DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22264/S-001 **SUPPLEMENT APPROVAL**

Ortho-McNeil-Jansen Pharmaceuticals, Inc.
Attention: Rodney Malchow, J.D.
Associate Director, Regulatory Affairs
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, N.J. 80560

Dear Mr. Malchow:

Please refer to your Supplemental New Drug Application (sNDA), dated and received April 2, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Invega Sustenna (paliperidone palmitate) Extended-Release Injectable Suspension.

This Changes Being Effected supplemental new drug application provides for the following revisions to product labeling:

1. Under Adverse Reactions: Subsections 6.1 (Incidence if Treatment Emergent Adverse Events in ≥2% of INVEGA® SUSTENNA®-Treated Subjects with Schizophrenia in Four Fixed-Dose, Double-Blind, Placebo-Controlled Trials), 6.2 (Adverse Reactions Observed During the Clinical Trial Evaluation of INVEGA® SUSTENNA® and Not Listed in Table 2), 6.9 (Adverse Reactions in Clinical Trials with Oral Paliperidone), & a new subsection 6.10 (Postmarketing Experience).
2. Under Overdosage: Subsection 10.1 (Human Experience)
3. Throughout labeling, "TM" replaced with "®".

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 1
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22264	SUPPL-1	JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC	Invega Sustenna

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/s/

THOMAS P LAUGHREN
05/13/2010