DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-461/S-138

GlaxoSmithKline
Attention: Debra Hackett
Associate Director, Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Ms. Hackett:

Please refer to your supplemental new drug application dated January 27, 2004, received January 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ANCEF® (cefazolin for injection) Intravenous. 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 also acknowledge receipt of your submission dated March 26, 2004, received March 29, 2004, which constituted a complete response to the Agency's request of March 18, 2004.

These "Changes Being Effected" supplemental new drug applications provide revisions that address the requirements of the Final Labeling Rule for Systemic Antibacterial Drug Products Intended for Human Use (68 FR 6062, February 6, 2003) and additional minor labeling changes.

We completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-461/S-138." Approval of this submission by FDA is not required before the labeling is used.

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 J. Christopher Davi, Regulatory Project Manager, at (301) 827-2217.

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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