DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-672/S-025
NDA 50-605/S-039

GlaxoSmithKline
Attention: Edward Yuhas, Ph.D.
Senior Director, U.S. Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Yuhas:

Please refer to your supplemental new drug applications dated December 16, 2003, received December 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ceftin® (cefuroxime axetil) for Oral Suspension (NDA 50-672/S-025) and Ceftin® (cefuroxime axetil) Tablets (NDA 50-605/S-039). 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 label was updated for (b)(4)-------- -------- (b)(4)---------- -- -------- -

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 December 17, 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.

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

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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