DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-590/S-040
NDA 50-658/S-009

GlaxoSmithKline
Attention: Deneen Stewart, Ph.D.
Senior Regulatory Associate
One Franklin Plaza
Philadelphia, Pennsylvania 19101-7929

Dear Dr. Stewart

Please refer to your supplemental new drug applications dated September 1, 2000, received September 6, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

> Timentin (sterile ticarcillin disodium and clavulanate potassium) Injection, NDA 50-590; and Timentin (sterile ticarcillin disodium and clavulanate potassium) Galaxy Plastic Container, NDA 50-658.

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.

These supplemental new drug applications provide for revisions to the **ADVERSE REACTIONS** section of the package insert. Specifically, the **Hypersensitivity Reactions** subsection now includes **erythema multiforme, toxic epidermal necrolysis** and **Stevens-Johnson Syndrome.**

We have completed the review of these supplemental applications, 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 labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

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 Susmita Samanta, M.D., 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

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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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