



NDA 50445/S-031

**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 22, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Minocin (minocycline hydrochloride) oral suspension.

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 to place in alphabetical order.
- **INDICATIONS AND USAGE** section: *Enterobacter aerogenes* was renamed as *Klebsiella aerogenes*.
- **ADVERSE REACTIONS** section, **Post-Marketing Experience** subsection:
  - Added the statement, “The following adverse reaction has been identified during post-approval use of minocycline products when taken orally. Because this reaction is reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure”
  - 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
- Manufacturer and distributor changed from Valeant Pharmaceuticals North America, LLC to Bausch Health US, LLC.

Minor editorial revisions were made throughout 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.<sup>1</sup> 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 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*.<sup>2</sup>

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 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

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

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, 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:**

- Content of Labeling
  - Prescribing Information

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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.**

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/s/

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DMITRI IARIKOV  
07/18/2024 01:24:21 PM