DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-999/S-006

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 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Invega (paliperidone) Extended-Release Tablets.

Reference is also made to an Agency e-mail communication dated August 20, 2008, from CAPT Paul David, of this office, to you proposing revised labeling, and to your e-mail dated September 2, 2008, accepting this labeling.

This supplemental new drug application provides for revisions to labeling regarding the results of a carbamazepine drug interaction study.

We completed our review of this application, and it is 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-006."**

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

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
9/4/2008 09:50:24 AM