



NDA 50-590/S-061
NDA 50-590/S-060
NDA 50-658/S-024

SUPPLEMENT APPROVAL

Glaxo Group Limited d/b/a GlaxoSmithKline
Attention: Edward M. Yuhas, Ph.D.
Senior Director, US Regulatory Affairs, Antibacterials
One Franklin Plaza
Philadelphia, PA 19101

Dear Dr. Yuhas:

Please refer to your Supplemental New Drug Applications (sNDAs) dated January 27, 2009 [NDA 50-590/S-061], January 28, 2009 [NDA 50-590/S-060] and January 29, 2009 [NDA 50-658/S-024], submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

- NDA 50-590/S-061 - Timentin (sterile ticarcillin disodium and clavulanate potassium) for Intravenous Administration
- NDA 50-590/S-060 - Timentin (sterile ticarcillin disodium and clavulanate potassium) for Intravenous Administration Pharmacy Bulk Package (PBP)
- NDA 50-658/S-024 – Timentin Galaxy (PL2040) Plastic Container (sterile ticarcillin disodium and clavulanate potassium)

These “Prior Approval” supplemental new drug applications provide for revisions to the quality control parameters for *Escherichia coli* ATCC 35218. This submission is in response to the Agency’s letter of January 6, 2008, requesting review of the *in vitro* susceptibility test interpretive criteria (breakpoints) and quality control (QC) parameters for the *in vitro* susceptibility testing of organisms listed in the package insert.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the labels submitted on January 27, 28, & 29, 2009 [copies attached].

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content

of labeling must be identical to the submitted labeling (text for the package inserts), with the addition of any labeling changes approved since the time of submission of this supplement, as well as those in pending “Changes Being Effected” (CBE) supplements along with any annual reportable changes.

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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 regarding these supplements, call Maureen Dillon-Parker, Chief, Project Management Staff at (301) 796-0706. For all other issues regarding these NDAs, please contact Susmita Samanta, M.D., Senior Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumati Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Attachment(s): Content of labeling
- Timentin IV
- Timentin PBP
- Timentin in Galaxy Plastic Container Label

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

/s/

SUMATHI NAMBIAR
06/09/2011