems, Inc , Electrobiology, Inc and Biomet, Inc Upon due consideration of the Defendant's Motion and the argument of counsel in open Court on November 15, 2000, the Motion is hereby GRANTED upon the grounds stated in the Motion to Exclude filed herein, and the Court specifically FINDS that (1) Dr Parisian's testimony is an inadmissible legal opinion, (2) there is no private cause of action for violations of the FDCA or FDA regulations and Plaintiff cannot rely on such violations as the basis for a tort claim, (3) Dr Parisian is not qualified to render an opinion as to the adequacy of the warnings that accompanied the device at issue in this case, and (4) Dr Parisian's opinions lack sufficient foundation and are speculative and inherently unreliable

Let the Clerk send copies hereof to counsel of record

Cy Carr
Boone
22-01

Parisian EXHIBIT 13
DATE 8-18-06
Jody L Lenschow RMR CRR

EXHIBIT G

JON INS
ATTORNEY AT LAW
10511 JUE DRIVE 22030
FAIRFAX
703 273 2005

RECORDED IN LAW ORDER
BOOK 35 PAGE 000451

ENTERED this 26 day of January, 2001 ~~2000~~

Judge, Caroline County Circuit Court

WE ASK FOR THIS

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Counsel for Stephen M Carley, Ilene S H Terrell
and the Foot Doctor of Rappahannock, Ltd

STATE OF SOUTH CAROLINA
IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND

MONICA WESTON,

Plaintiff,

v

KIM'S DOLLAR STORE and CIBA VISION, a division of NOVARTIS COMPANY,

Defendants

COPY

Civil Action
No 05-CP-40-0655

DEPOSITION OF PHILIP JAMES PHILLIPS

Washington D C

Thursday, August 24, 2006

10 21 a m

RECEIVED
AUG 29 2006
McNair Law Firm P.A.

Job No 1-85097

Pages 1 - 156

Reported by Carl W Girard, Notary Public

Computer-Aided Transcription By
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Charlotte, NC (704) 573-3919

Q Where did you go to college?
A University of Maryland, College Park
Q When did you finish?
A 1976
Q Did you finish in four years?
A Yes, I did
Q What was your degree?
A Bachelor of science in microbiology
Q Do you have any other degrees other than your BS in microbiology from Maryland?
A I have a master's degree
Q In what?
A Business administration
Q Where did you receive your MBA?
A The George Washington University in Washington, D C
Q What year was that?
A 1982
Q I'm sorry When did you get your BS?
A '76
Q What did you do between college and business school?
A Much of the time was working in a clinical microbiology laboratory I was a full-time employee I was employed

Page 8

Q Did you do a professional MBA? Were you working at the same time?

A I would say it was half and half I worked for part of the time I was employed at The Food & Drug Administration for the latter part when I received my degree, but there was a period of time for a semester so that I went full-time

Q How long did it take you to get your MBA?

A I believe it was just under three years I believe I started in 1979 and finished in 1982

Q Any other degrees other than your BS and your MBA?

A No

Q When you got out of college, where did you go to work, please?

A Prince George's General Hospital in Cheverly, Maryland

Q Where do you do for Prince George's?

A I was a clinical microbiologist

Q What were your duties and responsibilities there?

A Primarily assessing various body fluids to determine presence or absence of various microorganisms to determine various forms of

disease

Q So you worked in a lab?

A Yes, I did

Q How long did you work there?

A Almost three years

Q Why did you leave that job?

A I had an opportunity to go into the consulting field

Q So you left that job voluntarily?

A Yes, I did

Q You immediately started with another position?

A Yes, I did

Q What was that position?

A I was a research microbiologist for a consulting firm in Rockville, Maryland, the name was Enviro Control

Q What were your duties and responsibilities there?

A It was an environmental consulting firm and during the duration of my time with them, we were involved in a contract with the Environmental Protection Agency, looking at germicides and indexing data that comes from germicide labeling

Q How long did you stay there?

Page 10

A It was probably a year and-a-half to two years, in that window

Q Why did you leave that position?

A Got a job offer from the federal government

Q Was that the FDA?

A Yes

Q Before I go into your time at the FDA, how many times have you been deposed?

A Before going to FDA?

Q No, no I apologize I meant to ask the question before I asked you about your education and your work

How many times have you been deposed?

A I provided a list this morning that actually has the numbers

MR RAWL Mark this as an exhibit

(Exhibit 1 marked for identification)?

A What was the number, three or four times?

BY MR RAWL

Q It was four times, actually I'll show it to you

A Okay

Q I hand you what's been marked as Exhibit

FDA approval of that application

So, therefore, it wasn't that they were completely being distributed just for investigational purposes, they were being used for other purposes

Q Do you have a copy of that deposition, also?

A I believe so

Q Ever testified at trial?

A In a particular period of time or ever? Usually that question has been raised in the last five years or so, have I ever been in a trial A number of years ago while I was at FDA, yes, I did testify in a case against a medical device company as an FDA employee I can't remember the exact date of that, but it was back in the early 1990s

Q Let me ask this Since you have decided to go into consulting, have you ever given testimony at trial?

A No, I have not

Q Is the only time you've given testimony at trial several years ago when you were an employee of the FDA?

A That's correct

Q So is it fair to say that you have never

Page 20

been qualified as an expert witness in any subject in any court?

A When I was an FDA employee I was qualified as an expert in that case

Q Okay And do you remember what year that was?

A Like I say, it was in the early 1990s I could get that information for you It was a case, the United States government against C R Bard, Incorporated

Q You never had any legal training? Ever go to law school?

A No, I have not I've taken food and drug law courses, though You said legal training I have not been to law school

Q Where did you the FDA law courses?

A FDA-sponsored law courses primarily through the Food and Drug Institute here in Washington, D C

Q Those are classes put on by the FDA?

A In conjunction with FDLI

Q What is that?

A Food and Drug Law Institute

Q How many such courses have you taken?

A That I cannot recall Half a dozen

courses But I've also taught in some of those courses as well

Q When was the last one you taught?

A I believe it was last fall

Q For FDLI?

A Yes, at the Food and Drug Administration

Q Do you remember what the topic was?

A Medical device regulation

Q How long was the course you taught?

A It was an afternoon, four-hour course

Q Did it have anything to do with classification?

A Yes, it did

Q Do you have materials that you hand out in those courses?

A I used a Power Point presentation

Q Do you still have that Power Point presentation?

A Probably I do I don't know that for a fact

Q Did you go into all issues like intended use and all that type stuff?

A Yes

Q You didn't talk about contact lenses in

have had to put in the federal government to get the retirement package that you have now?

A Well, I took a reduced retirement, so it's not -- if I spent additional time, I wouldn't have the exact retirement package that I have now But it is normally a 30-year retirement in the federal service

When I left, I had a total of 24 years in service, so it would have been another six years before I would have been able to get full retirement

Q Did you have the position with Becker & Associates prior to making a decision to accept early retirement?

A No, I did not

Q So you accepted the early retirement and then went looking for a job?

A That's correct

Q When did you officially resign from the FDA?

A I believe the date was February 18th 2005

Q When did you start with Becker & Associates?

A Again, I believe the date was April 28th

when I was working exclusively in the Division of Ophthalmic Devices, but it wouldn't surprise me if there aren't individuals that work at CIBA Vision that do not know my name There's no ongoing relationship that I have with anyone at CIBA Vision

Q Do you have any friends at CIBA Vision?

A No

Q While you were at the FDA did you have any role in the activities that were going on with regard to the Plano color contact cosmetic designations?

A Yes

Q What was your role in that?

A Well, I was a Deputy Director for Science and Regulatory Policy in the Office of Device Evaluation where all of the premarket activities occur regarding contact lenses and all medical devices, for that matter, but contact lenses in particular, and I was aware of the issues that were ongoing at that time

I had conversations with individuals in the Office of Chief Counsel during that period of time, and with the Review Division in the Office of Device Evaluation, the Division of Ophthalmic

CROSS-EXAMINATION

BY MR MUNSON

Q My name is Keith Munson I'm a lawyer with Womble Carlyle representing CIBA Vision in this case I've handed you what's been marked as Exhibit 9 to your deposition And is that the July 2003 package insert that you referred to in paragraph 6 of your affidavit?

A I believe it is

Q Okay Is that package insert something that would have been submitted and approved by the FDA as part of FDA's premarket oversight function?

A Yes In fact, this is probably what FDA looked at closer than any other aspect of labeling

Q In the gray-shaded area, does that indicate that this applies to FreshLook Colors contact lenses?

A (Witness perusing) Yes, it does

Q And as a FreshLook colored lens, that would include Exhibit 4 to your deposition and what's Exhibit 6 to your affidavit, this being Exhibit 4 (indicating)?

MR RAWL Object to the form You can answer

A Yes

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BY MR MUNSON

Q The information in the package insert, is that the type of information that an expert in your field would generally rely on in reaching opinions such as those you expressed today and in your affidavit?

A Yes, it is

Q I want to draw your attention back to questions involving 21 C F R 801 4 regarding labeling Would the FDA ever require or allow a manufacturer of a prescription medical device to add labeling to a accommodate illegal direct-to-consumer uses on a prescription medical device?

MR RAWL Object to the form

I do not believe that they would

BY MR MUNSON

Q What's the difference between a cosmetic product and a cosmetic device?

A Well, I believe earlier in the day we actually went through the two formal definitions that appear in the Federal Food and Cosmetic Act and clearly you can see that the differences between the two

but, basically, to take a very simple

REDIRECT EXAMINATION

BY MR RAWL

Q How can a product be both a cosmetic and a device at the same time by definition under the Act?

A Well, because they're not mutually exclusive In other words, you could have something that its primary intended use would be to simply alter the appearance of the human body, and it may still affect structure or function, for example, and I can give you an example of that

Probably within the last three to four years FDA cleared through 510(k) a product that was called the Rejuvenique Facial Mask, it was for reducing the appearance of fine lines and wrinkles It was something that was touted by the actress Linda Evans And FDA cleared that product under the Device Authorities because it used low power electrical stimulation into the face

There was absolutely no medical application for that product whatsoever it was simply for just temporary reduction of fine lines and wrinkles But because of the structure/function concerns, as a result of putting low levels of current into the face, the Agency

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PEEL

LIFT FOIL

NOT TO BE SOLD INDIVIDUALLY

SPH -0.00

LOT 098305

EXP 2008-06

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FRESHLOOK®

COLORS

Contents: One sterile soft contact lens, 45% phemfilcon A (with UV absorbing chromophores), 55% water, in borate buffered saline containing 0.005% Poloxamer.

UV

Rx only

BC: MEDIAN

DIA: 14.5

CE 0086

CIBA Vision®

A Novartis Company

CIBA Vision Corporation
Duluth, GA 30097 U.S.A.
Made In U.S.A.
Patented

STERILE

L467

AUG 2 4 2005

Ex. 9 Id. Ev.
CARL V. GIRARD
096527/D7400B

CIBA Vision

A Novartis Company

PACKAGE INSERT for FreshLook® (phemfilcon A) Spherical and Toric Soft Contact Lenses, including: FreshLook® ColorBlends®, FreshLook® Color Enhancers, FreshLook® Radiance, and FreshLook® Dimensions (phemfilcon A) Soft Contact Lenses When Prescribed for Frequent Replacement or Disposable Wear

Important This package insert is effective as of July 2003 and supersedes all prior inserts for the products described below Please read carefully and keep this information for future use This package insert is intended for the eye care professional but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient s prescribed lenses Copies of this package insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service at 1 800 241 5999 or download from our web site at www.cibavision.com CIBA Vision makes available a Patient Instruction Booklet that is recommended to be given to the patient.

℞ only

CAUTION FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL

DESCRIPTION

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are available in Handling Tint Colors Color Enhancers ColorBlends Radiance and Dimensions FreshLook Toric soft contact lenses are available in Handling Tint and ColorBlends The FreshLook soft contact lens family contains several products that incorporate a UV absorber Each of these products is identified appropriately on the product package The lens wearing schedule may be prescribed for either Disposable Wear or Frequent Replacement. In the **Disposable Wear Program** the lens wearing time prescribed by the eye care profess onal is for either daily wear or extended wear from 1 to 7 days/6 nights Patients should be instructed to dispose of the lenses at each removal and to use lens care products only on an emergency basis In the **Frequent Replacement Program** the lens wearing time prescribed by the eye care professional is for either daily wear or extended wear from 1 to 7 days/6 nights. Each time the lens needs to be removed before the replacement time period has elapsed the lens must be both cleaned and disinfected prior to placing it back on the eye CIBA Vision recommends that the lens be discarded and replaced with a new lens every 2 weeks, or as recommended by the eye care professional The eye care professional is encouraged to determine the wearing schedule based on response of the patient.

PRODUCT DESCRIPTION Lens Material

The lens material phemfilcon A, is a hydrophilic copolymer of 2 hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate and methacrylic acid crosslinked with ethyleneglycol dimethacrylate FreshLook UV contact lenses contain a proprietary UV absorbing monomer which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light.

FreshLook Colors F eshLook ColorBlends FreshLook Color Enhancers and FreshLook Radiance soft contact lenses are made by modifying the clear FreshLook lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the ins. FreshLook Dimensions soft contact lenses are made by modifying the tinted FreshLook lens by affixing a colored pigme t on that portion of the front surface of the lens which corresponds to the ins Additionally a colored pigment is affixed to the front surface of the Tonc lens to act as a unique orientation mark Identified as (FreshMark) The colored p gments consist of the following color additives listed in the color additive prov sions of 21 CFR iron oxides, titanium dioxide [phthalocyaninato (2)] copper chromium oxide carbazole violet mica coated with iron oxide and mica coated with titanium dioxide

eshLook Spherical and Tonc with Handling Tint soft contact lenses are ited green with the color additive phthalocyanine green for easy vis bility for handling FreshLook Dimensions lenses are also tinted green with the color additive phthalocyanine green for a better contrast In the printed port on of the lens These color additives are not removed by lens handling or cleaning/disinfecting procedures The lens coloring process does not alter the optical and performance characteristics

Lens Properties

The physical properties of the lens are

Specific Gravity	1 152
Refractive Index	1 409
Light Transmittance	
FreshLook with Handling Tint with or without UV	95% minimum
FreshLook Colors with or without UV	95 / minimum
Surface Character	Hydrophilic
Water Content	55%
Optical Zone (FreshLook Colors)	5mm
Optical Zone (FreshLook with Handling Tint)	5mm to 9mm (varies with power)
UV Transmittance†	0-10% in the ultraviolet portion of the spectrum (250 400nm) averaged across the spectrum
Oxygen Permeability (Dk)	16 1x10⁻ ml O₂cm /sec ml mmHg
Oxygen Transmissibility (Dk/L)	20x10 ml O cm/sec ml mmHg @ 35 C

(Dr Irving Fatt Method)

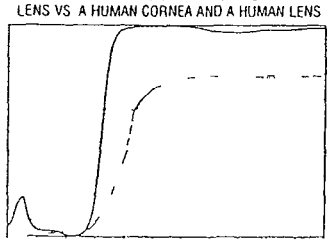
†The referenced data was dete mined from Methods for Determining Ultraviolet Transmission of UV blocking Contact Lenses by Dr H Faubl International Contact Lens Clinic Vol 25 no 5 1998

Representative of the thinnest lens design

Figure 1 (below) illustrates the transmittance of a typical FreshLook UV and/or FreshLook Progressive Bifocal with Handling Tint lens (thinnest lens to be marketed) a human cornea and a human lens

Curve 1 represents the transmittance of the thinnest (0 08mm nominal center thickness) lens to be marketed

FIGURE 1 TYPICAL TRANSMITTANCE PROFILE OF A FRESHLOOK UV WITH HANDLING TINT CONTACT LENS VS A HUMAN CORNEA AND A HUMAN LENS



A small transmittance peak appears in Curve 1 in the 250 290 range The transmittance across this waveband is 0 12% average with a maximum of 29% This peak is located in the wavelength of ultraviolet radiation (250-290nm) which is not transmitted to the earth s surface.

