DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50814/ S-016

APPROVAL LETTER

Gilead Sciences, Inc.
Attention: Barbara Klarich
Senior Associate Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Klarich:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 2, 2015, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cayston® (aztreonam for inhalation solution).

This "Changes Being Effected in 30 Days" supplemental new drug application provides for the following change:

- Reduction of shelf-life of diluent from 48 to 36 months for Cayston (aztreonam for inhalation solution).

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LCDR Luz Rivera, Senior Regulatory Business Process Manager, at (301) 796-4013.

Sincerely,

Ramesh Raghavachari -S

Digitally signed by Ramesh Raghavachari -S
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Date: 2015.12.28 14:04:36 -05'00'

For:
Hasmukh Patel, Ph.D.
Division Director (Acting)
Division of Post Marketing Activities I
Office of Lifecycle Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research