NDA 020505/S063
NDA 020844/S054

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
Attention: Jenna Giacchi, MS
Manager, Global Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Ms. Giacchi:

Please refer to your supplemental new drug applications (sNDAs) dated and received January 15, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Topamax (topiramate) Tablets and Sprinkle Capsules.

We also refer to our communication dated November 20, 2020, requesting sNDA submissions to include additional information pertaining to the risk of a syndrome consisting of acute myopia associated with secondary angle closure glaucoma, which is described in the Warnings and Precautions section (subsection 5.1) of the Topamax prescribing information (PI).

These prior approval sNDAs provide for the requested revisions, adding the following ophthalmologic findings to Section 5.1 (Warnings and Precautions; Acute Myopia and Secondary Angle Closure Glaucoma Syndrome): choroidal detachments, retinal pigment epithelial detachments, and macular striae.

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.

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 Medication Guide), 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 these NDAs, 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 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).

[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.

If you have any questions, call Alina Salvatore, Regulatory Project Manager, at 240-402-0379.

Sincerely,

{See appended electronic signature page}

Alice T.D. Hughes, MD
Deputy Director for Safety
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

ALICE HUGHES
06/30/2021 11:39:25 AM