



NDA 50-590/S-054
NDA 50-658/S-020

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 June 27, 2006, received July 3, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TIMENTIN[®] (sterile ticarcillin disodium/clavulanate potassium) Injection (NDA 50-590/S-054), and TIMENTIN[®] Galaxy[™] (PL2040) Plastic Container (sterile ticarcillin disodium/clavulanate potassium) (NDA 50-658/S-020). These applications are 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 February 1, 2007.

These supplemental applications provide for a Geriatric Use subsection in the labeling for TIMENTIN in accordance with 21 CFR 201.57 (f)(10).

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the labeling submitted on February 1, 2007.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Susmita Samanta, MD, Regulatory Project Manager, at (301) 796-1400.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.

Director

Division of Anti-Infective and Ophthalmology Products

Office of Antimicrobial Products

Center for Drug Evaluation and Research

Attachment

**This is a representation of an electronic record that was signed electronically and
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/s/

Janice Soreth
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