Curves 2 and 3 represent the transmittance characteristics of a human cornea from a 24-year old person and a human lens from a 25 year-old person respectively

1 Human cornea from a 24 year old person as described in Lerman S Radiant Energy and the Eye MacMillan, New York, 1980 p 58 figure 2 21
2 Human crystalline lens from a 25 year old person as described in Waxler M Hitchins V M Optical Radiation and Visual Health CRC Press Boca Raton Florida 1986 p 19 figure 5

ACTIONS

When placed on the cornea a hydrated FreshLook Spherical soft contact lens acts as a refracting medium to focus light rays on the retina The FreshLook Toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina The thinnest FreshLook UV lenses (3 50 diopters and lower) block 98% UVA radiation and 94% UVB radiation averaged across the spectrum The degree of UV radiation blockage of FreshLook UV lenses will increase for thicker lenses FreshLook Spherical and Toric soft contact lenses with Handling Tint provide ease of patient handling and easy visibility but do not affect iris color The visibility tint allows the lens to become visible to wearers when not on the eye

Patients should be advised of the following

Warning UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area You should continue to use UV absorbing eyewear as directed

NOTE. Long term exposure to UV radiation is one of the risk factors associated with cataracts Exposure is based on a number of factors such as environmental conditions (altitude geography cloud cover) and personal factors (extent and nature of outdoor activities) UV absorbing contact lenses help provide protection against harmful UV radiation However clinical studies have not been done to demonstrate that wearing UV absorbing contact lenses reduces the risk of developing cataracts or other eye disorders Consult your eye care professional for more information

Available Lens Parameters

FreshLook soft contact lenses are hemispherical shells of the following dimensions

Spherical Lens Parameters

Chord Diameter	12 0 to 15 0 mm	
Center Thickness	Extended Wear and 0 08 to 0 19mm (Varies with power)	Daily Wear 0 08 to 0 56mm (Varies with power)
Base Curves	7 80 to 9 00 mm	
Powers:	20 00 Diopters to +20 00 Diopters for Daily Wear 20.00 Diopters to +4.50 Diopters for Extended Wear	

Toric Lens Parameters

Chord Diameter	12 0 to 15 0 mm	
Center Thickness	Extended Wear and 0 08 to 0 19mm (Varies with power)	Daily Wear 0 08 to 0 56mm (Varies with power)
Base Curve	7 80 to 9 00 mm	
Powers	20.00 Diopters to 20 00 Diopters for Daily Wear 20.00 Diopters to +4.50 Diopters for Extended Wear	
Cylinder	-0 75 Diopters to 6 00 Diopters	
Prism Ballasted	0 25 Diopters	
Axis	0 to 180 in 1 steps	

INDICATIONS (USES)

Vision Correction

Spherical

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2 0 diopters that does not interfere with visual acuity The FreshLook Spherical Colors Color Enhancers ColorBlends Radiance and Dimensions lenses act to enhance or alter the apparent color of the eye

Toric

FreshLook Toric (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6 0 diopters The FreshLook Toric ColorBlends lenses act to enhance or alter the apparent color of the eye

The lenses may be prescribed for Daily Wear or Extended Wear in not aphakic persons from 1 to 7 days between removal for cleaning and disinfection or disposal as recommended by the eye care professional or for Daily Wear in aphakic persons The eye care professional may prescribe the lens in either the single use disposable wear or for frequent replacement with cleaning disinfection and scheduled replacement When prescribed for frequent replacement the lens may be disinfected using a chemical disinfection system FreshLook soft contact lenses with UV absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye

CONTRAINDICATIONS (REASONS NOT TO USE)

FreshLook soft contact lenses are contraindicated when any of the following conditions exist.

Acute and subacute inflammation or infection of the anterior chamber of the eye
Active disease injury or abnormality affecting the cornea, conjunctiva or eyelids.
Microbial infection
Insufficiency of lacrimal secretion (dry eyes)
Corneal hypoesthesia (reduced corneal sensitivity if not aphakic)
Use of medication that is contraind cated I luding e/e medications
Patient history of recurring eye or eyelid infections including styes or of adverse effects associated with contact lens wear or of intolerance or abnormal ocular response to contact lens wear
History of patient non compliance with contact lens care and disinfection regimens wearing restrictions wearing schedule or follow up visit schedule
Patient's inability or unwillingness because of age infirmity or other mental or physical conditions or an adverse working or living environment to understand or comply with any lens care requirements warnings precautions restrictions or directions
Allergy to any ingredient such as mercury or Thimerosal in a solution which must be used to care for the lens
Patients who require only vision correction and who would not or could not adhere to a recommended care system for lenses or who are unable to place and remove lenses should not be provided with them
Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
If eyes become red or irritated
Any active corneal infection (bacterial fungal or viral) Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products Therefore after a thorough eye examination, including appropriate medical background patients must be fully apprised by the prescribing professional of all the risks associated with contact lens wear To minimize these risks the need for strict compliance with the care regimen including cleaning of the lens case if the patient is on the Frequent Replacement Program wearing restrictions wearing schedules and follow up visit schedule must be emphasized to the patient (see considerations listed in CONTRAINDICATIONS and PRECAUTIONS Sections)

Since eye injury can develop rapidly it is most important that patients be instructed in the possible signs or symptoms of problems and the need to remove the lenses and be examined by the prescribing eye care professional or a corneal specialist immediately if they experience any symptoms such as those listed below under the ADVERSE EFFECTS Section (Professionals examining patients presenting such symptoms should refer to the Professional Fitting Guide and Patient Instruction Booklet)

Extended Wear The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses The risk among extended wear lens users increases with the number of consecuti e days that the lenses are worn between removals beginning with the first overnight use Some researchers believe that these complications are caused by one or more of the following a weakening of the cornea s resistance to infections particularly during a closed-eye condition as a result of hypoxia an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms particularly when a regular periodic lens removal and disinfection or disposal schedule has not been adhered to by the patient contamination of lens and/or lens care products poor personal hygiene by the patient patient unsuitability to the particular lens or wearing schedule accumulation of lens deposits damage to the lens improper fitting length of wearing time and the presence of ocular debris or environmental contaminants Additionally smoking increases the risk of ulcerative keratitis in contact lens users While the great majority of patients successfully wear contact lenses extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates and endothelial polymegathism which require consideration of discontinuation or restriction of extended wear The epithelial conditions are reversible upon discontinuation of lens wear The reversibility of endothelial effects of contact lens wear has not yet been established As a result professionals views of extended wearing times vary some do not prescribe extended wear at all others prescribe flexible wearing times with occasional overnight wear and others prescribe extended wearing periods from 1 to 7 days/6 nights with specified intervals of no lens wear for certain patients with follow up visits as in the case of the Frequent Replacement Program with a proper care regimen Some professionals also recommend frequent replacement of lenses at intervals such as one to two weeks

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear

Serious eye injury scarring of the cornea and loss of v sion may result from problems associated with wearing contact lenses and using contact lens care products To reduce these risks emphasize to the patient the need for strict compliance with the lens care regimen including hand washing proper lens disinfection cleaning of the lens case wearing restrictions wearing schedules and follow up visit schedules

Eye problems Including corneal ulcers can develop rapidly and if left untreated lead to loss of vision Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and promptly contact their eye care professional if they should experience eye discomfort foreign body sensation excessive tearing vision changes redness of the eye or other problems with their eyes

Non-compliance with the manufacturer s labeled lens care instruction may put the patient at significant risk of developing a serious eye infection

Tap water distilled water or homemade saline solution should NOT be used as a substitute for any component in the lens care process The use of tap and distilled water has been associated w th Acanthamoeba keratitis a corneal infection that is resistant to treatment and cure

Smoking Increases the risk of corneal ulcers for contact lens users especially when lenses are worn overnight or while sleeping

PRECAUTIONS

In prescribing contact lenses the Precautions should be ca efully observed It is also strongly recommended that the professional review with the patient the appropriate Patient Instruction Booklet (describing either the Frequent Replacement Program or the Disposable Wear Program) available from CIBA Vision prior to dispensing the l nses and ensure that the patient understands it contents

CIBA000109

Due to the small number of patients enrolled in clinical investigation of lenses not all refractive powers design configurations or lens parameters available in the lens material are evaluated in significant numbers Consequently when selecting an appropriate lens design and parameters the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health including oxygen permeability wettability central and peripheral thickness and optic zone diameter

The potential impact of these factors on the patient s ocular health should be carefully weighed against the patient s need for refractive correction, therefore the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care professional

In the Disposable Wear Program the FreshLook soft contact lenses are intended to be disposed of once they are removed from the patient s eye Therefore it is important that patients be instructed to always have available a pair of new sterile lenses In the event that a lens must be removed from the eye because of dust a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry) the lens should be removed and replaced with a new sterile replacement lens If replacement lenses are not available the patient should follow emergency lens care directions

In the Frequent Replacement Program, in the even that a lens must be removed from the eye because of dust, a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry) the lens should be removed cleaned and disinfected before reinsertion. If the lens becomes dehydrated the patient should follow the lens care directions for CARE FOR A DEHYDRATED LENS In the Frequent Replacement Program, or in the event of Emergency Lens Care in the Disposable Wear Program chemical disinfection solution may not be used with heat unless specifically indicated in the labeling for heat and chemical disinfection

In the Frequent Replacement Program or in the event of Emergency Lens Care CIBA Vision recommends use of sterile solutions Sterile non-preserved solutions should be used if the patient is allergic to preservatives such solutions must be discarded after the time specified in their label directions

Contact lens wear may not be suitable for certain occupations or in other instances may require eye protection equipment Therefore the patient should always inform his/her employer that contact lenses are being worn Environmental fumes smoke dust vapors and windy conditions must be avoided in order to minimize the chances of lens contamination or physical trauma to the cornea.

Eye injury from irritation or infection and damage to lenses may result from lens contamination The patient should be instructed to refrain from using saliva or anything other than the recommended solution for lubricating or wetting lenses The patient should also be informed to wash and rinse hands before handling contact lenses at all times

Eye care professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated

The patient should be informed that contact lenses should not come into contact with any cosmetics lotions soaps creams hairsprays or deodorants that it is best to put on lenses before putting on makeup and that water based cosmetics are less likely to damage lenses than oil based products

The patient should be informed not to use aerosol or pump products such as hairspray while the lenses are worn since liquid and vapors may damage the lens

The patient should be instructed to handle the lenses carefully and avoid dropping or touching them w th fingernails which can cause contamination or damage of the lens The patient should also be told that f the lens becomes nicked or torn it should not be worn

Tweezers or other tools should not be used by patients to remove a lens from the lens container The lens should be poured into the hand Lenses should be cleaned in the palm of the hand rather then between thumb and finger Patients should be instructed on and be able to demonstrate prompt removal of the lenses

Fluorescein should not be used while the lenses are on the patient's eye The lenses abso b this dye and become discolored Fluorescein in the eye should be thoroughly flushed with a sterile saline solution recommended for in eye use and a new lens should be reinserted only after at least one hour

A lens must move freely on the eye for a proper fit For further information refer to the appropriate FreshLook soft contact lens Professional Fitting Guide

Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis Patients should be carefully evaluated for extended wear prior to prescription and dispensing and professionals should conduct early and frequent follow up examinations to determine ocular response to extended wear To prevent contamination and avoid serious eye injury the patient should be instructed to empty and rinse the lens case with fresh rinsing solution and allow the lens case to air dry between each lens disinfection cycle as in the F equent Replacement Program or in the event of Emergency Lens Care

The patient should be instructed to inform his or her physician that contact lenses are worn and to consult his or her eye care professional before using any medication in the eye

Exposure to water while wearing contact lenses in activities such as swimming water skiing and hot tubs may increase the risk of ocular infection including but not limited to Acanthamoeba keratitis

Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly

Certain medications such as antihistamines decongestants diuretics muscle relaxants tranquilizers and those for motion sickness may cause dryness of the eye increased lens awareness or blurred vision Should these conditions exist, proper remedial measures should be prescribed Depending on the severity this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discont uance of contact lens wear while such medication is being used

A patient who has been prescribed FreshLook contact lenses on a daily wear schedule should be cautioned to remove the lenses before sleeping

ADVERSE EFFECTS

Potentially serious complications are usually accompanied by one or more of the following signs and symptoms

- Foreign body sensation
- Excessive watering (tearing) of the eyes or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning stinging itching or other pain associated with the eyes
- Comfort is less compared to when lens was first placed on eye
- Poor visual acuity
- Blurred vision rainbows or halos around objects
- Feeling of dryness

If the patient notices any of the above signs or symptoms he or she should be instructed to **IMMEDIATELY REMOVE THE LENSES**

- If the discomfort or problem stops look closely at the lens
  - If the lens is in any way damaged DO NOT put the lens back in the eye Discard the lens
  - If the lens has dirt an eyelash or other foreign body on it, or the problem stops clean disinfect and reinsert the lens If in the Frequent Replacement Program or discard the lens and replace it with a new sterile replacement lens if in the Disposable Wear Program
- If the discomfort or problem continues after removal of the lens or upon reinsertion immediately remove lenses and promptly contact his or her eye care professional The eye care professional must determine the need for examination treatment or referral without delay

Patients should be informed that a serious condition such as infection, corneal ulcer corneal vascularization or iritis may be present and may progress rapidly Less serious reactions such as abrasions epithelial staining and bacterial conjunctivitis should be treated appropriately to avoid complications Additionally contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear These include but are not limited to local or generalized corneal edema epithelial microcysts epithelial staining infiltrations neovascularization endothelial polymegathism tarsal papillary changes conjunctival infection or iritis

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of FreshLook (phemfilcon A) contact lenses eye care professionals please notify CIBA Vision Corporation technical consultation at 1 800-241 7468

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS

The lens must move adequately on the eye for a proper fit and continued health of the eye When prescribing FreshLook lenses for extended wear It is important to reevaluate the lens fit for adequate movement at various times after the patient sleeps while wearing lenses This reevaluation should include a follow up visit as soon as possible after the patient awakens as well as at other times of the day If the fit is judged to be too tight or steep the patient must be refit into a lens that provides the criteria of a well fitted lens

Conventional methods of fitting contact lenses apply to FreshLook soft contact lenses For a detailed description of the fitting technique refer to the appropriate CIBA Vision *Professional Fitting Guide.*

It is strongly recommended that the patient be provided appropriate *Patient Information Booklet* available from CIBA Vision and understands its contents prior to dispensing the lenses

Copies of **Fitting Guides and Patient Information Booklets** for FreshLook lenses are available without charge from. CIBA Vision Corporation Duluth Georgia USA 30097 or by calling a CIBA Vision customer service representative at 1 800 241 5999

LENS REPLACEMENT SCHEDULES

In a planned replacement program the replacement schedule is determined by the eye care professional based upon the patient s physiological condition CIBA Vision recommends frequent replacement of FreshLook lenses at intervals of every two weeks The eye care professional may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary When FreshLook lenses are prescribed for **disposable wear** the contact lens is considered a single use medical device in which the lenses are worn from 1 to 7 days and **discarded upon removal** from the eye

WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional CIBA Vision recommends that contact lens wearers see their eye care professional twice each year or if directed more frequently The maximum suggested wearing time each day should be determined by the eye care professional based upon the patient s physiological eye condition because individual responses to contact lenses vary The eye care professional may prescribe the lens for frequent replacement with cleaning disinfection and scheduled replacement. When prescribed for frequent replacement, the lens may be disinfected usi g a chemical (not heat) disinfection system

DAILY WEAR There may be a tendency for the daily wear patient to over wear the lenses initially Therefore the importance of adhering to a proper initial daily wearing schedule should be stressed to these patients The wearing schedule should be determined by the eye care professional and provided to the patient. These lenses may be worn in the Frequent Replacement Program

EXTENDED WEAR (Greater than 24 hours or while asleep) The wearing schedule should be determined by the prescribing eye care professional for each individual patient based upon a full examination and patient history as well as the professional s experience and professional judgment

CIBA Vision recommends beginning extended wear patients with the recommended initial daily wear schedule followed by a period of daily wear and then the gradual introduction of extended wear one night at a time unless individual considerations indicate otherwise. The eye care professional should examine the patient in the early stages of extended wear in order to determine corneal response The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens as determined by the prescribing eye care professional (See the factors discussed in WARNING Section) Once removed a lens should remain out of the eye for a period of rest overnight or longer as determined by the prescribing eye care professional

LENS CARE DIRECTIONS

Disposable Wear (Emergency Lens Care)

No lens care is indicated as lenses are discarded upon removal from the eye Lenses should only be cleaned rinsed and disinfected on an emergency basis when replacement lenses are not available (See BASIC INSTRUCTIONS FOR LENS CLEANING RINSING AND DISINFECTION below)

Planned Replacement

Patients must adhere to a recommended care regimen Lenses must be cleaned rinsed and disinfected after removal and prior to reinsertion on the eye according to the package inserts and patient instructions provided with the lens care products recommended by the eye care professional Failure to follow the complete regimen in accordance with the manufacturer s package inserts and patient instructions may contribute to problems (see ADVERSE EFFECTS) and/or result in the development of serious ocular complications as discussed in WARNINGS

Basic Instructions for Lens Cleaning and Disinfection

When lenses are dispensed the patient must be provided with appropriate and adequate instructions and warnings for lens care handling The eye care professional should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system The specific instructions for such products and the particular charactenstics of the patient should also be taken into consideration

The basic general instructions for general lens care are as provided below

- Always wash and rinse your hands before handling your contact lenses
- The lenses should be cleaned and disinfected before reinsertion into the eye Use a suggested chemical (not heat) lens care system recommended by the professional since heat may cause discoloration
- Use and follow the instructions of lens care products intended for use with soft (hydrophilic) contact lenses
- Always use lens care solutions before they reach the expiration date
- Always keep the lenses completely immersed in the recommended storage solution when they are not being worn (stored)
- In the Frequent Replacement Program CIBA Vision recommends that sterile solutions be used in the soft lens care system Sterile non preserved solutions should be used only if the patient is allergic to preservatives When used sterile non preserved solutions must be discarded after the time specified in their label directions

Refer to the PRECAUTION Section for further information on lens care and handling.

