



NDA 50-658/S-023
NDA 50-590/S-058
NDA 50-590/S-059

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Edward M. Yuhas, Ph.D.
Senior Director, Regulatory Affairs, Antibacterials
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Yuhas:

Please refer to your Supplemental New Drug Applications (sNDA) dated September 22 (NDA 50-590/S-058), September 23 (NDA 50-590/S-059), and September 25 (NDA 50-658/S-023), 2008, received September 22, September 23, and September 25, 2008, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TIMENTIN (sterile ticarcillin disodium and clavulanate potassium) for Intravenous Administration and Pharmacy Bulk Package (NDA 50-590) and TIMENTIN Galaxy (PL2040) Plastic Container (sterile ticarcillin disodium and clavulanate potassium) (NDA 50-658).

We acknowledge receipt of your amendments dated December 17, 2010.

These "Changes Being Effected" supplemental new drug applications propose to add "hemorrhagic cystitis" to the ADVERSE REACTIONS section.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We request that the labels approved today be available on your website within 10 days of receipt of this letter.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that are identical to the enclosed labels (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any annual reportable changes not included in the enclosed labels. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

<http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in these supplemental applications.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about these drug products (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter(s), an electronic copy of the letter to these NDAs to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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 Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling (3 labels)

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

/s/

KATHERINE A LAESSIG
12/20/2010