



NDA 50-461/S-135

GlaxoSmithKline
Attention: Debra Hackett
U.S. Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Ms. Hackett:

Please refer to your supplemental new drug application dated December 3, 2001, received December 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ancef[®] (cefazolin) Injection. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated August 16, 2002, December 18, 2002, and June 16, 2003. Your submission of June 16, 2003, constituted a complete response to our February 25, 2003, action letter.

This "Changes Being Effected" supplemental new drug application provides updated safety information related to hepatic and renal events associated with treatment with cefazolin, in order to align the U.S. labeling in line with the Core Safety Information of Ancef labeling globally. In addition, information referring to the 500 mg conventional vials and the ANCEF GALAXY[®] container has been deleted from the **DESCRIPTION, DOSAGE AND ADMINISTRATION**, and **HOW SUPPLIED** sections of the label.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-461/S-135." Approval of this submission by FDA is not required before the labeling is used.

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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