CARE FOR A DEHYDRATED LENS

Disposable Wear Program If a soft (hydrophilic) contact lens is exposed to air while off the eye it may become dry and brittle Dehydrated lenses should be disposed of Therefore it is important that the patient always have a pair of new sterile replacement lenses available

Frequent Wear Program If a soft (hydrophilic) contact lens is exposed to air while off the eye it may become dry and brittle and need to be rehydrated If the lens is adhering to a surface such as a counter top apply sterile saline solution before handling

Eye care professionals should review the following information on rehydrating the lens with the patient

- Handle the lens carefully
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking the lens does not become soft, the lens should not be used until examined by the eye care professional

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye the patient should be instructed to apply several drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non movement of the lens continues after several minutes the patient should be instructed to immediately consult the eye care professional

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses

Each contact lens is shipped sterile in a sealed blister pack containing borate buffered saline Hands should be thoroughly washed rinsed and dried with a lint free towel prior to handling a lens In order to insure sterility the blister pack should not be opened until immediately prior to use For fitting and diagnostic purposes the lenses should be disposed of after a single use and not be re used from patient to patient

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products gardening solutions laboratory chemicals etc) are splashed into the eyes the patient should flush eyes immediately with tap water and call or visit the eye care professional or a hospital emergency room without delay

HOW SUPPLIED

Each sterile lens is packaged in a foil sealed plastic container containing a borate buffered saline solution with 0 005 % poloxamer and is steam sterilized The package is marked with the lens power diameter base curve cylinder and axis (if applicable) expiration date manufacturing lot number and if applicable UV absorber lens tint and opaque color

ADDITIONAL INFORMATION

For answers to your questions about FreshLook soft contact lenses or to report any adverse reactions contact our Professional Consultation Services at 1 800 241 7468 during regular business hours

For additional copies of the Eye Care Professional Package Insert Professional Fitting Guide and Patient Instruction Booklets contact our Customer Service Department at 1 800-241 5999

PATENT PROTECTED

U S Patents 4 976 533 5 062 701 5 020 898 5 936 705 4 668 240 4 720 188 4 704 017 4 582 402 4 668 240 5 414 477 5 637 726

Patents Pending for FreshLook Progressive Bifocal

GB Patents 0346032 0498835 0158999 0187137 0440107

FR Patents 0346032 0498835 0158999 0187137 0440107

AUS Patents 620886 636679 569649 634624

CN Patents 26003 4158 4136 3788 4157

PH Patents 26412 29984 23319

SG Patents 9790790 1 9790791 9 9090530 8 9290545 4

TW Patents NI 42746 NI 63667 NI 26506 NI 51612

BR Patents P18600017 9 P190078012 P18600017 9

HK Paten

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth Georgia USA 30097
Date/Part No July 2003
D7400B/096137

CIBA Vision

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND	)	IN THE COURT OF COMMOM PLEAS
Monica Weston, Plaintiff, v	)	C A No 05-CP-40-0655
Kims Dollar Store and CIBA Vision, a division of Novartis Company, Defendants	)	

AFFIDAVIT OF PAUL ORIS

I PAUL ORIS SWEAR AS FOLLOWS

1

My name is Paul Oris I am more than twenty-one years of age and am competent to give this affidavit I have personal knowledge of the facts contained herein I give this affidavit for use in the above-styled case and for any other use allowed by law

2

I am Head Global Regulatory Affairs for Defendant CIBA Vision Corporation ("CIBA or the Company) I have been with CIBA and in this position for approximately five years

3

The department which I head is functionally responsible for communications with regulatory authorities concerning the Company's products

4

My department maintains all documents relating to the U S Food and Drug Administration's approval of colored contact lenses manufactured and marketed by CIBA

5

My department is responsible for reporting adverse events to the U S Food and Drug Administration concerning the Company's color contact lenses, including without limitation, adverse events suffered as a result of the sale of color contact lenses without a prescription by unauthorized dealers

6

My department has met with and provided information to the U S Food and Drug Administration regarding the sale of the Company's color contact lenses without a prescription by unauthorized dealers

7

In effort to comply with discovery in this case, my department undertook a comprehensive search for files, including electronic files, maintained in the ordinary course of business and produced approximately 55,000 pages of documents which were made available to plaintiff's counsel over the course of three days To my knowledge all documents relating to the approval of colored contact manufactured and marketed by CIBA, adverse events reported to the U S Food and Drug Administration concerning the use of Company's color contact lenses and meetings with the U S Food and Drug Administration regarding the sale the Company's color contact lenses without a prescription by unauthorized dealers have been produced in this litigation

FURTHER AFFIANT SAYETH NOT

This 27th day of July, 2006

By _____
PAUL ORIS, AFFIANT

Sworn to and subscribed before me
this 27 day of July, 2006

_____
Notary Public

My commission expires

Notary Public
Forsyth County Georgia
My Commission Expires
September 17, 2007

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND	)	IN THE COURT OF COMMON PLEAS
Monica Weston, Plaintiff, v Kims Dollar Store and CIBA Vision, a division of Novartis Company, Defendants	)	Civil Action No 05-CP-40-0655 **AFFIDAVIT OF PHIL PHILLIPS**

AUG 2 4 200 6

Ex. 2nd Ev

CARL W GIRARD

I, Philip J Phillips, MBA, hereby depose and state as follows

1 I am employed by Becker & Associates Consulting, Inc as Director, Medical Device Practice

2 Previously, from 1994-2005, I served as Deputy Director, Science and Regulatory Policy, Office of Device Evaluation, Center for Devices and Radiological Health United States Food and Drug Administration The Office of Device Evaluation (ODE) is the organizational unit in the FDA that is responsible for the premarket evaluation of medical devices intended for commercial distribution in the United States As the ODE's chief scientist and administrator, I planned, managed and directed all premarket review programs that ensure the safety and effectiveness of medical devices marketed and used in the United States I provided executive leadership in managing and directing six review division See the attached Resume for complete details of my professional background and associations (Ex A)

3 Soft contact lenses prior to 1976 were regulated by the FDA as drugs After the Medical Devices Amendments (MDA) of 1976, all soft contact lenses were considered 'transitional

medical devices" and automatically classified in Class III by the MDA In 1994, FDA reclassified daily wear soft contact lenses as Class II medical devises, but continued the classification of Class III medical devices for extended wear soft contact lenses These classifications applied equally to plano (zero power) lenses and corrective lenses In 2003, the FDA issued Import Alert 86-10, which allowed for the possibility of obtaining cosmetic classification for solely decorative color plano contact lenses under certain conditions This did not effect the classification of previously approved color contact lenses, such as FreshLook Colors In 2005, Congress passed legislation to remove the ' loophole" for classifying plano contact lenses used solely for decorative purposes as a cosmetic, and currently all plano contact lenses are regulated as medical devices by the FDA

4 FreshLook Colors Lenses of the type represented by Ex B, hereto, are Class III medical devices This would include plano (zero power) FreshLook Colors lenses in 2004 It is the intended use of the device by the manufacturer and the inherent risks of the device that determines the medical device classification, not how it is ultimately purchased in an individual case It is possible for a device to be both a 'cosmetic and a ' device , and in such case, FDA s medical device regulations would apply

5 FreshLook Colors plano (zero power) contact lenses are approved in the Premarket Approval (PMA) P830037 and the relevant supplements thereto The PMA process represents the highest level of FDA regulation applicable to medical devices CIBA Vision (and Wesley-Jessen) PMA approval was in accord with all applicable FDA requirements and resulted in legitimate approval of CIBA Vision FreshLook Colors contact lenses as Class III medical devices

6 FreshLook Colors lenses of the type represented by Ex B, hereto, contain UV absorbing chromophores In PMA Supplement 33, CIBA Vision obtained approval from the FDA to incorporate the UV absorber ingredient into FreshLook Colors lenses As of at least July 2003, the FDA approved CIBA Vision package insert for FreshLook Colors lenses included significant information about UV absorbing properties and UV protection This included the health related statement that "Long term exposure to UV radiation is one of the risk factors associated with cataracts UV-absorbing contact lenses help provide protection against harmful UV radiation" [ACTIONS] In addition, the INDICATIONS (USES) section of the approved package insert states that 'FreshLook soft contact lenses with UV absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye' UV protection, would constitute a "medical use" under Import Alert 86-10 and therefore further make FreshLook Colors plano lenses ineligible for regulation as a "cosmetic" For example Import Alert 86-10, specifically uses the example of UV protecting sunscreen claims making a product a drug, rather than merely a cosmetic Import Alert 86-10 concludes that contact lenses that have medical uses are "properly regulated as medical devices under the act" [Section II Guidance]

7 With each approved PMA or PMA Supplement the FDA provides an approval letter and encloses "Conditions of Approval" The approval letters and/or the Conditions of Approval required CIBA Vision (Wesley-Jessen) to submit approved labeling in final printed form before commercial distribution of the device

8 The FDA is the federal regulatory body with the authority to clarify, modify, enforce limit vacate, withdraw or suspend approval of Class III medical devices, including CIBA Vision FreshLook Colors contact lenses that Ms Weston allegedly purchased Allowing inconsistent state obligations would interfere with the FDA's federal regulatory scheme Even putting on

every suggested state warning on a product's label could run contrary to another state's requirement and dilute the impact of necessary warnings The FDA is uniquely qualified and solely vested by the MDA with the authority to regulate Class III medical devices, including the CIBA Vision FreshLook Colors contact lenses that Ms Weston allegedly purchased

9 CIBA Vision's packaging, product information, warnings and labeling for FreshLook Colors contact lenses, were in accordance with the FDA's PMA and PMA Supplement approvals and the agency's labeling regulation

10 FDA conducts field investigations and other reviews of medical device manufacturers Through 2004, CIBA Visions compliance with the Conditions of Approval good manufacturing practices, medical device reporting requirements and other requirements reviewed by FDA were sufficient to maintain the PMA approval status for FreshLook Colors contact lenses

AFFIANT FURTHER SAYETH NAUGHT

Philip J Phillips

Sworn to before me this
22 day of August, 2006

Donna Aldea

Notary Public for Georgia
My Commission Expires

Notary Public Forsyth County Georgia
My Commission Expires Sept 3 2006

BECKER & ASSOCIATES
CONSULTING INC

RESUME

Philip J Phillips, MBA

EDUCATION

1982	MBA George Washington University School of Government and Business Administration Washington, DC
1976	BS Microbiology, University of Maryland College Park MD

EXPERIENCE

Current

Director, Medical Device Practice
Becker & Associates Consulting, Inc

Philip J Phillips is the Director of the Medical Device Practice at **BECKER, INC** The firm provides strategic scientific consulting services to healthcare clients and their counsel with a focus on managing the most challenging issues in regulatory public policy and litigation forums He has 24 years of experience in FDA regulation of medical devices, having focused on the development and implementation of numerous regulatory strategies regarding the design manufacture and marketing of medical devices in the United States Mr Phillips brings an in depth knowledge of a wide range of regulatory matters including FDA jurisdiction and compliance device classification and evaluation, clinical trials human subject protection product labeling post-marketing surveillance, and promotion and advertising His device experience crosses all medical specialties, including in vitro diagnostic devices He has promulgated regulations and developed numerous guidance documents aimed at clarifying FDA premarket requirements and expectations

Previous Positions

1994 2005	Deputy Director Science and Regulatory Policy Office of Device Evaluation United States Food and Drug Administration Center for Devices and Radiological Health Rockville Maryland

EX A

The Office of Device Evaluation (ODE) is the organizational unit in FDA that is responsible for the premarket evaluation of medical devices intended for commercial distribution in the United States ODE applies principles of sound science and exercises good regulatory judgment in the review of safety and effectiveness data and in granting medical device market authorizations As the Office s chief scientist and administrator, Mr Phillips planned, managed and directed all premarket review programs that ensure the safety and effectiveness of medical devices marketed and used in the United States Mr Phillips provided executive leadership in managing and directing six review divisions that encompassed all medical specialties three support staffs and a total work force of over 300 scientists, engineers and clinicians

2003-2005 Acting Deputy Director, Office of Science and Engineering Laboratories
United States Food and Drug Administration
Center for Devices and Radiological Health
Rockville MD

The Office of Science and Engineering Laboratories (OSEL) performs product testing develops reliable standardized test methods for government and industry use performs anticipatory scientific investigations on emerging technologies, contributes laboratory data to national and international standards used in CDRH decision making provides scientific and technical training for CDRH staff members and maintains laboratory collaborations and relationships with scientific researchers in academia and other Federal laboratories OSEL also coordinates and oversees CDRH s activities that support the development of national and international standards Mr Phillips integrated OSEL s laboratory scientists into ODE s premarket review programs including a streamlined guidance development initiative for the Commissioner of Food and Drugs

1987 1994 Director of Program Operations, ODE

1993-1993 Interim Director Division of General and Restorative Devices ODE

1986 1987 Acting Deputy Director Division of Ophthalmic Devices, ODE

1984-1987 Chief Surgical and Diagnostic Devices Branch
Division of Ophthalmic Devices ODE

1981 1984 Interdisciplinary Scientist Division of Ophthalmic Devices ODE

1979 1981 Research Biologist
Enviro Control Inc
Rockville MD 20852

1976 1979 Clinical Microbiologist
Prince George's General Hospital and Medical Center
Cheverly MD 20745

Committee Participation

Radiofrequency Identification (RFID) Working Group 2004 to 2005
Tobacco Legislation Working Group 2004
Project BioShield Implementation Team 2003 to 2005
FDLI Medical Device Committee 2000 to 2005
Industry Least Burdensome Task Force 2000 2001
CDRH Management Council 1996 to 2005
FDA Good Guidance Practices Working Group 1996 1997
Management Action Plan Development Team 1993
Human Tissue Products Working Group 1987 1988
Postmarket Product Management Steering Committee 1987
Ophthalmic PMS Committee (Chairperson) 1986 1988
Ophthalmic Program Management System (PMS) Committee 1983-1985

Representative examples of the scope of experience

- Streamlined premarket evaluation processes and reduced the time required for safe and effective medical devices to receive Agency marketing authorization In the premarket approval (PMA) program introduced modular review, revived product development protocols (PDPs) and instituted numerous procedures designed to streamline agency review and decision-making In the premarket notification (510(k)) program applied a systems approach to design and institute the most sweeping changes in the history of the program relying on voluntary standards guidance documents and design control requirements in lieu of the submission and in-depth analysis of data In the investigational device exemptions (IDE) program instituted procedures that have allowed greater access by the American public to promising new and emerging medical technologies while continuing to provide a high level of protection of the rights safety and welfare of study participants

- Ensured that the proper statutory and regulatory requirements were consistently applied across all ODE review divisions in the evaluation of 20,000 premarket submissions each year and that the appropriate testing and evaluation was performed on the devices before they were cleared for marketing or permitted to be used in clinical trials

- As a nationally and internationally recognized authority on all aspects of medical device regulation provided expert guidance, interpretation, and recommendations to senior Agency and Departmental officials scientific, medical, and professional personnel industry representatives intra/inter governmental counterparts and others on medical device policies regulations and law Represented the agency at meetings and conferences with Departmental officials representatives of the regulated industry healthcare community national and international scientific and health related professional organizations the United States Congress and representatives from foreign governments and Federal, State and local agencies

- Over 24 year career with ODE, solved numerous complex regulatory and scientific problems that affected the organization ability to effectively carry out its mission Accepted numerous short-term assignments to address problem situations including accumulation of backlogs in pending premarket submissions

- In November 2002, developed and presented a regulatory strategy for the FDA review of implantable radiofrequency microchips at the National Academy of Sciences Implemented the strategy involving the Evaluation of Automatic Class III Designation (de novo classification) program resulting in Implantable Radiofrequency Transponder Systems being classified as class II devices exempt from 510(k) requirements (21 CFR 880 6300)

- In cooperation with AdvaMed s Least Burdensome Industry Task Force developed and issued the guidance document entitled *The Least Burdensome Provisions of the FDA Modernization Act of 1997 Concept and Principles*

- Developed and implemented a regulatory strategy for the approval of a PMA for an implantable pulse generator for the treatment of pain based on preclinical testing and an evaluation of peer reviewed literature The Genesis™ Neurostimulation (IPG) System by Advanced Neuromodulation Systems Inc was evaluated and approved by FDA in less than 180 days (P010032)

- Classified Acute Upper Airway Obstruction Devices through de novo classification process into class II, exempt from 510(k) requirements (K993284) with the exemption principally based on conformance with design control requirements under the quality system regulation (21 CFR 868 5115)

- Developed and implemented an interagency agreement with the Centers for Medicare & Medicaid Services (formerly the Healthcare Finance Administration) for the categorization of all clinical investigations of medical devices permitting reimbursement for a majority of investigational medical devices for the first time in the history of the Medicare program

- Signed the approval order for the first Humanitarian Device Exemption authorizing distribution of the Harrison Fetal Bladder Stent (Lowery Modification) by Cook OB/GYN® on September 14, 1997 (H960001)

- In cooperation with the medical device industry, developed and issued the guidance document entitled *Deciding When to Submit a 510(k) for a Change to an Existing Device* that addresses which changes or modifications to devices are subject to 510(k) requirements (Blue Book Memorandum K97 1)

- Provided intermittent training for all advisory panel members on the Federal Food Drug and Cosmetic Act and medical device regulation

- Functioned as an expert witness for the government in numerous court cases relating to medical device regulation

- Provided expert advice to CDRH s Office of Compliance, FDA s Office of General Counsel and the Department of Justice regarding enforcement activities relating to medical devices

