DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-999/S-001, S-002

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 January 26, 2007, received February 27, 2007, and dated and received March 9, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Invega (paliperidone ER) tablets.

We acknowledge receipt of your submissions dated –
February 27, 2007 April 12, 2007 April 23, 2007 July 6, 2007

These submissions consisted of a supplemental new drug application which provided for new information regarding paliperidone and its effects on QT prolongation and also a supplemental new drug application which provided for information regarding the pharmacokinetic effects of paliperidone on paroxetine. These supplements also provided for the conversion of the USPI to the new Physician's Labeling Rule (PLR) format.

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.

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-001, S-002."**

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, PharmD, 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
12/21/2007 07:59:32 AM