CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-814/S001

Trade Name: Cayston

Generic Name: aztreonam

Sponsor: Gilead

Approval Date: 08/20/2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-814/S001

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Reviews / Information Included in this NDA Review.

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Other Action Letters	
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Cross Discipline Team Leader Review	
Medical Review(s)	✓
Chemistry Review(s)	✓
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-814/S001

APPROVAL LETTER

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)

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/s/

KATHERINE A LAESSIG
08/20/2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-814/S001

LABELING

Car on Cay ton 28 Day Kit US Page 1 of 2
PART NO 4001005

PMS 193 Logo | PMS Coo G ay 11 ogo | PMS Cool Gray 11 (0%) | PMS 312 | B ack | arn sh Free for lear 2 n se l & g ue) (o ppear on p oof on y) | Die ine

Laser copy may appear darker than Pantone Matching System PMS) color standards
Please refer to PMS book and/or approved color standa d

CAD# 169C
D MENSIONS 12 1/2" x 5 3/16" x 3 7/32"
DATE 09 DEC 2010
PROOF # 1

GILEAD

NDC 61958 0901 1

Cayston®

(aztreonam for inhalation solution)

75 mg/vial

For Oral Inhalation Only

Store Refrigerated, 2 °C to 8 °C (36 °F to 46 °F)

Contains:
84 S ngle Use Vials of Aztreonam for Inhalation Solution
88 Diluent Ampules of Sodium Chloride 0 17% 1 mL
(4 extra ampules provided in case of sp llage)

For use only with the Altera® Nebulizer System

28-Day Supply

℞ only

GILEAD

NDC 61958 0901 1

GILEAD

NDC 61958 0901 1

Cayston®

(aztreonam for inhalation solution)

75 mg/vial

For Oral Inhalation Only

Store Refrigerated, 2 °C to 8 °C (36 °F to 46 °F)

Contains:
84 Single Use Vials of Aztreonam for Inhalation Solution
88 Diluent Ampules of Sodium Chloride 0 17% 1 mL
(4 extra ampules provided in case of spillage)

For use only with the Altera® Nebulizer System

28-Day Supply

℞ only

GILEAD

NDC 61958 0901 1

Cayston®

(aztreonam for inhalation solution)

75 mg/vial

For Oral Inhalation Only

GILEAD

Contents Includes 84 sterile single use vials of CAYSTON® and 88 ster le ampules of d luent for reconstitution Each vial conta ns 75 mg aztreonam and 46 7 mg lys ne lyophilized Each d luent ampule contains 1 mL of 0 17% sodium chloride solut on

Dosage and Administration Each 75 mg dose consists of one v al of CAYSTON reconstituted with one ampule of diluent Reconstituted solution must be used immed ately For oral inhalation use only

Storage CAYSTON v als and diluent ampules should be stored in the refrigerator at 2 °C to 8 °C (36 °F to 46 °F) until expiration date is reached or at room temperature (up to 25 °C/77 °F) for up to 28 days Do not separate the CAYSTON v als f om the d luent ampules

See package insert for dosage and administration

4001005

Manufactured for
Gilead Sc ences Inc
Foster City CA 94404

Cayston®
(aztreonam for
inhalation solution)

Important information about using CAYSTON®

Enclosed is:

- Your 28 day supply of CAYSTON treatment
- Your 28 day supply of diluent for CAYSTON

There are 4 trays holding 7 days of CAYSTON treatment each **for a total of 84 vials of CAYSTON** Also there are 2 trays holding 14 days of di uent each plus 4 extra ampu es of diluent in case of spi lage **for a total of 88 ampules of diluent**

How should I take CAYSTON?

You should take a CAYSTON **dose** three (3) times a day at least four (4) hours apart as d rected by your physician **Each dose consists of one vial of CAYSTON mixed with one ampule of diluent to be adm nistered with the Altera® Nebulizer System** Be sure to take your full 28 day course of treatment with CAYSTON in order to obtain the full treatment effect

How should I store CAYSTON?

