



NDA 20-272/S-046/S-047
NDA 20-588/S-036/S-037
NDA 21-444/S-020/S-021

Johnson & Johnson PR&D
Attention: Heddie Martynowicz, M.S.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-2022

Dear Ms. Martynowicz:

Please refer to your supplemental new drug applications dated and received December 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal (risperidone) Tablets (NDA 20-272), Risperdal (risperidone) Oral Solution (NDA 20-588), and Risperdal M-Tab (risperidone) Orally Disintegrating Tablets (NDA 21-444).

We acknowledge receipt of your submission dated June 25, 2007.

Your submission of June 25, 2007 constituted a complete response to our June 20, 2007 action letter.

Supplemental new drug applications 20-272/S-046, 20-588/S-036, & 21-444/S-020 provide for the use of oral risperidone HCL for the treatment of schizophrenia in adolescents (ages 13-17), and supplemental new drug applications 20-272/S-047, 20-588/S-037 & 21-444/S-021 provide for the use of oral risperidone HCL for the treatment of bipolar I disorder in children (ages 10-12) and adolescents (ages 13-17).

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.157(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling. These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission

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“SPL for approved supplemental NDAs 20-272/S-046/S-047, 20-588/S-036/S-037, and 21-444/S-020/S-021.”

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that, with regard to both bipolar disorder and schizophrenia, you have fulfilled the requirements for adolescents aged 13–17. In addition, you have fulfilled the bipolar disorder requirement for children aged 10–13 years. We are waiving the requirement for assessment of safety and effectiveness of the product in pediatric patients below the age of 10 with regard to bipolar disorder. Your current studies have met the terms of the initial Pediatric Written Request.

Promotional Materials

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Kimberly Updegraff, Regulatory Project Manager, at (301) 796-2201.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Thomas Laughren
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