

NDA 209481/S-024

SUPPLEMENT APPROVAL

Mylan Laboratories Limited
c/o Mylan Pharmaceuticals Inc., a Viatris Company
Attention: Amy Lynn Martin
Senior Director, Regulatory Affairs
3711 Collins Ferry Road
Morgantown, WV 26505

Dear Amy Lynn Martin:

Please refer to your supplemental new drug application (sNDA) dated and received December 21, 2023, and your amendments, submitted under section pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vancomycin Hydrochloride for injection.

We acknowledge receipt of your amendment dated April 26, 2024, which constituted a complete response to our April 18, 2024, action letter.

This resubmission provides for the addition of two new strengths (1.75 g/vial and 2 g/vial) to the approved application, revisions to the prescribing information (PI) as follows:

- Revisions to the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, and **FULL PRESCRIBING INFORMATION**. Specifically,
 - Under the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, the **RECENT MAJOR CHANGES** section and **DOSAGE FORMS AND STRENGTHS** section were updated to reflect changes made to subsequent sections 2.5, 3, and 11.
 - Under the **FULL PRESCRIBING INFORMATION**, the following revisions were made:
 - Under section **2 DOSAGE AND ADMINISTRATION**, subsection **2.5 Preparation of Vancomycin Hydrochloride for Injection for Intravenous Administration and Storage Instructions**, new strengths of 1.75 g and 2 g were added to Table 1.
 - Under section **3 DOSAGE FORMS AND STRENGTHS**, the new strengths of 1.75 g and 2 g were added.

- Under section **11 DESCRIPTION**, the equivalent amounts, 1.79 g and 2.05 g, of vancomycin hydrochloride, pertaining to the new strengths of 1.75 g and 2 g were added.
- Under section **16 HOW SUPPLIED/STORAGE AND HANDLING**, the new strengths of 1.75 g and 2 g were added and the National Drug Code (NDC) numbers for the new strengths of 1.75 g and 2 g were added.

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.

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).

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>.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling **and** submitted carton and container labeling, except with the minor revisions listed above [e.g., changes consistent with annual reportable changes under 314.70(d)], 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 Carton and Container Labeling for approved NDA 209481/S-024.**” Approval of this submission by FDA is not required before the labeling is used.

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, please contact Jennifer Grant, MSHS, Regulatory Project Manager, at jennifer.grant@fda.hhs.gov or (301) 796-0480.

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
- Carton and 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
06/26/2024 10:16:41 AM