

NDA 021999/S-037
NDA 022264/S-030
NDA 207946/S-009

SUPPLEMENT APPROVAL

Janssen Research & Development, LLC
Attention: Beth Geter-Douglass, PhD
Associate Director, Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Dr. Geter-Douglass:

Please refer to your supplemental new drug applications (sNDAs) dated and received July 25, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Invega (paliperidone) extended-release tablets (NDA 021999), Invega Sustenna (paliperidone palmitate) extended-release injectable suspension (NDA 022264), and Invega Trinza (paliperidone palmitate) extended-release injectable suspension (NDA 207946).

We acknowledge receipt of your amendment dated October 11, 2019, which constituted a complete response to our January 25, 2019, action letter.

These Prior Approval supplemental new drug applications provide for the following revisions to the Prescribing Information:

Invega (paliperidone palmitate) extended-release tablets: The term “catatonia” was added to Adverse Reactions-Postmarketing Experience (Section 6.2) and revisions were made to Warnings and Precautions (Section 5) and Patient Counseling (Section 17) to align with class labeling language. In addition, terms were added to Adverse Reactions-Postmarketing Experience (Section 6.2) and Use in Specific Populations (Section 8.8) was added to align with revisions in Warnings and Precautions.

Invega Sustenna (paliperidone palmitate) extended-release injectable suspension: The term “catatonia” was added to Adverse Reactions-Postmarketing Experience (Section 6.2), “in single-dose prefilled syringes” was added to Dosage Forms and Strengths (Section 3), “single-dose” was added to Description (Section 11), and revisions were made to Section 5 (Warnings and Precautions) and Section 17 (Patient Counseling) to align with class labeling language. In addition, Drug Interactions (Section 7) was revised to align with other paliperidone labeling.

Invega Trinza (paliperidone palmitate) extended-release injectable suspension: The term “catatonia” was added to Adverse Reactions-Postmarketing Experience (Section

6.2), “in single-dose prefilled syringes” was added to Dosage Forms and Strengths (Section 3), “single-dose” was added to Description (Section 11), and revisions were made to Warnings and Precautions (Section 5) and Patient Counseling (Section 17) to align with class labeling language. In addition, Drug Interactions (Section 7) was revised to align with other paliperidone labeling.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and text for the Patient Package Insert for Invega Sustenna and Invega Trinza), 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 *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

We acknowledge your April 1, 2020 and April 9, 2020, submissions containing final printed carton and container labeling for Invega Sustenna and Invega Trinza.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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}

Tiffany R. Farchione, MD
Director
Division of Psychiatry
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
- Carton and Container Labeling

U.S. Food and Drug Administration

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TIFFANY R FARCHIONE
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