



NDA 20272/S-073
NDA 20588/S-062
NDA 21444/S-048
NDA 21346/S-051

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
Attention: Jacqueline Brown, R.Ph.
Associate Director, Global Regulatory Affairs
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Brown:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received April 30, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Risperdal (risperidone) 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg tablets (NDA 20272), Risperdal (risperidone) 1 mg/ml oral solution (NDA 20588), Risperdal M-TAB (risperidone) 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg orally disintegrating tablets (NDA 21444), and Risperdal Consta (risperidone) long acting injection, 12.5 mg, 25 mg, 37.5 mg, and 50 mg (NDA 21346).

We acknowledge receipt of your amendments dated November 12, and 13, 2013.

The November 12, and 13, 2013 submissions constituted complete responses to our September 25, 2013, action letter.

These "Prior Approval" supplemental new drug applications propose adding "ileus" as an adverse event in the Postmarketing Experience section (6.2, 6.8) of labeling. NDA 21346/S-051 the following statement in the Postmarketing Experience section (6.8): "Very rarely, cases of anaphylactic reaction after injection with RISPERDAL[®] CONSTA[®] have been reported during postmarketing experience in patients who have previously tolerated oral risperidone."

APPROVAL & LABELING

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

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CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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, please email Ann Sohn, Regulatory Project Manager, at ann.sohn@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

MITCHELL V Mathis
04/28/2014