DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-814/S-007

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Marissa Braff, PhD
Senior Manager, Regulatory Affairs
199 East Blaine Street
Seattle, WA 98102

Dear Dr. Braff:

Please refer to your Supplemental New Drug Application (sNDA) dated December 12, 2011, received December 23, 2011, 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 proposes the following:

> Section 6.2 Postmarketing Experience – addition of RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS: Dyspnea
>
> Section 6.2 Postmarking Experience – addition of MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS: Arthralgia, Joint swelling

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text with the following being removed from the label.

> Section 6.2 Postmarketing Experience – addition of RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS: Dyspnea

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling test for package insert, 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 titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1023.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
09/24/2012