- A ways keep your CAYSTON and sa ine together
- Store CAYSTON and sal ne n the refrigerator at 2 °C to 8 °C (or 36 °F to 46 °F) unt l needed
- f refrigeration is not ava lab e (for example during the school or work day or when travel ng) CAYSTON may be stored at room temperature (up to 25 °C/77 °F) for up to 28 days Do not use any CAYSTON that has been stored at room temperature for more than 28 days
- Keep CAYSTON away from l ght
- Do not use CAYSTON after the expiration date on the vial
- Do not use the saline d luent after the exp ration date on the ampule
- Mix (reconstitute) CAYSTON with the sal ne only when ready to take a dose Use CAYSTON right away after you mix with the sa ine Do not mix more than one dose of CAYSTON at a t me

---

NOTE: Please review the enclosed FDA Approved Patient Labeling for CAYSTON insert carefu ly before you or the person in your care start taking CAYSTON Also please refer to the manufactu er's instruct ons for use provided w th your A tera Nebulizer System for complete details on the assembly preparation use and care of your A tera Nebulizer System

If you need add tional informat on or have other questions please call 1 877 7CAYSTON (1 877 722 9786)

Car on Cay ton 28 Day Kit US Inside Lid Prin ing Page 2 of 2
PART NO 4001005

PMS Cool G ay 11

D e ine
(to appear on p oof only)

Laser copy may appear darker than Pantone Matching System PMS) color standard
Please refer to PMS book and/or approved color standa d

CAD# 169C (Reverse)
D MENSIONS 12 1 2" x 5 3/16" x 3 7 32"
DATE 09 DEC 2010
PROOF # 1

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-814/S001

MEDICAL REVIEW(S)

Medical Officer Review of Labeling Supplement
NDA 050814/S-001

Sponsor:	Gilead Sciences, Inc. 199 East Blaine Street Seattle, WA 98102
Regulatory Contact:	Jennifer Stephens (206) 792-3020
Trade Name:	CAYSTON
Generic Name:	Aztreonam for Inhalation Solution
Drug Class:	Aminoglycoside Antibacterial
Date of Submission:	February 25, 2010 (SDN #060)

Background

CAYSTON, aztreonam for inhalation solution (AZLI), was approved in Feb. 2010 for the treatment of respiratory symptoms in cystic fibrosis (CF) patients colonized with *Pseudomonas aeruginosa.* Safety and effectiveness have not been established for patients <7 years old and for patients with an FEV1 % predicted <25% or >75%. On Feb. 24, 2010, the sponsor submitted proposed labeling for its 28 day carton (inside lid of carton). The labeling focuses on description of contents, instructions for use, and storage information. This document represents a review of the proposed labeling as well as recommended changes.

Proposed Labeling

1. Carton Labeling Column #1

Medical Reviewer Comments: Overall, the sponsor's proposal is acceptable. However, further specification of the quantity of vials and ampules in each carton might be helpful to the patient. The MO recommends that the text be revised as follows:

Important information about using CAYSTON®

Enclosed is:

- your 28 day supply of CAYSTON treatment
- your 28 day supply of diluent for CAYSTON.

There are 4 trays holding 7 days of CAYSTON treatment each **for a total of 84 vials of CAYSTON**. Also, there are 2 trays holding 14 days of diluent each, plus 4 extra ampules of diluent in case of spillage, **for a total of 88 ampules of diluent**.

1a. Carton labeling Column #1 (continued)

How should I take CAYSTON?

Medical Reviewer Comments: Overall, the sponsor's proposal is acceptable. However, it would be helpful to specify to the patient what exactly constitutes one dose. The MO recommends that the labeling text be revised as follows:

How should I take CAYSTON?

You should take a CAYSTON **dose** three (3) times a day at least four (4) hours apart as directed by your physician. **Each dose consists of one vial of Cayston mixed with one ampule of diluent**. Be sure to take your full 28-day course of treatment with CAYSTON in order to obtain the full treatment effect.

2. Carton Labeling Column # 2

(b) (4)

(b) (4)

Medical Reviewer Comments: We would recommend removing this section as it is self-evident and is overly promotional.

4. Carton Labeling Column # 3

How should I store CAYSTON?

(b) (4)

Medical Reviewer Comments: This proposal might be somewhat confusing to the patient. We would avoid using terms such as (b) (4) ***that may be difficult for patients to understand, particularly children. We would recommend using language similar to that contained in the current label (shown below)***:

How should I store CAYSTON?

