DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-605/S-042

GlaxoSmithKline
Attention: Edward M. Yuhas, PhD
Senior Director, US Regulatory Affairs
One Franklin Plaza
PO Box 7929
Philadelphia, PA 1901-7929

Dear Dr. Yuhas,

Please refer to your supplemental new drug application dated February 1, 2007 received February 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CEFTIN® (cefuroxime axetil tablets), 125 mg, 250 mg, and 500 mg.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental application provides for revisions to the **WARNINGS** and **PRECAUTIONS** sections of the CEFTIN® prescribing information to address recent epidemiologic and scientific data regarding outbreaks of highly virulent strains of *C. difficile* in health care facilities.

We completed our review of this application and it is 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 February 1, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-605/S-042**." Approval of this submission 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 on February 1, 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

7/23/2007 07:10:10 PM