



NDA 020272 S-066 S-060
NDA 021444 S-042 S-035
NDA 020588 S-054 S-048

**SUPPLEMENT APPROVALS
AND
RETAIN PENDING BUT
SUPERCEDED SUPPLEMENTS**

Ortho McNeil Janssen Pharmaceuticals, Inc.
Attention: Patricia Treichler,
Associate Director Regulatory Affairs
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Treichler:

Please refer to your Supplemental New Drug Applications (sNDAs) dated January 7, 2010 (S-060, S-035), March 16, 2011 (S-048), and June 23, 2011 (S-066, S-042, S-054), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Risperdal (risperidone) Tablets (NDA 020272), Risperdal oral solution (NDA 020588), Risperdal M-Tab orally disintegrating tablets (NDA 021444).

S-066, S-042, S-054

These "Prior Approval" supplemental new drug applications provide for changes to Warnings and Precautions, specifically Section 5.5, Metabolic Changes.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

S-060, S-035, S-048

These "Prior Approval" supplemental new drug applications proposed relocating the Weight Gain section of labeling from Adverse Reactions to the Warnings and Precautions section.

We note that supplements S-066, S-042, and S-054 supersede these applications. Therefore, we will not review these supplemental applications but they will be retained in our files.

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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 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).

If you have any questions, call Keith Kiedrow, Team Leader, Senior Regulatory Project Manager, at (301) 796-1924.

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(S):
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/

THOMAS P LAUGHREN
09/24/2011