NDA 022264 S-037
NDA 207946 S-014/S-015

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc
Attention: Kelly Rudnick, MSPH
Associate Director, Global Regulatory Affairs
1125 Trenton-Harbourton Rd
P.O. Box 200
Titusville, NJ 08560

Dear Kelly Rudnick:

Please refer to your supplemental new drug applications (sNDAs) dated and received March 1, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Invega Sustenna (paliperidone palmitate) extended-release injectable suspension (NDA 022264), Invega Hafyera (paliperidone palmitate) extended-release injectable suspension (NDA 207946), and Invega Trinza (paliperidone palmitate) extended-release injectable suspension (NDA 207946).

NDA 022264 S-037 (Invega Sustenna) provides for updates to the administration instructions under Section 2.7 Instructions for Preparation and Administration of the Prescribing Information (PI), which include additional instructions to reduce the risk of needle hub cracks or damage. Corollary revisions were included in the Instructions for Use (IFU) document. The supplement also includes revisions to Section 12.2 Pharmacodynamics to align with NDA 207946 and revision to Section 13.2 Animal Toxicology and/or Pharmacology to remove unnecessary text. Additional editorial revisions were made throughout the PI and IFU.

NDA 207946 S-014 (Invega Hafyera) provides for updates to the administration instructions under Section 2.5 Instructions for Preparation and Administration of the PI, which includes additional instructions to reduce the risk of needle hub cracks or damage. Corollary revisions were included in the IFU document. The supplement also provides for revisions to Section 2.4 Dosage Recommendations for Patients with Renal Impairment and Section 8.6 Renal Impairment to include dosage recommendations for patients with creatinine clearance ≥50 mL/min to <80 mL/min. Additional editorial revisions were made throughout the PI and IFU.

NDA 207946 S-015 (Invega Trinza) provides for updates to the administration instructions under Section 2.8 Instructions for Preparation and Administration of the PI, which include additional instructions to reduce the risk of needle hub cracks or damage. Corollary revisions were included in the IFU document. The supplement also includes

revisions to Section 12.2 Pharmacodynamics to align with NDA 022264. Additional editorial revisions were made throughout the PI and IFU.

APPROVAL & LABELING

We have completed our review of these applications. 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 waivers 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 (Prescribing Information, Patient Package Insert, and Instructions for Use), 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 these supplemental applications, 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 Word version. The marked-up copy should provide appropriate annotations, including supplement numbers and annual report dates.

[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.

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 applications, you are exempt from this requirement.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplements for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDAs that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplements pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[3]

[3] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products

If you have any questions, contact Sharon Na, Regulatory Project Manager, at Sharon.Na@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information
    - Patient Package Insert
    - Instructions for Use

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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
09/12/2024 08:30:26 AM

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