- Functioned as ODE s principle arbiter of scientific and regulatory disputes with the regulated industry regarding decisions affecting individual premarket submissions including, data requirements, appeals of not filing decisions for PMAs and not substantially equivalent determinations for 510(k)s

- Developed and implemented the concept of special controls guidance documents for class II devices as a means of promoting abbreviated 510(k) submissions and least burdensome premarket requirements

- Developed a streamlined guidance document development program integrating national and international consensus standards in support of the Commissioner of Food and Drug s Critical Path Initiative to reduce regulatory burden for industry and facilitate the agency s premarket review of medical devices

- As the Director of Program Operations, provided overall direction coordination and advice to the Director, Office of Device Evaluation, the Center Director and the agency for the establishment development, and operation of the Office's IDE, PMA 510(k), and reclassification efforts Specific responsibilities included the review and evaluation of decisions and recommendations rendered by the ODE review divisions concerning IDEs PMAs 510(k)s and reclassification petitions, the development and administration of regulations and guidance documents regarding the Office s program areas the development implementation and evaluation of the Office's document tracking system including data collection and analysis of the Office's overall performance and being a spokesperson for the Agency on all matters of policy procedures and requirements pertaining to the premarket evaluation of medical devices

- As the Interim Director of the Division of General and Restorative Devices lead and directed the planning, organization and execution of the responsibilities of ODE s largest review division Responsibilities included, all scientific and regulatory recommendations and decisions made by the division regarding dental infection control general hospital plastic and reconstructive restorative and orthopedic devices all recommendations to the Office Director concerning original PMAs and IDEs as well as petitions for reclassification and all decisions regarding supplemental IDE and PMA applications and 510(k)s, as well as the activities of the Division s advisory panels

- As the Acting Deputy Director of the Division of Ophthalmic lead and managed the Division's investigational device exemption program for all significant risk

ophthalmic device clinical investigations including investigations involving contact lenses and related products intraocular lenses and surgical/diagnostic devices Streamlined the processes by which the Division evaluated all regulatory submissions involving ophthalmic devices

- As the Chief of the Surgical and Diagnostic Devices Branch within the Division of Ophthalmic Devices, planned and organized the activities of the individual branch members in the review and evaluation of PMAs, IDEs, and 510(k)s involving surgical and diagnostic ophthalmic devices Developed a broad understanding of the diverse scientific disciplines that are necessary for the responsible regulation of the ophthalmic medical device industry

- As a team leader in the Division of Ophthalmic Devices managed review teams responsible for the evaluation of PMAs, IDEs and 510(k)s Coordinated the complete scientific and regulatory evaluation of the submissions and made recommendations regarding their approvability to senior Division management

- As an interdisciplinary scientist, evaluated scientific information and data regarding the safety and effectiveness of ophthalmic medical devices Functioned principally as a microbiologist, but relied on knowledge in other scientific disciplines to evaluate virtually all aspects of device performance

- As a board certified Clinical Microbiologist with the American Society of Clinical Pathology (M A S C P) performed diagnostic procedures involving the differentiation isolation and identification of microorganisms from body fluids and sites insured that quality control criteria were met before computerized patient diagnostic reports were prepared and forwarded to attending physicians and evaluated new or modified diagnostic techniques and methods

PROFESSIONAL AFFILIATIONS

Food and Drug Law Institute (FDLI)
Regulatory Affairs Professional Society (RAPS)
American Society of Clinical Pathologists (ASCP)
Food and Drug Administration Alumni Association (FDAAA)

PUBLICATIONS

Phillips PJ and Lynne, JC 2005 Unnecessary 510(k) Filings A Waste of FDA and Industry Resources *Regulatory Affairs Journal (Devices)* 13 341 345

Brown RP, Stratmeyer ME Alonge LA, Phillips PJ 2003 Use of Safety Assessment to Support Regulatory Decision Making and Risk Communication Efforts in CDRH DEHP in PVC Medical Devices (W 01) *9th Annual Science Forum FDA Science Protecting America s Health Abstracts* 189

Phillips PJ Less JR 1999 The Development of a New 510(k) Program *Medical Device & Diagnostic Industry* 21(6), 151-159

Marlowe, DE, Phillips, PJ 1998 FDA Recognition of Consensus Standards in the Premarket Notification Program *Biomedical Instrumentation & Technology*, 32(3), 301 304

Phillips PJ 1996 EMC Information for Premarket Approval of Medical Devices *Electromagnetic Compatibility for Medical Devices Issues and Solutions* Arlington VA Association for the Advancement of Medical Instrumentation

Phillips PJ 1994 Medical Lasers, FDA Review and Regulatory Status *Medical Laser Marketplace 94* Nashua NH PennWell Publishing Company

INVITED PRESENTATIONS *(selected)*

18th Annual Meeting of the National Electrical Manufacturer s Association s (NEMA s) Diagnostic Imaging and Therapy Systems Division
San Diego CA September 1993

Medical Laser Marketplace 94
Los Angeles, CA January 1994

HIMA Meeting on Product Approval Initiatives
Washington DC May 1994

HIMA Board of Directors Meeting
Washington DC June 1994

FDLI Device Update Conference
Washington, DC June 1994

Division of Small Manufacturer's Assistance (DSMA) Device Submissions Workshop
Boston MA July 1994

4th Annual HIMA Device Submissions Workshop
Crystal City VA July 1994

19th Annual Meeting of NEMA's Diagnostic
Imaging and Therapy Systems Division
Martha's Vineyard MA September 1994

International Conference on Medical Devices
Minneapolis MN September 1994

CAL BIO Summit '94
LaJolla, CA October 1994

Biomedical Engineering Society (BMES) Annual Meeting
'Frontiers in Biomedical Engineering"
Tempe AZ October 1994

HIMA Annual Meeting
Washington, DC October 1994

American Society for Cataract and Refractive Surgery
' Congress on Ophthalmic Management
San Diego CA April 1995

BIOEAST 95
Washington DC January 1995

American Society for Laser Medicine and Surgery (ASLMS) Annual Meeting
San Diego CA April 1994

Radiology Centennial Commemorative Conference
National Institutes of Health (NIH)
Bethesda MD May 1995

FDA Third Party Review of Premarket Notifications Workshop
Rockville MD June 1995

Howard A Paul Memorial Symposium
Washington DC June 1995

American Academy of Ophthalmology Spring Symposium
Seattle, WA June 1995

FDA/American Association for Medical Instrumentation (AAMI) Electromagnetic Compatibility Conference
Anaheim CA May 1995

FDLI Medical Device Seminar
Washington DC June 1995

FDLI Medical Device Update
Washington, DC June 1995

5th Annual HIMA Device Submissions Workshop
Washington DC July 1995

FDA Southwest Region Grassroots Meeting
Denver, CO August 1995

BIO West '95
San Jose CA October 1995

NIH Biomaterials and Medical Implant Science Workshop
Bethesda MD October 1995

FDA Science Advisory Board Meeting
Arlington VA November 1995

FDA/FDLI Video teleconference
Rockville MD April, 1996

American Society for Artificial Internal Organs (ASAIO) Annual Meeting
Washington DC May 1996

HIMA Meeting on FDA Advisory Committee Meetings
Washington DC June 1996

Association of Food and Drug Officials (AFDO) Medical Device Workshop
San Francisco CA June 1996

FDLI Medical Device Update
Washington DC June 1996

6th HIMA Annual Device Submissions Workshop
Washington DC July 1996

FDA Field Committee Meeting
Potomac MD August 1996

RAPS Annual Meeting
Washington DC September 1996

Medical Alley FDA Seminar
Minneapolis MN December 1996

HIMA 510(k) Task Force Meeting
Washington DC April 1997

7th Annual HIMA Device Submissions Workshop
Washington DC July 1997

Indiana Medical Device Manufacturers Council
Indianapolis, IN August 1997

HIMA Board of Directors Meeting
Washington DC September 1997

FDA/FDLI Video Teleconference
Rockville MD October 1997

FDLI Medical Device Update 97
Washington DC December 1997

FDA/FDLI Video Teleconference
Rockville, MD February 1998

Hearing Industry Association Annual Meeting
Sarasota FL February 1998

ASLMS Annual Meeting
San Diego CA April 1998

FDA Intended Use Workshop
Rockville MD June 1998

FDA/FDLI Video teleconference
Rockville MD July 1998

8th Annual HIMA Device Submissions Workshop
Washington, DC July 1998

FDLI 42nd Annual Educational Conference
Washington, DC December 1998

FDLI Medical Device Update 1999
Washington DC March 1999

ASLMS Annual Meeting
Orlando FL April 1999

9th Annual HIMA Device Submissions Workshop
Washington DC July 1999

RAPS Annual Meeting
Washington DC October 1999

Medical Technology Leadership Forum
United States Capitol, Washington, DC October 1999

HIMA Workshop ' Getting to Market Sooner
Washington DC December 1999

BEMA Roundtable
Washington, DC February 2000

10th Annual AdvaMed Device Submissions Workshop
Washington, DC July 2000

Medical Alley Device Workshop
Minneapolis MN December 2000

AAMI/FDA/AdvaMed Conference on Standards
Rockville MD January 2001

FDLI/FDA Educational Conference
Washington DC April 2001

11th Annual AdvaMed Device Submissions Workshop
Washington DC June 2001

American College of Cardiology (ACC)/FDA Workshop
Bethesda MD June 2001

Medical Device Manufacturers Association (MDMA) 2001 Annual Meeting
Washington DC July 2001

RAPS Annual Meeting
Baltimore, MD October 2001

FDLI Annual Conference
Washington DC April 2002

12th Annual AdvaMed Device Submissions Workshop
Rockville MD June 2002

Human Microchip Symposium
National Academy of Sciences
Washington DC November 2002

FDLI Annual Conference
Washington, DC April 2003

13th Annual AdvaMed Device Submissions Workshop
Washington DC June 2003

FDLI Annual Conference
Washington DC April 2004

14th Annual AdvaMed Device Submissions Workshop
Washington DC June 2004

AAMI/FDA/AdvaMed Conference on Standards
Arlington VA February 2005

CDRH Staff College – Instructor
Rockville MD 1995 2005

AWARDS

FDA Commendation (September 2004) For extraordinary effort in assuring the enactment of the Project Bioshield legislation

FDA Group Recognition Award (April 2004) For outstanding initiative and teamwork to expedite the many actions needed to successfully implement the Medical Device User Fee and Modernization Act '

FDA Group Recognition Award (April 2004) For outstanding teamwork in the successful development and implementation of the CDRH Emergency Preparedness Plans

FDA Commendation (November 2002) For extraordinary efforts in developing the Medical Device User Fee and Modernization Act of 2002

DHHS Secretary s Award for Distinguished Service (June 2001) "For outstanding dedication diplomacy and diligence in developing the QuIC Errors Report Doing What Counts for Patient Safety

FDA Award of Merit (May 1999) For dramatically increasing efficiency bringing safe and effective devices to market in an expedient manner, and maximizing the contribution of Agency resources to public health and safety

National Partnership for Reinventing Government Hammer Award (January 1999) For contribution to building a government that works better and costs less

FDA Award of Merit (May 1998) "For significant impact on the programs and personal contributions to the quality of work performed by the Office of Device Evaluation "

FDA Group Recognition Award (May 1998) "For leading the Organizational Transformation efforts within the Center for Devices and Radiological Health "

FDA Group Recognition Award (May 1998) "For exceptional commitment to the public health while concluding a Mutual Recognition Agreement with the European Union "

CDRH Staff College Faculty of the Year Award (March 1998)

FDA Deputy Commissioner's Special Recognition Award (June 1997) "For outstanding contribution to the development of FDA's Good Guidance Practices, which set forth the Agency's procedures for developing, issuing, and using guidance documents '

CDRH Special Recognition Award (May 1997) "For outstanding team work and exceptional performance in developing a process to recognize third-party reviewers in an effort to improve the Agency's review of premarket applications "

U S Department of Health and Human Services Secretary's Award for Distinguished Service (June 1996) "For extraordinary accomplishments and outstanding teamwork in developing and implementing a policy for the expanded development and availability of new generation medical devices "

CDRH Reengineering Special Service Award (August and October 1997) ' For extraordinary effort and coordination and planning for the development of an improved process as part of the Center for Devices and Radiological Health's Organizational Transformation efforts "

CDRH Special Recognition Award (October 1996) "In appreciation of the efforts leading to the Center's commemoration of the Twentieth Anniversary of the enactment of the Medical Device Amendments to the Federal Food Drug and Cosmetic Act "

FDA Award of Merit (May 1995) For sustained outstanding performance in providing significant contributions to the regulation of medical devices as a supervisor and spokesperson "

FDA Group Recognition Award (May 1993) ' For outstanding performance in gathering and analyzing data used in the development of CDRH's Management Action Plan "

FDA Commendable Service Award (January 1990) "For evaluating and processing a backlog in intraocular lens premarket approval applications

I DA Administration s Commendable Service Award (June 1986) For outstanding resourcefulness in the development and implementation of an effective system to process and review IDE PMA, and 510(k) submissions for ophthalmic laser devices

FDA Commendable Service Award (June 1984) 'For outstanding performance in evaluating the safety and effectiveness of intraocular lenses

CONTINUING EDUCATION

Executive Level

Contemporary Executive Development
The George Washington University
Washington DC 1989

Executive Leadership Development
U S Food and Drug Administration
Rockville MD 1992 93

Issues in Science and Technology
The Brookings Institute
Charlottesville, VA 1994

Others

Equal Employment Opportunity (EEO)
McClure Lundberg Associates
Rockville MD 1982

Experimental Statistics
University of the District of Columbia
Silver Spring MD 1982

Clinical Lasers
Washington DC 1984

Lasers in Surgery
Laser Institute of America
Cincinnati OH 1985

The Basic Food and Drug Law Course
Rockville, MD 1985

FDLI 31st Annual Educational Congress
Washington DC 1987

Regulation of Human Tissue and Organs
Washington, DC 1990

The Safe Medical Device Act of 1990
The Food and Drug Law Institute (FDLI)
Washington, DC 1990

34th Annual FDLI Training Conference
Washington, DC 1990

Ethics Training
Rockville MD 1992 2002

Health Industry Manufacturers Association (HIMA)
Seminar on the GMP Regulation
Washington, DC 1994

EEO for Supervisors
College Park, MD 1994

No Nonsense Negotiation
Rockville, MD 1996

Ex B

724

Plaintiff's Exhibit

Alexander Gallo & Associates, Inc.

STATE OF SOUTH CAROLINA PLEAS COUNTY OF RICHLAND	)))	IN THE COURT OF COMMON
Monica Weston, Plaintiff, vs Kim's Dollar Store and CIBA Vision, a division of Novartis Company, Defendants	))))))))))	Civil Action No 05-CP-40-0655
STATE OF Arizona COUNTY OF Maricopa	)))	**AFFIDAVIT OF SUZANNE PARISIAN**

1 The following affidavit is an addendum to my affidavit of February 24, 2006 After reviewing the deposition of Mr Paul G Oris, CIBA Vision Global Regulatory Affairs, June 27, 2006, and attached Plaintiff's exhibits, which including communications between CIBA Vision and FDA during winter of 2003, I have come to the following opinions based on my training and experience and made to a reasonable degree of professional certainty

2 **OPINION 1** In 2004 CIBA Vision commercially distributed cosmetic decorative color plano contact lens to consumers as beauty products intended to change eye color The CIBA Vision lenses met the definition of a cosmetic per Section 201(i) (21 U S C 321(i)) of the Federal Food, Drug and Cosmetic Act (the act) At the same time, CIBA Vision commercially distributed prescription contact lenses, which met the definition of medical devices per Section 201(h) (21 U S C 321(h)) of the act

3 **OPINION 2** CIBA Visions' cosmetic decorative plano color lenses sold to Ms Monica Weston in 2004 at Kim's Dollar Store where provided to her in prescription device packaging bearing an "Rx Only" designation The decorative plano color lenses sold to her were cosmetic devices, a beauty product, not a medical device, and were intended to change the color of her eyes in a decorative fashion She purchased her CIBA Vision cosmetic lenses as over-the-counter beauty products, without involvement of an eye-care professional, without receiving device prescription labeling or patient information, and without adequate consumer labeling and warnings Her cosmetic lens were adulterated and misbranded per Sec 601(21 U S C 361(a)) and Sec 602 (21 U S C 362(a)) of the act in that the cosmetic products had inadequate consumer information regarding safe and effective use The failure of CIBA Vision to provide adequate instructions for use and warnings to a lay consumer purchasing a cosmetic product and its failure to reveal the consequences of use of the cosmetic product in the eye directly contributed to the subsequent eye injuries of Ms Weston CIBA Vision packaged its cosmetic lenses with a medical device "Rx Only" logo and failed to provide consumers with written warnings that cosmetic contact lenses should be used under the direction of an eye-care professional and with instructions for safe use

4 In an FDA warning letter to another distributor of cosmetic lenses, dated September 16, 2003, also marketing cosmetic decorative contact lens directly to consumers without eye-care professional involvement or adequate instructions for consumer use and warnings, FDA stated

> Because your firm's contact lenses are intended solely to change the appearance of the normal eye in decorative fashion, they are cosmetics within the meaning of 21 U S C 321(i) The distribution of these lenses without the involvement of a qualified

