DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-590/S-055
NDA 50-658/S-021

GlaxoSmithKline
Attention: Deneen Stewart, Ph.D.
Associate Director, US Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Stewart:

Please refer to your supplemental new drug applications dated August 31, 2006, received August 31, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TIMENTIN® (sterile ticarcillin disodium/clavulanate potassium) I.V. Administration and Pharmacy Bulk Pack (NDA 50-590/S-055), and TIMENTIN® Galaxy™ (PL2040) Plastic Container (sterile ticarcillin disodium/clavulanate potassium) (NDA 50-658/S-021). 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 "Changes Being Effected" supplemental new drug applications provide for the addition of text regarding the potential interaction between antibiotics and oral contraceptives in the "PRECAUTIONS" section of the label.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on August 31, 2006.

We note that your August 31, 2006 submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Susmita Samanta, MD, Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, M.D.
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on August 31, 2006

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kathrine Laessig
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