DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021346 S-055
NDA 022264 S-019
NDA 020272 S-077
NDA 021444 S-051
NDA 020588 S-065
NDA 021999 S-030
NDA 207946 S-001

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
Attention: Jacqueline Brown, R.Ph.
Associate Director, Global Regulatory Affairs
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Brown:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received April 28, 2015 (Risperdal Consta) and April 30, 2015 (Invega Sustenna), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal Consta (risperidone) long acting injection, 12.5 mg, 25 mg, 37.5 mg, and 50 mg (NDA 021346) and for Invega Sustenna (paliperidone palmitate) extended-release injectable suspension, 39 mg, 78 mg, 117 mg, 156 mg, and 234 mg (NDA 022264).

We acknowledge receipt of your amendments dated February 12, 2016, which constituted a complete response to our October 1, 2015, action letter.

Please also refer to your Supplemental New Drug Applications (sNDAs) dated and received February 16, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal (risperidone) Tablets 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4 mg (NDA 020272), Risperdal (risperidone) Oral Solution 1 mg/mL (NDA 020588), Risperdal M-Tabs (risperidone) Orally Disintegrating Tablets 0.5mg, 1mg, 2mg, 3mg, 4mg (NDA 021444), Invega (paliperidone) Extended Release (ER) Tablets 1.5mg, 3mg, 6mg, 9mg, 12 mg (NDA 021999), and Invega Trinza (paliperidone palmitate) extended-release injectable suspension 273mg, 410mg, 546mg, 819mg (NDA 207946)

These “Prior Approval” supplemental new drug applications provide for additions regarding hypersensitivity reactions to HIGHLIGHTS OF PRESCRIBING INFORMATION and CONTRAINDICATIONS sections of labeling.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, call Keith Kiedrow, Pharm.D, MS, RAC, Senior Regulatory Project Manager, at (301) 796-1924.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, 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/

MITCHELL V Mathis
03/01/2016