NDA 050649/S-028

SUPPLEMENT APPROVAL

Bausch Health US, LLC
Attention: Carla Sanders
Manager, Global Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Carla Sanders:

Please refer to your supplemental new drug application (sNDA) dated and received January 23, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Minocin (minocycline hydrochloride) capsules.

This Prior Approval sNDA provides for changes to the prescribing information (PI) as follows:

- **CLINICAL PHARMACOLOGY** section**, Microbiology** subsection**,**
  - Antimicrobial Activity subheading: *Enterobacter aerogenes* was renamed as *Klebsiella aerogenes*. Revised format for listing of organisms.
  - Susceptibility Testing subheading**:** Revised and updated with reference to https://www.fda.gov/STIC as per the Guidance for Industry: Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs.
- **INDICATIONS AND USAGE** section**:** *Enterobacter aerogenes* was renamed as *Klebsiella aerogenes*.
- **WARNINGS** section**, Use in Pregnancy subsection:** Added statement, "The safety of MINOCIN for use during pregnancy has not been established."
- **ADVERSE REACTIONS** section**, Post-Marketing Experience** subsection:
  - Added the statement"Skin and hypersensitivity reactions: Acute febrile neutrophilic dermatosis (Sweet's syndrome)"
  - At the end of the **ADVERSE REACTIONS** section, changed the contact information for reporting suspected adverse reactions to Bausch Health US, LLC
- **REFERENCES** section**:** Removed references to Clinical and Laboratory Standards Institute (CLSI) as per the Guidance for Industry, "Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria for Labeling for NDAs and ANDAs" at https://www.fda.gov/files/drugs/published/Systemic-Antibacterial-and-Antifungal-Drugs---Susceptibility-Test-Interpretive-Criteria-Labeling-for-NDAs-and-ANDAs.pdf

Minor editorial revisions were made throughout the PI.

The patient package insert (PPI) for Minocin capsules has been updated to align with the revisions made to the PI.

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 (text for the Prescribing Information and Patient Package Insert), 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).

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

[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.

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, call Alison Rodgers, Senior Regulatory Project Manager, at 301-796-0797.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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
07/18/2024 01:23:17 PM