NDA 208609/S-012

SUPPLEMENT APPROVAL

FULFILLMENT OF POSTMARKETING REQUIREMENTS

Renew Pharmaceuticals Limited
c/o Cardinal Health Regulatory Sciences
7400 W 110th St, Suite 150
Overland Park, KS 66210

Attention: Andrew M Trammel, PhD
US Agent

Dear Dr. Trammel:

Please refer to your supplemental new drug application (sNDA) dated and received February 2, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ephedrine sulfate injection,.

This Prior Approval sNDA provides for labeling changes to the prescribing information (PI) based on submission of nonclinical study reports for the fertility and early embryonic developmental (FEED), embryo-fetal developmental (EFD), and pre- and post-natal developmental (PPND) toxicology studies.

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.

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) 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.

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

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).

FULFILLMENT OF POSTMARKETING REQUIREMENTS

Your submissions dated April 13, 2018, December 21, 2018, January 29, 2019, February 28, 2019, and January 21, 2020, contained the final reports for the following postmarketing requirements listed in the March 1, 2017, approval letter.

3104-1 Conduct a fertility and early embryonic development toxicology study in the rat model for ephedrine sulfate.

3104-2 Conduct an embryo-fetal developmental toxicology study using the rat model for ephedrine sulfate.

3104-3 Conduct an embryo-fetal developmental toxicology study using the rabbit model for ephedrine sulfate.

3104-4 Conduct a pre- and post-natal developmental toxicology study in the rat model for ephedrine sulfate.

3104-5 Conduct an in vivo micronucleus genotoxicity assay with ephedrine sulfate.

We have reviewed your submissions and concluded that the above postmarketing requirements were fulfilled. We remind you that there is a postmarketing requirement listed in the July 3, 2017, supplement approval letter that is still open.

[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.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names* and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*.)

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 supplement 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 NDA 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 supplement 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).

If you have any questions, email Giang T. Le, Regulatory Health Project Manager, at giang.le@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Rigoberto Roca, MD
Director
Division of Anesthesiology, Addiction Medicine and Pain Medicine
Office of Neuroscience
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/

RIGOBERTO A ROCA
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