NDA 015923/S-093
NDA 015923/S-098
NDA 018701/S-071
NDA 018701/S-076

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
Attention: Kelly Rudnick, MSPH
Global Regulatory Affairs
1400 McKean Road
Spring House, PA 19477

Dear Ms. Rudnick:

Please refer to your supplemental new drug applications (sNDAs) dated and received September 3, 2015 (S-093 and S-071) and November 29, 2018 (S-098 and S-076), and your amendments submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NDA 015923 Haldol (haloperidol) Injection (for immediate release) and NDA 018701 Haldol (haloperidol decanoate) Intramuscular Injection.

We acknowledge receipt of your amendments dated August 20, 2019 (S-093 and S-071) and May 8, 2020 (S-098 and S-076), which constituted complete responses to our February 20, 2018 (S-093 and S-071) and November 8, 2019 (S-098 and S-076), action letters.

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

- Haldol (haloperidol) injection (NDA 015923)
  - S-093**:** Addition of a subsection titled “Cerebrovascular Reactions” to the Warnings section, removal of the Pregnancy Category, and minor revisions to the section titled “Instructions for Opening Ampule.”
  - S-098**:** Revisions to Clinical Pharmacology, Indications, Warnings, Precautions, Adverse Reactions, and Overdosage sections.

- Haldol Decanoate (haloperidol) Intramuscular Injection (NDA 018701)
  - S-071: Addition of a subsection titled “Cerebrovascular Reactions” to the Warnings section, removal of the Pregnancy Category, and minor revisions to the section titled “Instructions for Opening Ampule.”
  - S-076: Revisions to the Clinical Pharmacology, Warnings, Precautions, and Overdosage sections.

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.

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

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.

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[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.

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, please email Simran Parihar, PharmD, at simran.parihar@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Content of Labeling
Prescribing Information

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/

BERNARD A FISCHER on behalf of TIFFANY R FARCHIONE
11/17/2020 11:00:37 PM