> eye care professional causes them to be adulterated under 21 U S C 361(a) That section provides that a cosmetic shall be deemed to be adulterated 'if it bears or contains a poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions or use as are customary or usual ' Your lenses are also misbranded under 21 U S C 362(a) because their labeling fails to reveal material facts regarding the consequences that may result from use of the lenses under their labels, customary or usual conditions of use
>
> In addition, if you market, in the manner described above, contact lenses with claims that cause them to be [medical] devices within the meaning of 21 U S C 321(h), then they are misbranded under 21 U S C 352(f)(1) because their labeling does not bear adequate directions for use

5 **OPINION 3** Medical device contact lenses, unlike cosmetic color lenses, are commercially distributed in the United States by CIBA Vision as a result of either a premarket application approval (PMA) (21 CFR 814) or 510(K) notification clearance (21CFR 807) Ms Weston did not purchase CIBA Vision medical device contact lenses from Kim's Dollar Store CIBA Vision's medical device contact lenses are restricted to distribution as prescription devices by eye-care professionals and are required to have professional prescription labeling and patient labeling As medical devices there is a requirement for mandatory adverse event reporting (21 CFR 803) CIBA Vision's medical device contact lenses are required to be identified with "Rx Only" per 21 CFR 801 109 and to be promoted and marketed by CIBA Vision in compliance with FDA's restrictions per the conditions specified for legal marketing

6 If PMA approved medical device contact lenses are sold and promoted by CIBA Vision as intended for use without a prescription, or without eye-care professional involvement, or are not otherwise in compliance with FDA's restrictions for

legal commercial marketing and manufacturing, per the conditions of approval (COA) stated in the PMA approval letter, they would be marketed in violation of the PMA conditions of approval (COA) Violation of the PMA COA, according to FDA's PMA approval letter, invalidates PMA approval and violates the Federal Food, Drug and Cosmetic Act As an example, CIBA Vision's September 14, 2001 PMA approval letter for P830037/S44, Phemfilcone A soft (hydrophilic) contact lens, which are regulated as Class III medical devices, stated

> Failure to comply with the conditions of approval as attached invalidates this approval order Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug and Cosmetic Act

7 **OPINION 4** Unlike medical device contact lenses, in 2004, the Federal Food, Drug and Cosmetic Act does not require FDA premarket evaluation and approval of cosmetic products such as CIBA Vision's cosmetic plano colored contact lens Therefore, in 2004, ensuring compliance with the act by CIBA Vision for its cosmetic contact lens, a beauty product, meant that CIBA Vision was to ensure adequate consumer labeling and warnings for the lenses per the applicable cosmetic regulations, and the safety and effectiveness of the manufactured product, without premarket review, interaction or oversight by FDA Unlike medical devices with mandatory medical device reporting 21 CFR 803, cosmetics do not have mandatory adverse event reporting

8 **OPINION 5** Attachment 1 to CIBA Vision's December 9, 2003 letter to FDA (See Attachment 1 below) included a suggestion by CIBA Vision to FDA that a consumer seeing the "Rx Only" logo on a beauty product would be aware that safe use of decorative lenses required interaction with an eye-care professional In terms of a beauty

product purchased as an over-the-counter (OTC) nonprescription product, the assumption does not appear valid A consumer seeing an "RxOnly" logo on an already purchased over-the-counter beauty product receives no information about potential eye risks or a need to consult an eye-care professional, particularly if an eye-care professional is not immediately available at the site of lens purchase Most consumers are aware that prescription contact lenses require eye-care professional interaction in order to obtain a corrective contact lens prescription The consumer will not be able to independently determine that a beauty product cosmetic contact lens, used for an eye color change, may carry the same eye risk potential as a prescription corrective lens In fact, the labeling and packaging will be deceptive in that consumers will assume risks to the eye from a cosmetic beauty product, when received in what appeard to be medical device packaing, would be "less" when purchased without a need for obtaining a prescription The consumer will disregard the presence of an Rx Only logo on a package, assuming it is applicable to prescription corrective lens The consumer will not be aware of a need for eye safety vigilance unless provided adequate instructions for use and warnings

9 **OPINION 6** In January-February 2003, the FDA Consumer carried an article titled **FDA Issues Warning on Decorative Contact Lenses** On October 28, 2005 FDA issued **FDA Warns Consumers of the Dangers of Using Decorative Contact Lenses without Proper Professional Involvement** According to the FDA's Commissioner, Dr Crawford, and as CIBA Vision would have been aware as part of the contact lens industry, during 2004 FDA was using its full range of statutory authorities to attempt to inform and warn consumers about the eye risks of decorative contact lenses when used as a cosmetic beauty products without eye-care professional involvement or

adequate instructions and warnings FDA was concerned that after issuing an import alert, when examining detained decorative contact lenses, the products failed to comply with federal safety standards

II BASES for OPINIONS

10 CIBA Vision included attachment 4 CBA Vision Corporation, Plaintiff, v C&C Trading Company, Inc Michelle Singh, MAS Wholesale & Retail, and John Does 1-50 , in its December 9, 2003 letter sent to FDA's Center for Devices and Radiological Health, Mr Ulatowski, Director, Office of Compliance (Plaintiff's Exhibit 2) In CIBA Vision's attached 2002 civil action for preliminary injunction provided to FDA, CIBA Vision discussed its highly-recognized trade marks of colored contact lenses, including Freshlook, Colorblends, SoftColors and WildEyes and the damaging action of the Defendants against CIBA Vision in marketing CIBA Vision's lenses, both cosmetic and prescription, without a prescription or health professional involvement CIBA Vision's attachment 4, dated September 5, 2002 had the following information beginning on page 3

> Although some of CIBA's colored contact lenses are non-corrective lenses that are used for cosmetic rather than corrective purposes (' plano lenses"), federal law requires a written prescription from a licensed medical practitioner for the sale of all contact lenses, including plano lenses, which are considered by the Food and Drug Administration to be prescription devices within the meaning of 21 CFR ¶801 109 Georgia law also specifically prohibits the sale of any contact lenses without a prescription O C G A § 31-12-12
>
> Contact lenses are required by law to be sold pursuant to a prescription in order to ensure that the patient is medically able to wear contact lenses, that the patient receives lenses that fit the patient's eyes, and that the patient receives proper instruction and information on the care, cleaning, sterilization and use of the contact lenses (Complaint, ¶ 17) Misuse of contact lenses can lead to serious and permanent injuries to the eyes, including corneal abrasions, scarring of the eye, infections and loss of

> vision (Complaint ¶ 17) These risks are the same for corrective and plano lenses and for clear and colored lenses (Complaint ¶ 17)
>
> CIBA takes affirmative steps to prevent the misuse of its contact lenses and to ensure that its products are distributed, sold and used in the proper manner (Complaint, ¶ 18) To further ensure the safe use of its contact lenses, CIBA provides eye-care professionals with a fitting guide for practitioner use and patient instruction booklet containing instructions and medical advisories to be given to patients (Complaint, ¶ 18) CIBA requires that all authorized distributors of CIBA lenses comply with applicable federal, state and local laws and regulations (Complaint, ¶ 18)
>
> In spite of CIBA's efforts to prevent the misuse of its lenses, the Defendants are currently engaged in the widespread illegal distribution and sale of CIBA's contact lenses to consumers without prescriptions (Complaint ¶ 19) Defendant C&C Trading Company, Inc ("C&C Trading") is selling CIBA's contact lenses to consumers without requiring prescriptions and without the instructions for use and medical advisories that are needed by consumers to properly use and care for lenses
>
> Because contact lenses are prescription medical devices, Defendants' conduct is analogous to the selling of potentially harmful prescription drugs on the street without a prescription Even if a prescription was not required, Defendants' reckless conduct would threaten not only the valuable goodwill and reputation associated with CIBA Marks, but also the safety and welfare of the public CIBA seeks injunctive relief to stop Defendants' illegal and dangerous conduct and to protect the good reputation and valuable good associated with the CIBA Marks CIBA seeks to recover damages for the harm inflicted by the Defendants' illegal conduct

11 In Plaintiff's Exhibit 2, the CIBA letter to FDA focused on its discussion of the balancing of promotional claims by CIBA Vision for UV coating protection and "breathable" contact lenses, TV advertisements, promotions, competitor actions and the need for there to be a level playing field with FDA among contact lens manufacturers The letter places the burden for future actions to correct product confusion on FDA rather than allotting any responsibility to CIBA Vision for its actions as a contact lens manufacturer The letter also references an earlier November 21, 2003 meeting held between members of CIBA Vision and FDA (See Plaintiff's Exhibit 10- CIBA Vision

Corporation Meeting with FDA Advertising and Promotion of Contact Lenses) I have seen no subsequent agency response letter to CIBA Vision providing its written comments CIBA Vision acknowledged to FDA that for better marketing balance there may be a need for a future warning for the need for involvement of an eye-care professional for cosmetic lenses by writing that

> CIBA Vision does acknowledge that a general risk statement such as "Contact lenses, even when used to change eye color, should only be worn under the supervision of an eye care professional", and would better balance the beauty claims being made in the promotion of the product

12 The CIBA Vision letter to FDA included an Attachment 1, CIBA Vision positioning- advertising and promotion of Freshlook contact lenses as medical devices and cosmetics Attachment 1 was written to further point out to FDA what should be the agency's considerations in response to CIBA Vision's positions, particularly that FDA had not yet issued a regulation designating all contact lenses to be prescription devices and that plano color contact lenses are designated as cosmetics, and contained the following (page 4 of 106) information

> **2 Contact Lens Classification**
> Although historically contact lenses have been regulated as medical devices under Class II Premarket notification 510(k) for daily wear or Class III Premarket approval (PMA) for extended wear requiring a valid prescription, currently plano color contact lenses have received a cosmetic designation
>
> This creates the following inconsistencies across the broad contact lens category
> - Oversight will vary from FTC to FDA
> - Restrictions will vary based on device class
>   - Subject to general rules or restrictions for labeling only (Class II/DW)
>   - Subject to restricted device status for DTC advertising and promotion (Class III/EW)
>
> **2 1 Agency Consideration**

Except for the differences in rates for daily vs extended wear, the same types of concerns and risks apply to any contact lens The concerns being the same, unless extended wear is specifically being promoted, ads for color contact lenses should default to general requirements for a medical device (and/or cosmetic)

3 Restricted Device Status

While all contact lenses are prescription devices[1] [Footnote 1 Assumes Agency authority to require a prescription for plano cosmetic lenses per FR notice (Vol 68, No 65, Fri April 4, 2003)] not all contact lenses are restricted in terms of advertising and promotion [2]

- To date, there has not been a regulation designating any contact lenses as restricted A prescription is required per approval orders or clearance letters
- Selective assignment of restricted device status for some class III PMA contact lenses
  - Distinctive and different wording in PMA approval orders understood to mean different levels of restrictions
  - Historical promotional practices provide precedence for interpretation of different levels of restricted device status

7 General Balancing Risk Statement

For Ads for color contact lenses that are not promoting a wearing indication and not promoting UV claims, the fashion or beauty message in this case is not health oriented and is appropriately balanced with a general risk statement to consumers to see an eye care professional to obtain lenses

7 2 Agency Consideration

CIBA Vision agrees a balancing risk statement, such as the example below, is appropriate for a fashion oriented TV ad[3] ([Rx Only]) [Footnote 3 Unlike competitor print ads, CIBA Vision already includes a message of this type with Rx Only symbol in all it's (*sic) FreshLook print advertising]

- Contact lenses, even when used to change eye color, should only be worn under the supervision of an eye care professional[4] [Footnote 4 If the Agency considers essential an additional risk statement about safety, and if applied across the lens category to all manufacturers, an additional risk statement such as "Serious eye health problems may occur" would be considered]

8 Consistent implementation and requirements for restricted device information for color contacts across the contact lens industry

With varying levels of restrictions across the contact lens category (different device classes for daily and extended wear contacts, with cosmetic designation for plano color lenses), a situation exists where print or broadcast ads for color contacts could be appearing in the same magazine or airing on the same TV programs, some containing no or minimal restrictions such as "Rx Only", while others potentially containing a full brief summary (intended use, warnings, precautions, side effects, etc)

This situation could create the potential misleading impression by consumers that some, but not all, color contacts have special safety concerns This also puts manufacturers at a seemingly unjustified competitive disadvantage when their products have already been subject to a higher level of testing and Agency evaluation via the Class III PMA path

5 1 Agency Consideration
In order to ensure consistent messages to consumers and maintain a level playing field among manufacturers, it is requested that requirements for restricted device information for color contacts be consistently applied and implemented throughout the contact lens industry[5] [Footnote 5 As mentioned in the November 21 meeting, competitor TV Ads have been appearing prior to and after the FreshLook Ad and not containing any risk information or the "Rx Only" symbol, as required by 801 109]

Until resolution of this issue is obtained and modifications, if any, can be incorporated into the TV Ad, CIBA Vision would like to resume airing of the existing FreshLook TV commercial

13 The following are applicable definitions from the Federal Food, Drug and Cosmetic Act and 21 Code of Federal Regulations (CFR) for FDA- regulated products in general, medical devices and cosmetics

SEC 201 [21 U S C 321] For the purposes of this Act—

h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles, except that such term shall not include soap

k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article, and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article

(n) If an article is alleged to be "misbranded" because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual

SEC 301 [21 U S C 331] The following acts and the causing thereof are hereby prohibited

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded

(b) The adulteration or misbranding of any food, drug, device or cosmetic in interstate commerce

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded

SEC 601 [21 U S C 361] A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual,

SEC 602 [21 U S C 362] A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use

SEC 752 [21 U S C 379s] **PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS**

(a) IN GENERAL —Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U S C 1471 et seq), or the Fair Packaging and Labeling Act (15 U S C 1451 et seq)

(b) EXEMPTION —Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling or packaging that—

(1) protects an important public interest that would otherwise be unprotected,

(2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law, and

(3) would not unduly burden interstate commerce

(c) SCOPE —For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication

(d) NO EFFECT ON PRODUCT LIABILITY LAW —Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State

(e) STATE INITIATIVE —This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997

21 CFR Sec 1 21 Failure to reveal material facts

a) Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are

(1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof, or

(2) Material with respect to consequences which may result from use of the article under (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual

21 CFR 801 5 Medical devices, adequate directions for use

Adequate directions for use mean directions under which the layman can use a device safely and for the purposes for which it is intended Section

801 4 defines intended use Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of

(a) Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used, except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner

21 CFR Sec 801 109 Prescription devices

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met

(a) The device is

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device, and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice

(b) The label of the device, other than surgical instruments, bears

(1) The statement "Caution Federal law restricts this device to sale by or on the order of a ____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device, and 2) The method of its application or use

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant

hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device Upon written request, stating reasonable grounds therefore, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented This information will not be required on so-called reminder--piece labeling which calls attention to the name of the device but does not include indications or other use information

21 CFR Sec 740 1 Establishment of warning statements

(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product

(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part,

a regulation prescribing a warning for a cosmetic

Sec 740 2 Conspicuousness of warning statements

a) A warning statement shall appear on the label prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use

14 I reserve the right to amend my opinions

Further affiant sayeth not

Suzanne Parisian, M D

Sworn before me this 23rd day of August 2006

Notary Public for _____

My commission expires NOV 27 2009

JOHN W CRAWFORD
Notary Public Arizona
MARICOPA COUNTY
My Commission Expires
November 27, 2009

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston	)	Civil Action No 05-CP-40-0655
Plaintiff	)	
vs	)	
Kim s Dollar Store and CIBA Vision, a division of Novartis Company	)	
Defendants	)	

2006 FEB 27 PM 3 44
BARBARA A SCOTT
C C C & G S

STATE OF AZ	)	
	)	**AFFIDAVIT OF SUZANNE PARISIAN, M D**
COUNTY OF Maricopa	)	

PERSONALLY APPEARED BEFORE ME the undersigned Suzanne Parisian M D who being duly sworn deposes and states as follows

1 I am over the age of 18 and competent to give this affidavit

2 Please see Exhibit A for my qualifications and CV

3 The defendant CIBA Vision claims that it received pre-market approval (PMA) from the FDA which allowed it to market the contact lenses at issue in this case (FreshLook Colors contact lenses without any visual correction or plano (i e zero-powered or non-corrective)) The FreshLook Colors contact lenses were sold in 2004 to Ms Weston as noncorrective decorative lenses Ciba Vision has failed to provide or produce essential and specific FDA marketing information for its tinted plano phemfilcon contact lenses (which would establish the marketing controls required under the Act for the product sold to Ms Weston) Without this information CIBA Vision has produced no evidence that the FreshLook Colors lenses at issue received FDA approval for marketing

4 As will be discussed below both class II and class III contact lenses are prescription medical devices which are restricted in marketing to require involvement of a qualified eye care professional And as medical devices they require some form of premarket review and FDA authorization prior to the start of commercial distribution The manufacturer of both class II and class III devices are required to ensure compliance with medical device regulations (21 CFR part 800) as well as the requirements of the Food Drug and Cosmetic Act (FDCA) Class III contact lenses based on the indication for which it is intended to be marketed to consumers in terms of the type of manufacturing controls which will be required to protect public safety A class II contact lens can be a class III contact lens when marketed to consumers as intended for overnight/extended wear

