DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-578/S-042
NDA 50-634/S-014

GlaxoSmithKline
Attention: Anne N. Stokley, M.S.P.H.
Director, Antiviral/Antibacterial Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Stokley:

Please refer to your supplemental new drug applications dated March 9, 2001, received March 12, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fortaz® (ceftazidime sodium injection) (NDA 50-578/S-042) and Fortaz® (ceftazidime for injection) (NDA 50-634/S-014). We note that 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 the addition of "jaundice" to the **Observed During Clinical Practice, Hepatobiliary Tract and Pancreas** subsection of the **ADVERSE REACTIONS** section.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted March 9, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 LTJG Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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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