NDA 211150/Original 2 **NDA APPROVAL**

Harmony Biosciences, LLC
Attention: Michele A. Roy
VP, Regulatory Affairs
630 W Germantown Pike
Suite 215
Plymouth Meeting, PA 19462

Dear Ms. Roy:[1]

Please refer to your new drug application (NDA) dated December 14, 2018, received December 14, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wakix (pitolisant) tablets.

We also refer to our approval letter dated October 13, 2020, which contained the following error: incorrect dating period of 24 months.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain October 13, 2020, the date of the original approval letter.

NDA 211150 provides for the use of Wakix (pitolisant) tablets for the following indications which, for administrative purposes, we have designated as follows:

- NDA 211150/Original 1 – Treatment of excessive daytime sleepiness in adult patients with narcolepsy

- NDA 211150/Original 2 – Treatment of cataplexy in adult patients with narcolepsy

The subject of this action letter is NDA 211150/Original 2. A separate action letter was issued for NDA 211150/Original 1.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

[1] 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.

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.[2] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information) 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.*[3]

The SPL will be accessible via publicly available labeling repositories.

DATING PERIOD

The dating period for Wakix shall be 36 months from the date of manufacture when stored at 20 to 25 °C.

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 this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format – Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[4]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication,

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[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

[3] 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.

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

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, call Shin-Ye Sandy Chang, at (301) 796-3971, or email shinye.chang@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
- Content of Labeling
  - Prescribing Information

[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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/

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10/13/2020 12:00:00 AM