NDA 212862/S-004

SUPPLEMENT APPROVAL

Mylan Ireland Limited
c/o Mylan Pharmaceuticals Inc., a Viatris Company
Attention: Robert Barto
Senior Director, Regulatory Affairs
3711 Collins Ferry Road
Morgantown, WV 26505

Dear Mr. Barto:

Please refer to your supplemental new drug application (sNDA) dated and received July 15, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pretomanid tablets, 200 mg.

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

- In the **INDICATIONS AND USAGE (1) section**, the approved indication statement that describes the patient population has been revised based on the resistance profile studied rather than providing the tuberculosis (TB) category definitions. Updates to reflect this change were made to the **ADVERSE REACTIONS (6)** section, **Clinical Trials Experience (6.1)** subsection, **CLINICAL PHARMACOLOGY (12)** section, **Pharmacokinetics (12.3)** subsection, **CLINICAL STUDIES (14)** section, and the **PATIENT COUNSELING INFORMATION (17)** section.
- The following sections/subsections of the PI have also been revised:
    - **DRUG INTERACTIONS (7)** section, **Effect of Pretomanid on Other Drugs (7.2)** subsection
    - **CLINICAL PHARMACOLOGY (12)** section, **Pharmacokinetics (12.3)** subsection, *In Vitro Studies Where Drug Interaction Potential Was Not Further Evaluated Clinically*
    - **NONCLINICAL TOXICOLOGY (13)** section, **Carcinogenesis, Mutagenesis, Impairment of Fertility (13.1)** subsection, Carcinogenesis
- Additionally, minor revisions have been made throughout the PI.

The medication guide (MG) was also updated to reflect the changes made to the PI as appropriate.

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- Dates in Highlights of the PI (Recent Major Changes and Revision Date) have been updated.
- Page numbers in the PI have been corrected.
- Revision Date at the end of the MG has been updated.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 Medication Guide), 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.

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, call Kristine Park, PhD, RAC, Senior Regulatory Health Project Manager, at (301) 796-0471.

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

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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
12/21/2022 08:07:04 AM