THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

State of South Carolina ex rel. Alan Wilson in his capacity as Attorney General of the State of South Carolina, ... Respondent,

v.

Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and Johnson & Johnson, Inc., ... Defendants.

Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc. is ..... Appellant.

SUPPLEMENTAL RECORD ON APPEAL

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INDEX TO SUPPLEMENTAL RECORD ON APPEAL

PAGE

I. EXHIBITS

Plaintiff's Trial Exhibits:

Johnson & Johnson
PHARMACEUTICAL RESEARCH
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TRANSMITTED VIA FACSIMILE AND FEDEX

April 28, 2004

Thomas W. Abrams, R.Ph., M.B.A.
Director
Division of Drug Marketing,
Advertising and Communications
HFD-42, Rm. 8B-45
5600 Fishers Lane
Rockville, MD 20857

RE: NDA 20-272 and 20-588
RISPERDAL ® (risperidone) Tablets and Oral Solution
MACMIS # 12195

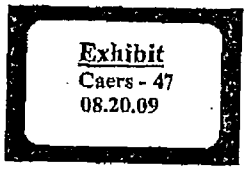
Dear Mr. Abrams:

On behalf of Janssen Pharmaceutica Products L.P. (Janssen), please refer to our approved New Drug Applications, NDA 20-272 and 20-588 for RISPERDAL® (risperidone) Tablets and Oral Solution, and MACMIS # 12195. Reference is also made to the Division of Drug Marketing, Advertising & *Communication 's (DDMAC) correspondence to Janssen dated* April 19, 2004, *sent in response to a* "Dear Healthcare Provider Letter (DHCP)" disseminated by Janssen on November 10, 2003. We have carefully reviewed your letter of April 19, 2004, and provide our response below.

Janssen and Johnson & Johnson Pharmaceutical Research & Development (J&JPRD) share FDA's *interest in accurate and timely communication of labeling changes to the healthcare community.* Janssen and J&JPRD received the Division of Neuropharmacological Drug Products' (DNDP) letter of September 11, 2003 to all manufacturers of atypical antipsychotics requesting that labeling for all atypical antipsychotics, including RISPERDAL, be updated to include information about diabetes mellitus adverse events. Within three days, Janssen and J&JPRD contacted DNDP to request an *opportunity to discuss the proposed class labeling.*

On November 6, 2003, after several correspondences between J&JPRD and DNDP regarding the proposed class labeling, which led to agreement on modified class labeling, J&JPRD submitted a "Special Supplement – Changes Being Effected" ("Special Supplement") to provide for changes in the WARNINGS section of the RISPERDAL® labeling. *Immediately thereafter, with the goal of informing* health care professionals in a timely manner regarding these labeling changes, Janssen voluntarily issued, to healthcare providers, the November 10, 2003 DHCP communication.

On November 21, 2003, DNDP approved our Special Supplement and at that time requested that *Janssen issue a "Dear Health Care Professional" letter regarding the addition of language relative to* hyperglycemia and diabetes mellitus to the WARNING section of the prescribing information for RISPERDAL®. On November 26, 2003, J&JPRD informed DNDP that a medical communication with this purpose was previously sent on November 10 and provided a copy of the letter to DNDP at that time.



PRD-1B

NDA #20-272, 20-588
MACMIS # 12195

Regarding your assertions of omission of material information and minimization of risks/misleading *comparative claims, it is important to note that the November 10, 2003 communication contained a* copy of the complete prescribing information for RISPERDAL containing the updated, FDA approved, WARNING language on hyperglycemia related events, with a prominent reference to the full *prescribing information in the body of the DHCP letter.*

Based upon Janssen's comprehensive review of the data pertaining to risperidone[1], we have a differing *view of the data on Risperdal and diabetes mellitus. However, we acknowledge the Agency's position.*

Notwithstanding our differing views, in order to address your concerns, we agree to do the following. *With your agreement, we will send the attached proposed DHCP letter (Attachment A) pursuant to 21* CFR 200.5 (c)(1) to the same audience that received the November 10, 2003 communication. Please be aware that the November 10, 2003 letter is no longer being disseminated. In addition, we are *providing as attachment B, pursuant to your request, a list of current RISPERDAL promotional* materials containing same or similar claims to those addressed in your April 19, 2004 letter, all of which are discontinued.

With regard to submission pursuant to post marketing requirements, we considered the November 10, 2003, letter a medical communication informing healthcare providers of an important change to labeling, and therefore did not consider it subject to 21 CFR 314.81(b)(3)(i). However, we acknowledge your position and will modify future submissions accordingly.

We trust that this letter adequately responds to your April 19 letter and we look forward to resolving this matter in a timely fashion. Should you have any questions, please contact James Burrus at 609-730-3617.

Sincerely,

Donna Ohye

Donna Ohye
Senior Director, Advertising and Promotion
Global Regulatory Affairs and Quality Assurance
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Attachments

[1] Including the eight published studies cited in the November 10 DHCP letter and other epidemiology, physiology, clinical trial and pharmacovigilance data (data submitted to DNDP 3/29/04)

NDA #20-272, 20-588
MACMIS # 12195

Attachment A

[insert date]

Dear Health Care Provider,

Janssen Pharmaceutica Products L.P., makers of RISPERDAL®(risperidone), distributed a "Dear Healthcare Provider" letter dated November 10, 2003, notifying you that the product labeling for RISPERDAL had been updated to include a WARNING regarding hyperglycemia and diabetes mellitus. FDA has informed us of their view that this letter was misleading, in part due to omission in the letter of certain information, and the inclusion of certain other information. FDA has requested us to further clarify the new WARNING information, which is provided below:

Hyperglycemia and Diabetes Mellitus

"Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including RISPERDAL. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available."

"Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug."

If you have any questions regarding this important safety information, please contact Janssen Medical Affairs at 1-800-JANSSEN. Please refer to the full prescribing information for RISPERDAL included with this letter. As always, we request that serious adverse events be reported to Janssen at 1-800-JANSSEN or to the FDA MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), or by email (www.fda.gov/medwatch).

Sincerely,

Ramy A. Mahmoud, MD, MPH
Vice President, CNS
Janssen Medical Affairs, LLC

NDA #20-272, 20-588
MACMIS # 12195

Attachment B

The following promotional items have been discontinued in accordance with the requested action.

Bipolar Mania Promotion aides:

- 01-RS-1374-PCP/CNS, 01-RS-1404, 01-RS-1377, 01-RS-1440,

Managed Care Promotional aide template: (Note: These are identical excluding the managed care plan name)

- 01-RS-MAN- (338, 349, 229, 252, 272, 278, 279, & 281)

Reprint Carriers & Reprint & Speaker Slide Kit:

- 01-RS-1433, 01-RS-1200R1, 01-RS-146101-RS-1126, 01-RS-1385

Exhibit Panels

- 01-RS-1290E, 01-RS-1299A

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Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc. is ..... Appellant.

CERTIFICATE OF COUNSEL

The undersigned certifies that the Supplemental Record on Appeal contains all material proposed to be included by any of the parties and not any other material.

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Columbia, South Carolina
May 8, 2013

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PROOF OF SERVICE

I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for Appellant, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) hereinbelow specified by mailing a copy of the same by United States mail, postage prepaid, to the following address(es):

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