- Always keep your CAYSTON and saline together
- Store CAYSTON and saline in the refrigerator at 36 ° F to 46° F (or 2° C to 8° C) until needed
- When you remove CAYSTON and saline from the refrigerator they may be stored at room temperature (up to 77° F) for up to 28 days. Do not use any CAYSTON that has been stored at room temperature for more than 28 days.
- Keep CAYSTON away from light
- Do not use CAYSTON after the expiration date on the vial
- Do not use the saline diluent after the expiration date on the ampule
- Mix (reconstitute) CAYSTON with the saline only when ready to take a dose. Use CAYSTON right away after you mix with the saline. Do not mix more than one dose of CAYSTON at a time

Carton Labeling Note below Columns 2 and 3:

NOTE: Please review the enclosed FDA-Approved Patient Labeling for CAYSTON insert carefully before you or the person in your care start taking CAYSTON. Also, please refer to the manufacturer's instructions for use provided with your AlteraNebulizer System for complete details on the assembly, preparation, use and care of your Altera Nebulizer System.

If you need additional information or have other questions, please call 1-877-7CAYSTON (1-877-722-9786).

Medical Reviewer Comments: The sponsor's proposal is acceptable.

Medical Officer Recommendations:

The sponsor's proposed labeling is overall acceptable provided the revisions outlined above are made. These recommendations should be conveyed to the sponsor.

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

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/s/

SHRIMANT MISHRA
07/20/2010
Changes made

JOHN J ALEXANDER
07/21/2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-814/S001

CHEMISTRY REVIEW(S)

Chemistry Review # 1	**1. Division:** HFD-520	**2. NDA Number:** 50-814

3. Name and Address of Applicant:
Gilead Sciences
2025 East 1st avenue, Suite PH
Seattle, WA 98121

4. Supplement(s):
Number: SLR-001
Date(s): February 24, 2010

5.Name of Drug:
Cayston

6. Nonproprietary name:
Aztreonam for inhalation solution

7. Supplement Provides for: Revised Drug Substance Test Method, Draft Labeling

8. Amendment(s):
None

9. Pharmacological Category:
Synthetic, monocyclic beta-lactam antibacterial

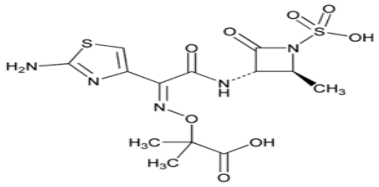
10. How Dispensed:
℞

11. Related Documents:
None

12. Dosage Form:
For inhalation solution

13. Potency: 75 mg aztreonam/vial; diluted with 1 mL sodium chloride, 0.17% w/v diluent

14. Chemical Name and Structure: Aztreonam: (1) Propanoic acid, 2-[[[1-(2-amino-4-thiazolyl)-2-[(2-methyl-4-oxo-1-sulfo-3-azetidinyl)amino]-2-oxoethylidene]amino]oxy]-2-methyl-, [2S-[2⟨,3®(Z)]]-;
$C_{13}H_{17}N_5O_8S_2$, M.W. 435.43



15. Comments: This supplement is for revision and validation of the Organic Volatile Impurity (OVI) test procedure for (b) (4) determination of (b) (4 (b) (4) contents. The proposed revision is for improved performance of the method.

The supplement also contains new labeling text for the inside lid of the 28 days carton providing important information for administration and storage of Cayston drug product. The new labeling text was submitted to the Medical Officer (MO) in Division HFD-520 for evaluation, the MO, Dr. Mishra, recommended text revisions as a result of his evaluation.

A new corporate address for Gilead and updated contactfor NDA 58-814 is included in this submission. That is:

Gilead Sciences, Inc.
333 Lakeside Drive, Building 300
Foster City, CA 94404
Contact: Carla Fiankan
Associate Director, Regulatory Affairs, CMC
Carla.Fiankan@gilead.com
Phone: 650-522-5393
Fax: 650-522-5816

Batch analysis of six lots of Aztreonam drug substance was conducted using the revised GC analytical method for (b) (4) among the methods for analysis. The results provided indicate that the batches analyzed conform with the acceptance criteria and that the revised analytical method is suitable for its intended

purpose.

16. Conclusions and Recommendations: The validation data demonstrates that the proposed, revised method is suitable for its intended purposes, from the CMC point of view this supplement is recommended for approval. However, the clinical review of the labeling changes recommends some revisions to the proposed labeling, therefore, the final recommendation for this supplements is for a complete response (CR) letter.

