NDA 201688/S-010

SUPPLEMENT APPROVAL

Mylan Specialty, L.P.
Attention: Robert A. Barto
Senior Director, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown WV 26504-4310

Dear Mr. Barto:

Please refer to your supplemental new drug application (sNDA) dated May 17, 2019, received May 17, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TOBI PODHALER (tobramycin inhalation powder), 28 mg.

This Prior Approval supplemental application provides for revisions to the prescribing information (PI) to comply with the requirements of the Pregnancy and Lactation Labeling Rule (PLLR) [79 FR 233, December 4, 2014]. This supplement was submitted in response to the December 11, 2018, Agency Prior Approval Supplement request letter.

This Prior Approval supplement provides for revisions to the **HIGHLIGHTS OF PRESCRIBING INFORMATION** section, **WARNINGS AND PRECAUTIONS (5)** section, **Embryofetal Toxicity (5.5)** and **Concomitant Use of Systemic Aminoglycosides (5.6)** subsections, **USE IN SPECIFIC POPULATIONS (8)**, **Pregnancy (8.1)** and **Lactation (8.2)** subsections, and to the **PATIENT COUNSELING (17)** section.

In addition, the Patient Package Insert (PPI) and Instructions for Use (IFU) have been updated with the revisions made to the package insert (PI). Minor editorial revisions have also been made throughout the PI and PPI.

APPROVAL & LABELING

We have completed our review of this application, as amended and 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, Patient Package Insert, Instructions for Use), 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).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[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.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

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
  - Patient Package Insert
  - Instructions for Use

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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