DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50814/S-001

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Jennifer Stephens
Director, Regulatory Affairs
199 E. Blaine St.
Seattle, WA 98102

Dear Ms. Stephens:

Please refer to your Supplemental New Drug Application (sNDA) dated February 25, 2010, received February 25, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cayston® (aztreonam for inhalation solution).

We acknowledge receipt of your amendment dated August 12, 2010.

We have completed our review of this supplemental application, containing new labeling text for the inside lid of the 28-day carton. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on August 12, 2010.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the content of carton and container labeling submitted on August 12, 2010 as soon as they are available, but no more than 30 days after they are printed.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Kyong Hyon, Regulatory Project Manager, at (301) 796-0734.

Sincerely,

{See appended electronic signature page}

Katherine Laessig, M.D.
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50814	SUPPL-1	GILEAD SCIENCES INC	CAYSTON(AZTREONAM FOR INHALATION SOL)

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

/s/

KATHERINE A LAESSIG
08/20/2010