5 Ms Weston did not purchase decorative lenses in 2004 as prescription or corrective lens nor did she purchase lens marketed to her as intended for extended/overnight wear She was able to purchase lenses in 2004 without the intervention or prescription of a qualified eye care professional and without adequate labeling and warnings for the indication of changing the color of her eyes

6 To protect public health before marketing a new medical device in the United States (21 USC 360) the FDCA requires device manufacturers of nonexempted devices to first obtain FDA s approval of a pre-marketing application (PMA) (21 CFR 814) or clearance through the 510(k) notification process (21 CFR 807) The 510(k) notification process requires that a manufacturer proposing to market a new device provide FDA with an application supporting substantial equivalence of the new device with an already marketed device (predicate) for the same intended use in terms of

safety and effectiveness Medical devices are classified by the FDA using a risk-based classification scheme as class I II or III The class refers to the type of manufacturing controls thought necessary by FDA to ensure safety and effectiveness of the device and to protect the public FDA has the regulatory authority to reclassify devices based on information that may have become available since initial classification New intended use/ new indications/ new marketing claims/ new features/ or new materials can change the class of a device since it may alter the potential risk to the public A class I device is considered the lowest risk to the public and has the lowest amount of manufacturing control and FDA oversight Most class I devices have been exempted by FDA from a requirement for FDA premarket review prior to start of market FDA has reserved certain types of issues/claims/features with class I devices that may alter safety and effectiveness to require premarket review FDA has recently exempted certain class II devices from a requirement for pre-market review However an exempted class II device is still required to adhere to manufacturing controls necessary for manufacturing safe and effective a class II medical device Class II devices can include implanted devices and contact lenses Class III devices usually are life-sustaining or implanted devices or devices where there is insufficient information available to FDA to determine risk and necessary manufacturing controls and due to the potential increased risk to the public have the highest manufacturing controls and FDA oversight A class II device can be considered a class III device when marketed or used for new intended use or indications Therefore not only the device itself but the marketing indications and intended use of the device being marketed to the public can differentiate between a class II and class III device

7 When a device is approved by the FDA for a sponsor pursuant to either the PMA process or 510K notification the manufacturer receives an official FDA letter notifying the manufacturer that the product can now begin commercial distribution in the United States The letter will also state restrictions for marketing and conditions for marketing If CIBA Vision received approval through either the PMA or 510(k) clearance process of medical device plano tinted phemfilcon contact lenses called FreshLook Colors contact lenses that were eventually marketed to Ms Weston in 2004 Ciba Vision should have letter(s) from FDA stating their ability to begin commercial distribution of that product as well as the restrictions and conditions for commercial marketing Please see sample FDA letter clearing a 510(k) product and sample order approving a PMA product (Attached hereto as exhibit B and C respectively) Also if Ciba Vision maintains that PMA approval is the route to market of the contact lenses received by Ms Weston the applicable PMA supplement approval letter as well as the applicable PMA supplement application will specify restrictions for manufacturing sale physician training or labeling that help ensure safety and effectiveness The PMA approval letter also will specify both general and specific conditions of approval (COA) for continued PMA approval and marketing in the United States

8 All manufacturers of 510(k) cleared or PMA approved products distributed and sold in the United States are required to have written procedures in place and operational to adhere to Good Manufacturing Practices/ Quality System Regulations 21 CFR part 820 GMP requires written procedures for maintaining records complaint handling failure investigation corrective and preventive action (CAPA) statistical methods and for updating and providing adequate labeling and marketing All medical

device manufacturers are required to file mandatory medical device reports (MDR) 21 CFR 803, therefore there must be written procedures in place for MDR filing as well as records associated with MDRs filed for reports of adverse events from the use of FreshLook Colors as either a prescription corrective product or cosmetic product There should also be a compliant file with MDR decision file for Ms Weston s reported injuries

9 Neither premarketing process PMA approval nor 510(k) clearance was designed by FDA to verify that a manufacturer remains in compliance with the Act once the product is on the market As stated in FDA s conditions of approval and in the warning letters to manufacturers it is the firm s responsibility to ensure its own continued compliance with the Act If the manufacturer is not in compliance then the approval is invalidated and the product is deemed to not have FDA approval

10 In 1993 FDA began to reclassify certain contact lenses from class III devices to class II devices to allow marketing clearance as class II devices via a 510(k) notification process but with adherence to FDA s specified Special Controls The FDA s reclassification of lenses to class II did not apply to contact lenses intended for extended wear nor to contact lens accessories all of which remained in class III

11 FDA s guidance for industry document released May 12 1994 - **Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses** – states the FDA s definition of a class II **soft (hydrophilic) contact lens**

> A daily wear soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent to the limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage The device is made of various polymer materials the main polymer molecules of which absorb of attract a certain volume (percentage) of water

12 Sponsors of contact lenses for marketing were no longer required to have premarketing approval of a PMA or PMA supplements per 21 CFR 814 but rather as class II devices could begin marketing following FDA s clearance of a 510(k) with Special Controls per 21 CFR 807 The 510(k) was to support substantial equivalence of the new contact lens to other already marketed contact lens including lenses that were approved under a PMA For predicates the manufacturer could claim substantial equivalence to either 510(k) contact lenses and/or to PMA approved contact lenses

13 There has been 510(k) clearance for marketing phemfilcon A as a tinted soft contact lenses intended for daily wear An example is K000439 a 510(k) for Wesley Jessen Corporation submitted to FDA February 3 2000 and cleared March 20 2000 The 510(k) application references as its predicate FDA s history of approval of **PMA N17-852** (N17-852 – a pre-1976 NDA number when the Durasoft (phemfilcon A) was approved under the an NDA number) The product for the 510(k) is **Durasoft 2** (phemfilcon A) According to the 510(k) Phemfilcon A has been used for daily wear lenses in Clear Colors Colorblends and LiteTint soft contact lenses

14 Each PMA approved product including the PMA extended wear lens for Ciba Vision carries mandatory requirements for a firm to adhere to the conditions of approval (COA) both specific and general that allow marketing of a PMA product in the United States According to FDA s PMA approval letters violation of the conditions of approval (COA) and/or restrictions on marketing invalidates the PMA approval In other words a product such as the FreshLook Colors prescription lenses if approved for marketing as corrective extended wear when not sold or distributed by Ciba Vision in compliance with COA or restrictions when not manufactured labeled distributed or

promoted in a manner consistent with COA and the Act and without compliance with GMP and adverse event reporting is not the PMA device approved by FDA as safe and effective and allowed for distribution and marketing in the United States under the PMA approval Without Ciba Vision s full compliance with PMA Supplement s conditions of approval restrictions on distribution, marketing labeling and requirements of the Act the device being sold by Ciba Vision to Ms Weston in 2004 is adulterated and misbranded Accordingly at this time there is still sufficient information provided by CIBA Vision to indicate what Ciba Visions views as its route through FDA to market FreshLook Color lens sold to Ms Weston in 2004 as a non-corrective nonprescription contact lenses (Please note that neither of the FDA letters attached to CIBA Vision s motion for summary judgment addresses the marketing notification of a FreshLook **Colors** contact lenses sold to Ms Weston)

15 The PMA and 510(k) approval processes both require that the manufacturer specifically set forth the intended use of its medical device when marketed in the United States Likewise an FDA approval letter would specifically set forth the intended use for which the medical device may be marketed While CIBA Vision has not produced an approval letter for FreshLook Colors it has produced approval letters for various other FreshLook products including letters for FreshLook ColorBlends and FreshLook Color Dimensions attached to its motion for summary judgment Both of those approval letters specifically state that the 'contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyper optic (farsighted) CIBA Vision has not produced any FDA approval letters allowing it to market contact lenses that are not indicated for the

correction of visual acuity In other words CIBA Vision has not produced any letter from the FDA approving the marketing of plano contact lenses (lenses with no visual correction), the product at issue in this case for eye color enhancement

16 The two letters from the FDA attached to defendant CIBA Vision s motion for summary judgment also state

> Failure to comply with the conditions of approval as attached invalidates this approval order Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food Drug and Cosmetic Act

17 While CIBA Vision did not attach the original conditions of approval the August 21 2001 version of the conditions of approval is attached to the letter attached hereto as Exhibit C Those conditions of approval limit the labeling advertising and marketing of the product to only the PMA approved intended use of the device Thus as CIBA Vision has advertised and marketed the device for cosmetic purposes only FDA approval would have been invalidated

18 Additionally if CIBA Vision did not obtain FDA s approval or clearance for FreshLook Colors without visual correction in 2004 the contact lenses at issue may not have been considered medical devices at all but rather cosmetic products If the FreshLook Colors contact lenses at issue in 2004 were not marketed to consumers as intended for vision correction or with claims that they effect physical or physiological change they could be considered as decorative contact lenses and may have been regulated as cosmetics under the FDCA 21 U S C 201(i) defines cosmetic to include articles intended to be rubbed poured sprinkled or sprayed on introduced into or otherwise applied to the human body or any part thereof for cleansing beautifying promoting attractiveness or altering the appearance See also Exhibit D attached

hereto (**Guidance for FDA Staff on Sampling or Detection without Physical Examination of Decorative Contact Lenses, Publ 4/4/03)** If the FreshLook Colors contact lenses purchased by Ms Weston were considered cosmetics then CIBA Vision would have violated the FDCA by not including adequate instructions for safe use and adequate warnings that the cosmetic lenses could be dangerous to wearers of the lenses CIBA Vision would have also violated the FDCA because their labeling was false or misleading in any particular" Under the act labeling can be misleading by failing to disclose facts material with respect to consequences which may result from the use of a product under customary usual or labeled conditions

19 The FDA prior to November 2005 has found other decorative contact lenses under certain circumstances to be cosmetic products In a warning letter to BWild Inc dated September 16 2003 the FDA stated

> Because your firm s contact lenses are intended solely to change the appearance of the normal eye in decorative fashion they are cosmetics within the meaning of 21 U S C 321(i) The distribution of these lenses without the involvement of a qualified eye care professional causes them to be adulterated under 21 U S C 361(a) That section provides that a cosmetic shall be deemed to be adulterated if it bears or contains a poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof or under such conditions or use as are customary or usual Your lenses are also misbranded under 21 U S C 362(a) because their labeling fails to reveal material facts regarding the consequences that may result from use of the lenses under their labels customary or usual conditions of use
>
> In addition if you market in the manner described above contact lenses with claims that cause them to be [medical] devices within the meaning of 21 U S C 321(h) then they are misbranded under 21 U S C 352(f)(1) because their labeling does not bear adequate directions for use

See Exhibit E attached hereto

20 At this point in order to formulate a final opinion with regard to whether the FreshLook contact lenses sold to Ms Weston are medical devices or cosmetic products whether Ciba Vision received any FDA approval or clearance and whether CIBA Vision has complied with the conditions or restrictions of any FDA approval Ciba Vision must identify the route of the FreshLook Colors lenses to United States marketing and then to Ms Weston as well as provide accurate and complete documentation requested in discovery Additionally the standard information related to the FDA approval and CIBA Vision s continued compliance related to the contact lenses at issue that I would normally review (and am hereby requesting in this case) is as follows

A All FDA documents including PMA Supplements to P830037 for FreshLook contact lenses and 510(k)s associated with FreshLook Color contact lenses Durasoft 2 or Fresh Look Color cosmetic lenses

B Any and all information and FDA documents related to CIBA Vision s disposable phemfilcon hydrophilic soft contact lenses both prescription and plano including the number of NDA and Drug Master Files (DMF)

C All communications between FDA and CIBA Vision regarding importation marketing or detention of FreshLook Color DuraSoft DuraSoft 2 Lenses phemfilicon A, plano or cosmetic lenses in the United States

D Copies of all CIBA Vision s Establishment Inspection Reports (EIRs) Warning Letters PMA Annual Reports PMA Supplements Submissions for marketing of FreshLook Color phemfilicon A and plano lenses and any and all related communications between CIBA and FDA

E Copies of all Letters/Communciations from FDA sent to the Contact Lenses Manufacturer Industry regarding marketing or distribution of prescription and cosmetic contact lenses

F All minutes of meetings/ presentations between FDA and Ciba Vision including copies of PowerPoint presentations emails summaries provided to or involving CDRH's ODE This is to include

presentations made during Real-Time PMA Supplements Copies of minutes and/or presentations by Ciba Vision to Center for Devices and Radiological Health s (CDRH) Office of Compliance regarding marketing labeling distribution of either prescription and/or cosmetic lenses

G All requests/ petitions/ or communications filed with FDA by Ciba Vision or its Trade Manufacturing Association requesting to market cosmetic contact lenses

H Any and all communications between Ciba Vision and Distributors/Suppliers related to adulteration and misbranding of prescription lenses documenting any steps taken by CIBA Vision to prevent the misbranding and adulteration of its prescription contact lenses

I Any and all documentation supporting that CIBA Vision took steps to protect public health and remain in compliance with the Federal Food Drug and Cosmetic Act

J All communications and actions taken by CIBA Vision to inform distributors/Suppliers regarding unsafe use of prescription lenses as cosmetic lens without providing consumers with adequate instructions for use

K CIBA Vision s complete Compliant file failure investigation corrective action trending and MDR decision and records regarding the adverse event reported for Ms Weston per 21 CFR 820 and 803

L All statistical analyses and/or trending or associated with either unapproved use of prescription lenses adverse events complaints from the field Customer Service reports associated with the use of the FreshLook Color and/or cosmetic lenses

M All Newsletters or product information sheets to CIBA Vision s Marketing or Sales intended for field representative/distributors/ suppliers/physicians regarding the FreshLook Color DuraSoft 2 or cosmetic lenses

Further affiant sayeth not

Suzanne Parisian M D

Sworn before me this 24th day of February 2006

Notary Public for Phoenix AZ

My commission expires 5/05/08

NOTARY PUBLIC
STATE OF ARIZONA
Maricopa County
DAVID L WARFIELD
My Appointment Expires 05/05/08

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB
Display Date 4-2-03
Publication Date 4-4-03
Certifier

Food and Drug Administration

[Docket No 03D–0118]

Guidance for FDA Staff on Sampling or Detention Without Physical Examination of Decorative Contact Lenses (Import Alert #86–10), Availability

'03 APR -2 P12 34

AGENCY Food and Drug Administration, HHS

ACTION Notice

SUMMARY The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for FDA Staff on Sampling or Detention Without Physical Examination of Decorative Contact Lenses (Import Alert #86–10)." The guidance document includes FDA's guidance to FDA district offices for sampling or detention without physical examination of plano (zero-powered or noncorrective) contact lenses intended solely to change the appearance of the normal eye in decorative fashion, when these products are presented for importation into the United States

DATES Submit written or electronic comments on the guidance by [*insert date 60 days after date of publication in the* **Federal Register**]

ADDRESSES Submit written requests for single copies of the Import Alert #86–10, to the Division of Import Operations and Policy (HFC–170), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 Send two self-addressed adhesive labels to assist that office in processing your request You may fax your request to 301–594–0413 Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm 1061

ora033

03D-0118

NAD 1

Rockville, MD 20852 Submit electronic comments to http //www fda gov/ dockets/ecomments See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document

FOR FURTHER INFORMATION CONTACT Thaddeus J Poplawski, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553

SUPPLEMENTARY INFORMATION

I Background

FDA has been receiving reports that certain commercial entities are planning to distribute or may already be distributing plano (zero-powered or noncorrective) contact lenses intended solely to change the normal appearance of the eye in decorative fashion (decorative contact lenses) FDA understands that these products are intended to be distributed without a prescription, without fitting by a qualified eye care professional, and without ongoing professional supervision

FDA believes that like other contact lenses, decorative contact lenses can cause a variety of eye injuries and conditions Lens wear has been associated with corneal ulcer, for example, which can progress rapidly, leading to internal ocular infection if left untreated Uncontrolled infection can lead to corneal scarring, which can lead to vision impairment In extreme cases, corneal ulcer can result in blindness and eye loss Other risks include conjunctivitis, corneal edema, allergic reaction, abrasion from poor lens fit, and reduction in visual acuity, contrast sensitivity, and other visual functions, resulting in interference with driving and other activities

FDA believes that these risks cannot be sufficiently controlled unless (1) The wearer obtains advice from an eye care professional, (2) the lenses are fitted by or under the supervision of such a professional, and (3) the wearer remains under appropriate professional supervision Eye care professional involvement is legally required (21 CFR 801 109) for contact lenses intended for medical purposes (i e , prosthetic use or vision correction) These products are regulated by FDA as medical devices under the Federal Food, Drug, and Cosmetic Act (the act) (21 U S C 301 *et seq*) [1] Such control is not available for decorative contact lenses because these products are cosmetics under section 201(i) of the act (21 U S C 321(i))

Section 201(i) of the act defines "cosmetic" to include "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance * * * " (21 U S C 321(i)(1)) Decorative contact lenses are articles intended to be introduced into the eye, which is a part of the body, to beautify the wearer, promote the attractiveness of the wearer, or alter the wearer's appearance They are claimed to achieve this cosmetic result by changing the apparent color of the iris, by appearing to add a design to the iris (e g , a professional sports team insignia) or by imparting a nonhuman or otherwise nonnormal appearance to the eye (e g , cat's eye) Provided they are not marketed with claims[2] that they effect physical or physiological change, decorative contact lenses are properly

