



NDA 21-999/S-005/S-008

Johnson & Johnson Pharmaceutical Research & Development, L.L.C  
Attention: Lori Birkenberger, PhD  
Director, Regulatory Affairs  
920 U.S. Highway 202  
P.O. Box 300  
Raritan, NJ 08869-0602

Dear Dr. Birkenberger:

Please refer to your supplemental new drug applications dated November 19, 2007 (S-005), and April 29, 2008 (S-008), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Invega (paliperidone) Extended-Release Tablets.

We acknowledge receipt of your submissions dated April 30, 2008 (S-005), and July 23, 2008 (S-008).

Your submission of April 30, 2008 to S-005 constituted a complete response to our March 20, 2008 action letter.

These supplemental new drug applications provide for the following changes:

**S-005**

- The addition of a new 1.5 mg strength.

**S-008**

- Addition of the Janssen-Cilag Manufacturing, LLC site in Guarbo, Puerto Rico for the manufacturing and release testing of the drug product.

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 (enclosed).

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplement NDA 21-999/S-005.**"

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly 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

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  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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, Pharm.D., 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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Thomas Laughren  
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