NDA 020272/S-083
NDA 020588/S-071
NDA 021444/S-057
NDA 021346/S-061

SUPPLEMENT APPROVAL

Janssen Research & Development, LLC
Attention: Kelly Rudnick, MSPH
Associate Director, Regulatory Affairs
1400 McKean Road
Spring House, PA 19477

Dear Ms. Rudnick:

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 Risperdal (risperidone) tablets (NDA 020272), Risperdal (risperidone) oral solution (NDA 205888), Risperdal M-Tab (risperidone) orally disintegrating tablets (NDA 021444), and Risperdal Consta (risperidone) long-acting injection (NDA 021346).

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:

Risperdal (risperidone) tablets, Risperdal (risperidone) oral solution, Risperdal M-Tab (risperidone) orally disintegrating tablets: The term “catatonia” and language about cases of extrapyramidal symptoms reported with concomitant use of risperidone and methylphenidate were added to Adverse Reactions-Postmarketing Experience (Section 6.2). In addition, a drug interaction for concomitant use of risperidone and methylphenidate was added to Drug Interactions (Section 7) and revisions were made to Warnings and Precautions (Section 5) and Patient Counseling (Section 17) to align with class labeling language.

Risperdal Consta (risperidone) long-acting injection: The term “catatonia” and language about cases of extrapyramidal symptoms reported with concomitant use of risperidone and methylphenidate were added to Adverse Reactions-Postmarketing Experience (Section 6.2). A drug interaction for concomitant use of risperidone and methylphenidate was added to Drug Interactions (Section 7) and revisions were made to Warnings and Precautions (Section 5) and Patient Counseling (Section 17) to align with class labeling language. In addition, “single-use” was added to Dosage Forms and Strength (Section 3) and Description (Section 11), terms were added to Adverse Reactions-Postmarketing

Experience (Section 6.2) and Use in Specific Populations (Sections 8.6 and 8.8) were added to align with the revisions to Warnings and Precautions.

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), 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).

[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.

CARTON AND CONTAINER LABELING

We acknowledge your April 1, 2020, submission containing final printed carton and container labeling for Risperdal Consta.

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
- Carton and Container Labeling

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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