[1]There are some lenses currently on the market under cleared 510(k)s covering contact lenses intended for both vision correction use and for solely decorative purposes The sponsors in these cases voluntarily included a plano lens in the range of corrective powers described in the 510(k) submissions

[2]*American Health Prods Co* v *Hayes* 574 F Supp 1498 1505 (S D N Y 1983) *aff d on other grounds* 744 F 2d 912 (2d Cir 1984) (The courts have always read the * * * statuatory definitions employing the term intended' to refer to specific marketing representations)

regulated as cosmetics under the act (cf *United States v An Article * * * "Sudden Change,"* 409 F 2d 734 (2d Cir 1969) ("claiming to affect the structure of the skin in some physiological way" makes a product a "drug"), 21 CFR 700 35 ("sunscreen" claims make a product a drug))

The fact that contact lenses are "devices" in the colloquial sense does not preclude cosmetic status under the act FDA has previously determined that section 201(i) of the act applies to appearance-enhancing devices such as wigs, hair brushes, stockings and toothpicks (Refs 1 through 3)

Moreover, the fact that a product is intended to come into contact with the eye does not make it ineligible for cosmetic regulation (Ref 4) Indeed, the legislative history accompanying the original 1938 act demonstrates that Congress enacted the cosmetic adulteration provisions to address the risk to users presented by cosmetic products that may cause blindness and other serious injuries (S Rept 74–361 at 21 (1935))

On October 22, 2002, FDA issued Import Alert #86–10, with respect to decorative contact lenses We are now publishing a revised Import Alert #86–10 in the **Federal Register** The Import Alert #86–10 does not cover contact lenses that are intended for vision correction or for prosthetic or other medical use

Section 801(a) of the act (21 U S C 381(a)) authorizes FDA to refuse admission to articles that appear to be adulterated or misbranded Based on the available evidence, FDA believes that decorative contact lenses presented for importation may appear to be adulterated under section 601(a) of the act (21 U S C 361(a)), in that they contain a deleterious substance that is dangerous to wearers of the lenses when they are put to a labeled, customary, or usual use The deleterious substance is the matrix in which colorants are

embedded This material can cause the potentially vision-threatening eye conditions discussed previously, particularly if the wearer fails to obtain appropriate professional counseling, fitting, and ongoing supervision, if the wearer trades lenses, fails to use proper disinfection and other care techniques, or if the wearer wears lenses for longer than the recommended period Consequently, FDA believes that decorative contact lenses appear to be adulterated under section 601(a)

Decorative contact lenses may also be subject to refusal if they appear to contain unsafe color additives (21 U S C 381(a) and 361(e)) FDA understands that certain overseas manufacturers or distributors might have selected color additives for use in decorative contact lenses intended for U S distribution based on the fact that they have been approved by FDA for use in medical devices To be used lawfully in decorative contact lenses, a color additive must be approved by FDA for use in eye area cosmetics Not all color additives approved for use in medical devices have been approved for eye area use in cosmetics Consequently, decorative contact lenses may also appear to be adulterated under section 601(e) of the act

Finally, decorative contact lenses may be subject to refusal on the ground that they are misbranded under section 602(a) of the act (21 U S C 362(a)) because their labeling is false or misleading "in any particular " Under the act, labeling can be misleading by failing to disclose "facts * * * material with respect to consequences which may result" from use of a product under customary, usual, or labeled conditions (21 U S C 321(n)) As noted previously, decorative contact lenses may cause serious health problems, including (in extreme cases) blindness FDA believes these risks are material If they are not disclosed in labeling, then the labeling would be misleading,

and the product would appear to be misbranded under section 602(a) of the act and subject to refusal under section 801(a) of the act

II Guidance

FDA's district offices may sample or detain without physical examination decorative contact lenses presented for U S importation

The Import Alert #86–10 applies to contact lenses that are (1) Intended to change the appearance of the normal eye in decorative fashion, and (2) intended for distribution directly to the wearer, without the involvement of a qualified eye care professional It does not cover contact lenses that are intended for vision correction or for prosthetic or other medical or therapeutic use and that are, therefore, properly regulated as medical devices under the act

III Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10 115) The guidance represents the agency's current thinking on the sampling or detention without physical examination of decorative contact lenses that appear to be adulterated under section 601(a) and (e) of the act because they contain a deleterious substance that is harmful to users and/or contain an unapproved color additive, or appear to be misbranded under section 602(a) because their labeling is false or misleading It does not create or confer any rights for or on any person and does not operate to bind FDA or the public An alternative approach may be used if such approach satisfies the applicable statute and regulations

This guidance is effective immediately because prior public participation is not feasible or appropriate due to the risks to the public health presented by these products

IV Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance Such comments will be considered when determining whether to amend the current guidance Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy Comments are to be identified with the docket number found in brackets in the heading of this document The guidance and received comments are available in the Dockets Management Branch between 9 a m and 4 p m , Monday through Friday

V Electronic Access

Persons with access to the Internet may obtain the guidance at http // www fda gov/ora/fiars/ora_import_ia8610 html

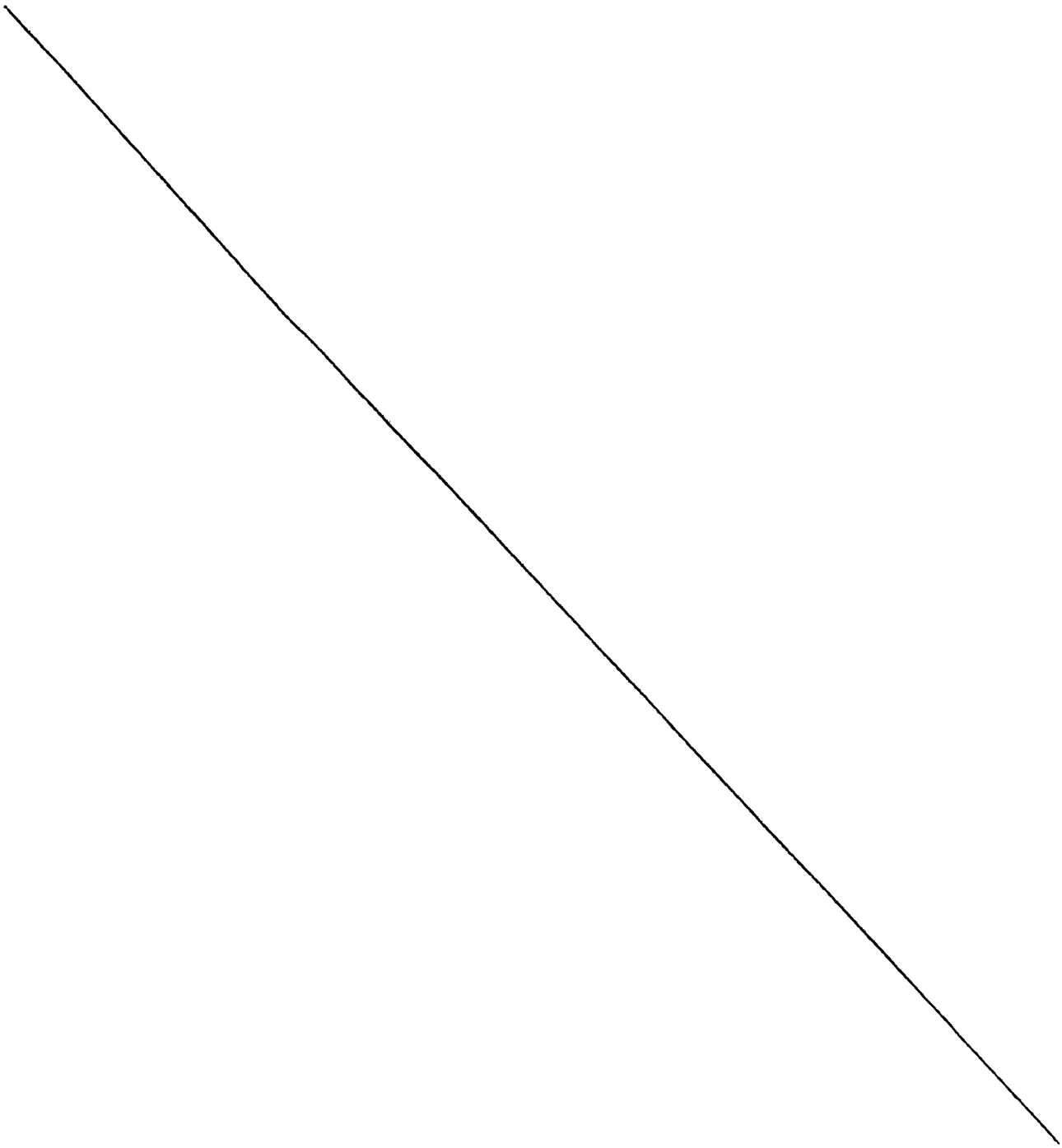
VI References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a m and 4 p m , Monday through Friday

1 Food and Drug Administration (FDA) Compliance Policy Guide (CPG) 7128 04 (revised August 1996) (hair brushes), (http //www fda gov/ora/compliance_ref/cpg/cpgfod/cpg590–400 htm)

2 FDA CPG 7128 05 (revised September 1 1986) (wigs), (http //www fda gov/ora/compliance_ref/cpg/cpgfod/cpg590–600 htm)

3 Hutt, Peter Barton "Reconciling the Legal, Medical, and Cosmetic Chemist Approach to the Definition of a 'Cosmetic,' " *Cosmetic Toiletry, and Fragrance Association Cosmetic Journal*", vol 3, 1971 (excerpted in Peter Barton Hutt & Richard A Merrill, Food and Drug Law Cases and Materials p 824–825 (2d ed 1991))



4 FDA, CPG 7128 03 (revised August 1996) (mascara is an eye-contact cosmetic), (http //www fda gov/ora/compliance_ref/cpg/cpgfod/cpg590–300 htm)

Dated 4-1-03

April 1, 2003

John R Marzilli,
Acting, Associate Commissioner for Regulatory Affairs

[FR Doc 03–????? Filed ??–??–03, 8 45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Guidance for FDA Staff

SAMPLING AND DETENTION WITHOUT PHYSICAL EXAMINATION OF DECORATIVE CONTACT LENSES

Comments and suggestions regarding this document should be submitted by [date] to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 10-61, Rockville, MD 20852

After [date], submit comments to Thaddeus J Poplawski, Division of Import Operations and Policy (HFC-170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 Comments should be identified with the docket number [03D-0118]

For questions regarding this document contact Thaddeus J Poplawski at 301-443-6553

U S Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
April, 2003

03D-0118

EXHIBIT tabbies B

GDL 1

IMPORT ALERT# 86-10 4/1/03 SAMPLING OR DETENTION WITHOUT PHYSICAL EXAMINATION OF DECORATIVE CONTACT LENSES

TYPE OF ALERT: Increased Coverage
Detention without Physical Examination (DWPE)

(Note This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public)

PRODUCT: Decorative contact lenses that are (1) intended to change the appearance of the eye in decorative fashion and (2) intended for distribution directly to the wearer, without the involvement of a qualified eye care professional The alert does not cover contact lenses that are intended for vision correction, prosthetic or other medical use

PRODUCT CODE:
86H[][]PX
86H[][]JK
86H[][]QD
86M[][]UW
86M[][]VN
86M[][]WL
86N[][]CZ
86N[][]IC
86L[][]PL
86L[][]PM

PROBLEM: FDA believes these products present substantial risks to ocular health including corneal scarring and blindness, when dispensed without the involvement of a qualified eye care practitioner In legal terms, they appear to be adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act

PAF: HAZ - Hazardous Conditions
AAP - Approvals

PAC FOR COLLECTION: 82008

COUNTRY: All (ZZ)

MANUFACTURER/ SHIPPER FEI: See Attachment

CHARGE: The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a poisonous or deleterious substance which may render it injurious to users under the conditions prescribed in the labeling or under

such conditions of use as are customary or usual [Adulteration, Section 601(a)]

or

The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it is not a hair dye and appears to bear or contain a color additive which is unsafe within the meaning of Section 721(a) [Adulteration, Section 601(e)] '

or

The article is subject to refusal of admission pursuant to Section 801(a)(3) in that its labeling appears to be false or misleading within the meaning of Section 201(n) [MISBRANDING, Section 602(a)]

OASIS CHARGE
CODE POISONOUS
COSM COLOR
COSM MISB

RECOMMENDING
OFFICE Office of the Chief Counsel (GCF-1)

PEASON FOR
ALERT This alert was initiated in response to information indicating a risk of permanent eye damage, including corneal infections resulting in scarring and (potentially) blindness, resulting from product use and particularly wear beyond the recommended period lens sharing between individuals, improper fit

GUIDANCE Review all entries of contact lenses to determine their PMA/510(k) status If a PMA/510(k) is not on file and the product is not listed on the Attachment, the product may be sampled and/or detained without physical examination as follows

* If the product is labeled solely to change the appearance of the eye in decorative fashion, districts may sample and/or detain the shipment using the charges cited in this alert For guidance contact James F Saviola, O D , F A A O, CDRH Office of Device Evaluation (HFZ-460) (FAX 301-480-4201)

* If the product is labeled for vision correction or prosthetic use, districts may detain the shipment using the appropriate charge as referenced in Import Alert# 89-08

Appropriate OASIS screening criteria has been set

PRIORITIZATION
GUIDANCE N/A

FOI No purging required

KEYWORDS Decorative Contact Lenses Noncorrective Contact Lenses, Cosmetic Contact Lenses Novelty Contact Lenses, Plano Contact Lenses

PREPARED
BY Ted Poplawski, DIOP (301) 443-6553

DATE LOADED
INTO FIARS April 1, 2003

ATTACHMENT FOR IMPORT ALERT# 89-10

Manufacturers/Shippers of Decorative Contact Lenses not recommended for DWPE

FIRM PRODUCT DESCRIPTION

At the time of publication in the Federal Register, there were no firms identified



scott chyatte@cibavisi
on novartis com

03/21/02 02 49 PM

To arlene mesnard@cibavision novartis com
larry macgirr@cibavision novartis com
cc shannon harper@cibavision novartis com
scott meece@cibavision novartis com
rick weisbarth@cibavision novartis com
Subject RE CV Accounts Selling Improperly

PRIVILEGED AND CONFIDENTIAL ATTORNEY CLIENT COMMUNICATION

My personal opinion is that we need to become much more aggressive on this issue We have knowledge of several recent cases in which minor children have suffered significant injuries as a result of obtaining lenses through unauthorized channels, one of which has already turned into litigation involving the company

Considered from a litigation perspective, I believe it would be very difficult for the company to defend a decision to continue to sell to an account once we had knowledge that the product was being resold to unauthorized channels that passed them out like lollipops to teens Consequently, my vote is that we terminate the account if we have verifiable evidence of resale to this Brian Cohen character (or other unauthorized resellers) In addition depending on our level of comfort with the supporting evidence, it might be an opportunity to generate some publicity

SGC

678-415-3055 (Phone)
678-415-3018 (Fax)
scott chyatte@cibavision novartis com

> -----Original Message-----
> From arlene mesnard@cibavision novartis com
> [SMTP arlene mesnard@cibavision novartis com]
> Sent Thursday, March 21, 2002 10 07 AM
> To scott chyatte@cibavision exc3 novartis com
> Cc shannon harper@cibavision exc3 novartis com
mbrecher@sweeneylev com
> Subject RE CV Accounts Selling Improperly
>
> Scott,
>
> As a little more background
>
> Account 004777, Tuscano and Hayden is ranked #44 in sales of ColorBlends
> for 2001 ColorBlends sales were $40,284 It might not be a bad idea to
> check on their WildEyes sales as well - another product that is often sold
> without an Rx
>
> Arlene
>
>
>
>
>
>
>
> Arlene Mesnard
>
> To
> scott chyatte@cibavision novartis com@N1
> 03/21/02 08 52 AM cc

CIBA SUPP
1122



Rick Weisbarth
03/07/2004 09 11 AM

To Scott Meece/CV/Novartis@PH
cc Kristie Madara/CV/Novartis@PH Shannon Harper/CV/Novartis@PH Holly Guest/CV/Novartis@PH Alicia Plesnarski/CV/Novartis@PH
Subject Re Latest on Plano Lens legislation

Scott

thanks for cc ing me on this

Very interesting
I would definitive want to be involved
We should also involve the American Optometric Association (AOA)

Given that 85% of our customers are OD s it would be a big mistake not to include them
Several years ago we quoted the Academy of Ophthalmology on something and it very quickly turned into a PR nightmare for us
OD s thought we were trying to abandon them and support the enemy
I know it sounds crazy but welcome to the realities of a multichannel marketplace

Regarding involving J&J it s a double edged sword
We could use their support
However 98% of the product sold illegally is our product - because we are the market leader in color lenses
They could very easily say that they have no problem and then turn the situation against us
(i e Why would you want to do business with a company that control it s distribution)
This whole topic is another one of those very emotional issues for the ecp and they expect us to be able to control it

