DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-578/S-053
50-634/S-020

GlaxoSmithKline
Attention: Edward N. Yuhas, PhD
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Dr. Yuhas:

Please refer to your supplemental new drug applications dated January 10, 2007, received January 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

- FORTAZ® (ceftazidime for injection) 0.5g, 1g, and 2g IM/IV vials 1g, 2g, and 6g IV infusion vials, and 1g and 2g ADD-Vantage® vials (NDA 50-578/S-053)

- FORTAZ® (ceftazidime sodium) Injection in 50 mL premixed frozen IV solution (NDA 50-634/S-020)

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected" supplemental new drug applications provide for Revisions to the prescribing information to address recent epidemiologic and scientific data that indicate that outbreaks of a highly virulent strain of *Clostridium difficile* have emerged in various health care facilities. In particular, this will involve changes to the **WARNINGS** and **PRECAUTIONS** sections of the FORTAZ® prescribing information.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling submitted January 10, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplement NDAs 50-578/S-053, and 50-634 S-020**." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 J. Christopher Davi, MS Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted January 10, 2007

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

/s/

Janice Soreth

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