NDA 50641/S-032

SUPPLEMENT APPROVAL

Chartwell RX Sciences, LLC
Attention: Ram Mohan Kathuroju
VP Reguatory Affairs
77 Brenner Drive
Congers, NY 10920

Dear Mr. Kathuroju:

Please refer to your supplemental new drug application (sNDA) dated and received August 16, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Doxycycline capsules, USP, 50 mg, 75 mg, 100 mg, and 150 mg.

This Prior Approval sNDA provided for the addition of a new 150 mg strength to the Prescribing Information (PI), and a new API source. The following sections of the PI have been updated with information pertaining to the new strength: **DESCRIPTION**, **INDICATIONS AND USAGE**, and **HOW SUPPLIED** sections**.** Monodox was replaced with doxycycline capsules, USP throughout the PI. Minor editorial changes were made to **CONTRAINDICATIONS**, **WARNINGS,** and **PRECAUTIONS**, under the **General** and **Information for Patients** subsections.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling. We acknowledge your agreement to print new container labeling at the next printing.

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

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

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).

CONTAINER LABELING

Submit final printed container labeling that are identical to the enclosed container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Container Labeling for approved NDA 50641/S-032**." Approval of this submission by FDA is not required before the labeling is used.

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 Carmen DeBellas, Chief Regulatory Project Manager, at 301-796-1203.

[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.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
- 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/

DMITRI IARIKOV
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