

NDA 050814/S-023

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: April Given
Senior Manager, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Given:

Please refer to your supplemental new drug application (sNDA) dated May 14, 2019, received May 14, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cayston (aztreonam for inhalation solution).

This Prior Approval supplemental new drug application has been submitted in response to the Agency's letters dated December 11, 2018, requesting labeling changes to **USE IN SPECIFIC POPULATIONS (Section 8)** to comply with the Pregnancy and Lactation Rule (PLLR), and November 6, 2014, requesting an update to **Pharmacokinetics (subsection 12.3)** and **PATIENT COUNSELING INFORMATION (Section 17)**. Additionally, edits have been made to **HIGHLIGHTS OF PRESCRIBING INFORMATION, INDICATIONS AND USAGE (Section 1)** and **Development of Drug-Resistant Bacteria (subsection 5.4)**.

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, 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.

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

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).

If you have any questions, call Christopher L. Smith, PharmD, MPH, Regulatory Project Manager, at (301) 796-4851.

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
 - Instructions for Use

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>.

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
11/20/2019 01:05:06 PM