DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21999/S-020, S-024

SUPPLEMENT APPROVAL

Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Attention: James Tan, Ph.D.
Director, Regulatory Affairs
920 Route 202
P.O. Box 300
Raritan, NJ 08869

Dear Dr. Tan:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received July 20, 2010 (S-020), and October 8, 2010 (S-024), and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Invega (paliperidone) extended-release tablets, 1.5 mg, 3mg, 6 mg, 9 mg, and 12 mg.

We acknowledge receipt of your amendments dated December 10, 2010 and February 29, 2011 for S-020 and December 9, 2010, December 13, 2010, December 15, 2010, January 28, 2011, February 18, 2011, February 23, 2011, February 24, 2011, February 25, 2011, March 1, 2011, and March 3, 2011 for S-024.

These "Prior Approval" supplemental new drug applications propose the following changes to product labeling:

S-020

- Relocation of the descriptive summary of experience with weight gain from the Adverse Reactions to the Warnings and Precautions section of the labeling as well as to reflect this information in the Highlights section of labeling.
- The addition of nonclinical safety information contained from the juvenile rat and dog toxicity studies in Section 8.4 (Pediatric).

S-024

- The indication for the treatment of schizophrenia in adolescents 12-17 years of age.

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

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 Effected" (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).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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

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: 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
04/06/2011