DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-999 / S-007

Johnson & Johnson Pharmaceutical R & D, L.L.C.
Attention: Lori Birkenberger, Ph.D., Director, Reg. Affairs
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869

Dear Dr. Birkenberger:

Please refer to your supplemental new drug application dated and received February 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Invega (Paliperidone) Extended-Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for class-labeling changes under ADVERSE REACTIONS, Extrapyramidal Symptoms. The following subsection has been added:

> **Dystonia** - *Class Effect:* Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

We note your February 15, 2008 submission of the content of the labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format. The final printed labeling (FPL) must be identical to the enclosed labeling. Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-999/S-007.**" Approval of this submission by FDA is not required before the labeling is used.

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, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@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

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
5/16/2008 12:08:17 PM