DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21999/S-013, S-014 **APPROVAL LETTER**

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: James Tan, Ph.D., Director, Global Regulatory Team Leader
920 U.S. Highway Route 202
P.O. Box 300
Raritan, NJ 08869-0602

Dear Dr. Tan:

Please refer to your supplemental new drug applications dated February 5, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Invega (paliperidone) Extended Release 1.5, 3, 6, and 9 mg tablets.

These supplemental new drug applications provide for the use of Invega (paliperidone) extended release tablets for the treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants.

We acknowledge receipt of your amendment dated July 16, 2009, which includes the clinical research report for Study R076477-BIM-1004 (drug interaction study with valproate) and corresponding proposed changes to the label. Please refer to your July 20, 2009 email to Ann Sohn, in which you agreed to change this amendment to a separate prior approval labeling supplement.

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

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients, unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application, because necessary studies are impossible or highly impracticable. It would not be feasible to identify a sufficient number of appropriate subjects in a reasonable timeframe to conduct a study. This is due to the low

prevalence of this diagnosis in the pediatric population and to the diagnostic instability of pediatric schizoaffective disorder.

POSTMARKETING COMMITMENTS SUBJECT TO THE REPORTING REQUIREMENTS OF SECTION 506B

We remind you of your postmarketing study commitment in your email submission dated July 28, 2009. This commitment is listed below.

1. To conduct and submit the results of an adequate and well-controlled long-term maintenance study to assess the efficacy and safety of paliperidone ER or paliperidone palmitate in the treatment of schizoaffective disorder.

Protocol Submission Date:	December 21, 2009
Trial Start Date:	March 30, 2010
Trial Completion Date:	October 18, 2013
Final Report Submission:	March 28, 2014

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, the number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Commitment Protocol**", "**Postmarketing Commitment Final Report**", or "**Postmarketing Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Psychiatry Products 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, 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: 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
07/31/2009