



NDA 50-578/S-046

NDA 50-634/S-016

Glaxo Group Limited  
c/o GlaxoSmithKline  
Attention: Anne N. Stokley, M.S.P.H.  
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 October 15, 2003, received October 16, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fortaz<sup>®</sup> (ceftazidime for injection), NDA 50-578/S-046 and Fortaz<sup>®</sup> (ceftazidime sodium injection), NDA 50-634/S-016. 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 supplemental applications, submitted as "Supplement - Changes Being Effected in 0 days," proposes the following change to be in compliance with the "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" Final Rule, as published in the Federal Register, Vol. 68, No. 25, February 6, 2003. In addition, the generic name will be updated to comply with the official monograph as published in the USP.

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 16, 2003.

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.

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If you have any questions, call LT 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

Enclosure: labeling

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/s/

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Janice Soreth  
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