17. Name: **Signature:** **Date:**
Libaniel Rodriguez, Ph.D., Review Chemist

18. Concurrence: **Signature:** **Date:**
Hasmukh Patel, Ph.D., Branch Chief ONDQA VIII

___6___ Page (s) Withheld

_✓___ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry#1 -50-814/S001

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

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/s/

LIBANIEL RODRIGUEZ
06/23/2010

HASMUKH B PATEL
06/23/2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-814/S001

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

From: Jennifer Stephens [jennifer.Stephens@gilead.com]
Sent: Wednesday, August 11, 2010 4:43 PM
To: Hyon, Kyong
Subject: RE: Labeling Proposal and comments for NDA 50814, submission dated 24Feb10

Thanks Kyong! We will get the formal submission out as soon as possible.

Best regards,
Jennifer

-----Original Message-----
From: Hyon, Kyong [mailto:Kyong.Hyon@fda.hhs.gov]
Sent: Wednesday, August 11, 2010 1:16 PM
To: Jennifer Stephens
Subject: RE: Labeling Proposal and comments for NDA 50814, submission dated 24Feb10

Hi Jennifer,

We accept your proposed changes to our proposals. Please submit it formally as an amendment to the labeling supplement submitted on February 25, 2010.

Thanks! ---- Kyong

-----Original Message-----
From: Jennifer Stephens [mailto:jennifer.Stephens@gilead.com]
Sent: Tuesday, August 10, 2010 11:23 PM
To: Hyon, Kyong
Subject: RE: Labeling Proposal and comments for NDA 50814, submission dated 24Feb10
Importance: High

Hi Kyong,

The Gilead team accepted all the changes requested by the Division, and we proposed a few additional edits. I have attached a track change Word version of our proposed edits, as well as a PDF file of the layout of the text on the inside lid of the carton. If the Division is in agreement with our proposed changes, we will send the PDF file to the NDA in a formal submission.

WORD version:

Important information about using CAYSTON®

Enclosed is:

- Your 28 day supply of CAYSTON treatment
- Your 28 day supply of diluent for CAYSTON

There are 4 trays holding 7 days of CAYSTON treatment each **for a total of 84 vials of CAYSTON**. Also, there are 2 trays holding 14 days of diluent each, plus 4 extra ampules of diluent in case of spillage, **for a total of 88 ampules of diluent**.

How should I take CAYSTON?

You should take a CAYSTON **dose** three (3) times a day at least four (4) hours apart as directed by your physician. **Each dose consists of one vial of Cayston mixed with one ampule of diluent to be administered with the Altera® Nebulizer System**. Be sure to take your full 28-day course of treatment with CAYSTON in order to obtain the full treatment effect.

How should I store CAYSTON?

- Always keep your CAYSTON and saline together.
- Store CAYSTON and saline in the refrigerator at 36 °F to 46 °F (or 2 °C to 8 °C) until needed.
- If refrigeration is not available (for example, during the school or work day, or when traveling), ~~When you remove~~ CAYSTON ~~and saline from the refrigerator they~~ may be stored at room temperature (up to 25 °C/77 °F) for up to 28 days. Do not use any CAYSTON that has been stored at room temperature for more than 28 days.

- Keep CAYSTON away from light.
- Do not use CAYSTON after the expiration date on the vial.
- Do not use the saline diluent after the expiration date on the ampule.
- Mix (reconstitute) CAYSTON with the saline only when ready to take a dose. Use CAYSTON right away after you mix with the saline. Do not mix more than one dose of CAYSTON at a time.

NOTE: Please review the enclosed FDA-Approved Patient Labeling for CAYSTON insert carefully before you or the person in your care start taking CAYSTON. Also, please refer to the manufacturer's instructions for use provided with your Altera Nebulizer System for complete details on the assembly, preparation, use and care of your Altera Nebulizer System.

If you need additional information or have other questions, please call 1-877-7CAYSTON (1-877-722-9786).

Please let me know if you have any questions.