Regarding increased demand over spring break
I know of NO data to support this comment
I have never heard this before and would guess that it is someone s personal belief which may or may not be based on experience
I would guess the hypothesis is something like you have such a high concentration of students together who influence one another s buying habits
However our complaint load on illegal sales does not increase during the spring time

Hope this helps

Thanks

Regards

Rick

ph (678) 415 3560
fax (678) 415 3151
e mail rick weisbarth@cibavision novartis com
Scott Meece



Scott Meece
03/07/2004 08 39 AM

To Tom Giles/GP/Novartis@PH
cc Kristie Madara/CV/Novartis@PH Rick Weisbarth/CV/Novartis@PH
Subject Re Latest on Plano Lens legislation

Tom

CIBA PMA
SUPP 0036

Joseph Mallof
05/23/2003 04 27 PM

To Scott Meece/CV/Novartis@PH
cc David Drake/GP/Novartis@PH Holly Guest/CV/Novartis@PH
Subject Re Plano Colored Lens Legislation INFORMATION

Makes sense to me
Scott Meece



Scott Meece
05/23/2003 12 13 PM

To Joseph Mallof/CV/Novartis@PH
cc David Drake/GP/Novartis@PH Holly Guest/CV/Novartis@PH
Subject Plano Colored Lens Legislation INFORMATION

Joe

I feel that I should give you a brief update on our plano colored contact lens issues As you know the FDA took the position that plano lenses are not regulated as medical devices under the FD&CA We have been working with David Drake in our Washington office Pharma Legal and CLI to change the law to ensure that plano lenses are regulated exactly like corrective lenses The process led here by Holly Guest has been quite complicated However I believe we will ultimately prevail

The new law will help the protect the consumer from unscrupulous and unregulated manufacturers help the consumer and practitioner in better ensuring that consumers will receive advice from practitioners before buying lenses and provide better insulation from baseless product liability litigation for us On a related note we have been sued by a teen for vision loss associated with a plano colored lens not purchased from a doctor

If you need any more information please notify me By the way both Holly and David have done a wonderful job on this matter

Scott

CIBA PMA
SUPP 0079

Food and Drug Administration
5600 Fishers Lane GCF 1
Rockville MD 20857

October 2002

VIA FACSIMILE

Jeffrey Gross Esq
Hyman Phelps & McNamara
700 Thirteenth Street N W
Suite 1200
Washington D C 20005-5929

Dear Mr Gross

This responds to your letters concerning Applied Digital Solutions (ADS)'s two separate written requests submitted to the Center for Devices and Radiological Health (CDRH or the Center) under Section 513(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requesting a determination that the VeriChip is not a medical device under the FD&C Act for the intended uses described in the requests Your requests cover two different intended uses of the product The first is for use of the VeriChip in health information applications ("health information VeriChip) The second is for security, financial, and personal identification\safety applications personal ID\security VeriChip") For the reasons discussed below FDA believes that the health information VeriChip is a medical device subject to FDA's jurisdiction FDA agrees however that the personal ID/security VeriChip is not covered by the FD&C Act

Background

Since 1986 Digital Angel Corporation, which is working with VeriChip Corporation has sold more than 20 million implantable RFID transponders for animals, including companion animals such as dogs and cats; livestock animals such as pigs and cattle, fish and a variety of other species VeriChip is one of those same chips with the same internal components, the same glass envelope, and a slightly revised number system The transponders provide access to information necessary to identify the animal

In January of 1984 the Center for Veterinary Medicine (CVM) within FDA issued a letter to the manufacturer of this product stating "This product is a microminiature transponder that is embedded in non reactive plastic and may be inserted by hypodermic needle into animals of all sizes The device does not have a medical\therapeutic function. Therefore, we have no objection to marketing of this identification device for use in animals "

EXHIBIT
1

In 1986, FDA again wrote the company stating

> 'This is in response to your March 21 and July 8 1986 letters concerning the status of your product System I D with the use of R6 Soda Lime glass for encapsulation rather than non reactive plastic as originally proposed
>
> "This product is a microminiature transponder inserted by hypodermic needle into animals of all sizes The device does not have a medical\therapeutic function That has not changed by the use of glass for encapsulating instead of plastic Therefore we have no objection to marketing of this device for use in animals

ADS has determined to market in the United States a version of the microminiature transponder, known by the trade name VeriChip, for a variety of uses in human beings We understand from ADS that the VeriChip is a microminiature transponder that is encapsulated in medical grade glass that may be inserted by hypodermic needle under the skin of the upper arm in humans The chip\transponder stores a unique identification number only A small handheld implant introducer is used to place the chip subcutaneously A small handheld battery powered scanner can read the identification number on the chip That number enables access to a database providing individual identity and access rights to information or facilities The personal ID\security VeriChip would allow access, via the database to information related to security, financial, and personal safety applications only You have represented that it will not contain any medical information By contrast, ADS and its representatives have asserted the health information VeriChip would allow access via the database to medical records and other information to assist medical personnel in diagnosing or treating an injury or illness

Regulatory Status of the VeriChip

We believe that the health information product, which facilitates access to information for use by medical professionals in treating the individual with the VeriChip embedded in his or her arm, is "intended for use in the diagnosis of disease or other conditions, or in the cure [or] mitigation of disease." The information in the database is meant to be used by medical professionals in diagnosing a disease or other condition Indeed the entire purpose of this product is for a medical professional to employ when treating a stricken individual For example, information about whether the person is allergic to a particular medicine or has an implanted pacemaker, which is accessed in connection with the VeriChip is intended for use in treating the person Accordingly, FDA has determined that the health information VeriChip is a medical device within the meaning of Section 201(h)(2) of the FD&C Act [1]

[1] The health information VeriChip does not meet any of the three broad categories of computer products not subject to regulation as a medical device It is not used for a traditional library function it is not used as a general

By contrast as CVM recognized with respect to the use of the VeriChip predecessor in animals it does not appear that the personal ID/securi VeriChip is a medical device even though it is an implant " It is of course true that virtually any product that comes into contact with the body—and many that do not—could be said to have an effect on the structure or a function of the body However as you note in your Section 513(g) submission FDA s medical device jurisdiction under Section 201(h)(2) extends only to such products that are marketed by their manufacturers or distributors with claims of effects on the structure or a function of the body In the language of the statute itself the product must be intended to affect the structure or a function of the body It is well settled that intended use is determined with reference to marketing claims

As early as Bradley v United States, 264 F 79 (5th Cir 1920) courts were finding intended use based upon marketing claims In 1953 the Second Circuit held that claims are essential to establish an intended use " FTC v Liggett & Myers Tobacco Co 203 F 2d 955 (2d Cir 1953) (per curiam) aff'g 108 F Supp 573 (S D N Y 1952) "The real test is how this product [is] being sold[ ]" United States v Nutrition Serv , Inc , 227 F Supp 375 386 (W D Pa 1964) aff'd, 347 F 2d 233 (3d Cir 1965) The courts have always read the statutory definitions employing the term intended to refer to specific marketing representations " American Health Prods Co v Hayes 574 F Supp 1498, 1505 (S D N Y 1983) (citations omitted) aff'd on other grounds, 744 F 2d 912 (2d Cir 1984) This is what has traditionally been understood as "objective intent." 21 C F R §§ 201 128 & 801 4

Indeed just four years ago, the United States Court of Appeals for the Fourth Circuit found that "no court has ever found that a product is intended for use' or 'intended to affect' within the meaning of the [FD&C Act] absent manufacturer claims as to that product's use " Brown & Williamson Tobacco Corp v FDA, 153 F 3d 155, 163 (4th Cir 1998) (internal quotation marks omitted) (citing Coyne Beahm, Inc v FDA, 966 F Supp 1374, 1390 (M D N C 1997)) aff'd, 529 U S 120 (2000), see also United States v Undetermined Quantities "Pets Smellfree," 22 F 3d 235 240 (10th Cir 1994) ("PSF's claims [in labeling and promotional materials] bring Smellfree within the scope of § 321(g)(1)(C) ") United States v Storage Spaces Designated Nos. "8" and "49," 777 F 2d 1363, 1367 n 6 (9th Cir 1985) (relying on "the manner in which the products [were] promoted and advertised" in finding that the products were drugs under Section 321(g)(1)(C)), United States v An Article of Device Amblyo-Syntonizer, 261 F Supp 243, 244 (D Neb 1966) (articles were sold to only those optometrists who take courses [from the distributor] concerning the purpose and use of the device")

In a 1994 case FDA stated that it "does not claim that a device which has no medical application could 'qualify as a device under the FD&C A " United States v Undetermined

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accounting or communications function and it is not solely for educational purposes FDA Policy for the Regulation of Computer Products (November 13 1989) (emphasis added)

Number of Unlabeled Cases, 21 F 3d 1026, 1030 (10th Cir 1994) (Cook J , concurring in part and dissenting in part) (quoting Brief for the United States at 16) (emphasis added) [2] Courts have held that Section 201(h)(3) only encompasses products claimed to affect the body in some medical—or drug type fashion, i e , in some way other than merely altering the appearance An Article "Sudden Change, 409 F 2d at 742 (internal quotation marks omitted) (emphasis added) See E R Squibb & Sons Inc v Bowen, 870 F 2d 678 682 83 (D C Cir 1989) (Section 201(h)(3) is interpreted to be relatively narrow ")

The pertinent legislative history supports this interpretation Specifically, the Senate Report accompanying the legislation that became the Federal Food, Drug, and Cosmetic Act of 1938 Pub L No 75-717, 52 Stat 1040 (1938), states

> The use to which the product is to be put will determine the category into which it will fall The manufacturer of the article through his representations in connection with its sale, can determine the use to which the article is to be put

S Rep No 74-361 at 240 (1935) (emphasis added), see also Foods Drugs, and Cosmetics Hearings on S 2800 Before the Sen Comm on Commerce 73d Cong 517-18 (1934) (a table would be subject to FDA jurisdiction only if claimed to have medical application) As the D C Circuit found that intended use is determined by manufacturer marketing claims "has now been accepted as a matter of statutory interpretation" by the federal courts Action on Smoking and Health v Harris, 655 F 2d 236 238-39 (D C Cir 1980)

Accordingly assuming that no medical claims are made for the personal ID\security VeriChip, and the product marketed for that purpose contains no health information FDA can confirm that it is not a medical device

It is of course foreseeable that any implant, such as the personal ID\security VeriChip, will have an effect on the structure and function of the body, indeed, it will be permanently embedded under a person s skin. However, as the Fourth Circuit recently held, a foreseeable effect on the structure or function of the body does not establish an intended use Sigma-Tau Pharmaceuticals, Inc v Schwetz, 288 F 3d 141 (4th Cir 2002) (rejecting the contention that under 21 C F R § 201 128, FDA must consider evidence of likely post-approval use), aff'g 2001 U S Dist LEXIS 11247 (D Md Aug 3, 2001) If the foreseeability theory had been accepted by the courts FDA would have won several cases that it lost See, e g, United States v Articles of Drug for Veterinary Use, 50 F 3d 497 (8th Cir 1995), National Nutritional

[2] Indeed as a 1937 Report from the House Interstate and Foreign Commerce Committee noted [s]peaking generally devices within the terms of the act means instruments and contrivances intended for use in the cure or treatment of disease Devices are included within the bill because of their close association with drugs as a means for the treatment of physical ills H R Rep No 75 1613 at 2

Foods Ass'n v Mathews, 557 F 2d 325 (2d Cir 1977) National Nutritional Foods Ass n v FDA 504 F 2d 761 (2d Cir 1974)

Also if foreseeability were a permissible basis for finding an intended use as that term is used in Section 201(h)(3) FDA s jurisdiction would encompass many articles having foreseeable physical effects Yet FDA only regulates products if they are marketed with claims of medical or therapeutic utility For example, FDA only regulates exercise equipment as a medical device when it is marketed with claims to prevent treat, or rehabilitate injury or disability Otherwise it is a consumer product See Letter from Thomas Scarlett to James V Lacy (May 6 1983) 21 C F R §§ 890 5350-890 5380, see also Pillow Used To Aid Sleep or Rest (Mother s Pillow)—Device Status (updated Jan 31, 2002) (available at <www fda gov/cdrh/devadvice/21aaa html>) Sun Protective Fabrics/Articles of Clothing (updated Apr 15 1998) (FDA has decided that it is not the appropriate agency to regulate SPC [(sun protective clothing)] for which no medical claims are made and which are only intended for general use ") (available at <www fda gov cdrh/devadvice/21a html>) Letter from Richard M Cooper Chief Counsel FDA to Stephen Lemberg, Ass't Gen Counsel CPSC (May 14 1979) (available at <http //www cpsc gov/library/foia/advisory/276 pdf>) (electrostatic air cleaners)

In addition if foreseeable effects were cognizable under Section 201(h)(3), FDA's legal authority would intrude into consumer product regulation—an area of responsibility delegated by Congress to another federal agency CPSC's jurisdiction extends to "consumer products," which means any article or component part thereof produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation or otherwise or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise " 15 U S C § 2052(a)(1) The definition expressly excludes "drugs, devices, or cosmetics (as such terms are defined in sections 201(g), (h), and (i) of the Federal Food, Drug and Cosmetic Act) " Id. § 2052(a)(1)(H)

Similarly if Section 201(h)(3) of the FD&C Act were interpreted to give FDA jurisdiction over any product foreseeably having an effect on the structure or a function of the body, then regulatory authority would shift from the CPSC to FDA for a host of non-health-related products Hiking boots; shirts, pants, and coats, exercise equipment, insulated gloves, airbags, and chemical sprays can be said to affect bodily structure or function Clothing and gloves, for example keep the body warm It is for this reason that FDA's regulations discuss objective, as opposed to subjective, intent 21 C F R §§ 201 128 & 801 4 Foreseeability by the manufacturer does not suffice to establish intended use Rather, there must be "objective intent" in the form of marketing claims

Moreover for FDA to treat as "intended" every foreseeable effect on the structure or a function of the body would subject off-label use to unintended regulation. Off-label use of

medical products is ubiquitous, often comprising the standard of care See, e g Janet Woodcock A Shift in the Regulatory Approach, 32 Drug Info J 367 367 (1998) GAO Report to the Chairman Sen Comm on Labor and Human Resources Off Label Drugs Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies 19 (Sept 1991) [3] Given that many off label uses are foreseeable for FDA to require pre approval for every use of a product made in the absence of claims would dramatically harm the public health As one court put it

> New uses for drugs are often discovered after FDA approves the package inserts that explain a drug's approved uses Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time consuming process of obtaining FDA approval before putting drugs to new uses

United States v Algon Chem Inc , 879 F 2d 1154 1163 (3rd Cir 1989) (quoting Chaney v Heckler 718 F 2d 1174 1180 (D C Cir 1983), rev d on other grounds, 470 U S 821 (1985))

Finally, adoption of a foreseeability theory of intended use would undermine the generic drug approval process The abbreviated new drug approval (ANDA) process, created by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), Pub L No 98 417 98 Stat 1585 provides for FDA approval of a generic drug based on a showing of bioequivalence to the innovator counterpart Approval is authorized only if the generic drug s labeling is substantially identical to the labeling for the innovator 21 U S C § 355(j)(2)(A)(v) (j)(4)(G), 21 C F R § 314 94(a)(3) Because the medical community's experience with an innovator product following approval frequently reveals clinically useful off label uses, by the time the generic version is approved it is likely to have foreseeable uses that its innovator predecessor did not have If foreseeable use constituted intended use, then FDA would lack authority to approve a generic drug because all foreseeable uses would have to be in the labeling, and the additional uses would cause the generic labeling to differ from the innovator labeling The generic drug manufacturer could only obtain approval of the new indications by developing the clinical and other data required in a full NDA Interpreting "intended use" to include foreseeable use would thus utterly defeat the purposes of the generic drug legislation, with ill effects for the cost and availability of drugs

Conclusion

---

[3] According to a 1991 report of the General Accounting Office 33 percent of all drugs being administered to treat cancer were being prescribed off label " and 56 percent of the cancer patients surveyed were given at least one drug for an unapproved use GAO Report to the Chairman, Sen Comm on Labor and Human Resources Off Label Drugs Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies 19 (Sept 1991)

For the reasons set forth above, FDA has determined that the VeriChip, when marketed to provide information to assist in the diagnosis or treatment of injury or illness, is a medical device CDRH will be in touch with you shortly as to what its expectations are with respect to that product In the meantime we expect that you will not market that product So long as no medical claims are made for the personal ID\security VeriChip, FDA can confirm that it is not a medical device

Please do not hesitate to contact us if you have any questions or wish to discuss this matter further

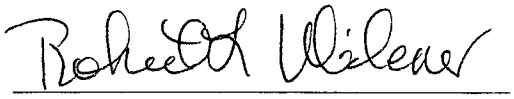
Sincerely

Daniel F Troy
Chief Counsel
Food and Drug Administration

cc Mark B McClellan, M D , Ph D
Lester Crawford, D V M , Ph.D
David Feigal, M D
Alex M Azar II

CERTIFICATE OF COUNSEL

The undersigned hereby certifies that this Record on Appeal contains all material proposed to be included by any of the parties and not any other material with the exception of one item designated by Appellant but not included herein because Respondent correctly observed the designated item had not presented to the trial court as required by Rule 210(c), SCACR



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ATTORNEYS FOR APPELLANT

May 29, 2008