Best regards,
Jennifer

_____

From: Hyon, Kyong [Kyong.Hyon@fda.hhs.gov]
Sent: Wednesday, August 04, 2010 12:11 PM
To: Jennifer Stephens
Subject: RE: Labeling Proposal and comments for NDA 50814, submission dated 24Feb10

Hello Ms. Stephens,

Based on our review of your Labeling Supplement submitted on February 25, 2010, we are proposing the following labeling text changes for the inside lid of the 28-day carton for Cayston® (aztreonam for inhalation solution), NDA 50814:

1. Carton Labeling Column #1

Division Comment: Overall, your proposal is acceptable. However, further specification of the quantity of vials and ampules in each carton might be helpful to the patient. Therefore, we recommend that the text be revised as follows:

Important information about using CAYSTON®
Enclosed is:

* your 28 day supply of CAYSTON treatment
* your 28 day supply of diluent for CAYSTON.

There are 4 trays holding 7 days of CAYSTON treatment each for a total of 84 vials of CAYSTON. Also, there are 2 trays holding 14 days of diluent each, plus 4 extra ampules of diluent in case of spillage, for a total of 88 ampules of diluent.

1a. Carton labeling Column #1 (continued)

How should I take CAYSTON?

(b) (4)

Division Comment: Overall, your proposal is acceptable. However, it would be helpful to specify to the patient what exactly constitutes one dose. Therefore, we recommend that the labeling text be revised as follows:

How should I take CAYSTON?
You should take a CAYSTON dose three (3) times a day at least four (4) hours apart as directed by your physician. Each dose consists of one vial of Cayston mixed with one ampule of diluent. Be sure to take your full 28-day course of treatment with CAYSTON in order to obtain the full treatment effect.

2. Carton Labeling Column # 2

(b) (4)

Division Comment: We would recommend removing this section as it is self-evident and is overly promotional.

4. Carton Labeling Column # 3

How should I store CAYSTON?

Division Comment: This proposal might be somewhat confusing to the patient. We would avoid using terms such as (b) (4) that may be difficult for patients to understand, particularly children. We would recommend using language similar to that contained in the current label (shown below):

How should I store CAYSTON?

* Always keep your CAYSTON and saline together
* Store CAYSTON and saline in the refrigerator at 36 ° F to 46° F (or 2° C to 8° C) until needed
* When you remove CAYSTON and saline from the refrigerator they may be stored at room temperature (up to 77° F) for up to 28 days. Do not use any CAYSTON that has been stored at room temperature for more than 28 days.
* Keep CAYSTON away from light
* Do not use CAYSTON after the expiration date on the vial
* Do not use the saline diluent after the expiration date on the ampule
* Mix (reconstitute) CAYSTON with the saline only when ready to take a dose. Use CAYSTON right away after you mix with the saline. Do not mix more than one dose of CAYSTON at a time

Best regards,
Kyong Hyon, CDR
Regulatory Project Manager
Food and Drug Administration (CDER)
Division of Anti-Infective Ophthalmology Products, HFD-520
10903 New Hampshire Ave.
BLDG #22/Room 6345
Silver Spring, MD 20993-0002
Tel: 301-796-0734
Fax: 301-796-9881
kyong.hyon@fda.hhs.gov
Please note: My e-mail address is now kyong.hyon@fda.hhs.gov. If you have a different address, please change it.

__1__ Page (s) Withheld

____ Trade Secret / Confidential (b4)

__✓__ Draft Labeling (b4)

____ Draft Labeling (b5)

____ Deliberative Process (b5)

Withheld Track Number: Administrative-50-814s001

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

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/s/

KYONG M HYON
08/18/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-814/S-001 **PRIOR APPROVAL SUPPLEMENT**

Gilead Sciences, Inc.
Attention: Jennifer Stephens
Director, Regulatory Affairs
2025 1st Street, Suite PH
Seattle, WA 98121

Dear Ms. Stephens:

We have received your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Cayston (aztreonam for inhalation solution)
NDA Number:	50-814
Supplement number:	001
Date of supplement:	February 24, 2010
Date of receipt:	February 24, 2010

This supplemental application proposes the following: revision of the organic volatile impurity (OVI) test procedure for (b) (4) that includes provision for determining (b) (4) content (unspecified OVI).

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on April 25, 2010, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be June 24, 2010.

Please cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-infective and Ophthalmology Products

5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have questions, call me at (301) 796-4061.

Sincerely,

{See appended electronic signature page}

Althea Cuff
Regulatory Health Project Manager
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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)

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/s/

ALTHEA CUFF
03/12/2010