



NDA 50-605/S-043 & S-046

SUPPLEMENT APPROVALS

Glaxo Group Limited
d/b/a GlaxoSmithKline
Attention: Willa B. Phyll, PhD
Senior Director, US Regulatory Affairs
2301 Renaissance Boulevard, Mail Code 0420
King of Prussia, PA 19406

Dear Dr. Phyll:

Please refer to your Supplemental New Drug Applications (sNDA) dated January 19, 2009, received January 20, 2009 (S-043), and submitted December 6, 2013, received December 6, 2013 (S-046), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CEFTIN (cefuroxime axetil) Tablets, 125, 250 and 500 mg.

We also acknowledge receipt of your amendments dated July 25, 2012 (S-043), and September 10, 2014 (S-043 and S-046). The July 25, 2012, submission constituted a complete response to our August 10, 2011, action letter for S-043.

These "Prior Approval" supplemental new drug applications provide for the following:

- **S-043:** Updates to the interpretive criteria and quality control parameters for *in vitro* susceptibility testing of the organisms listed in the package insert.
- **S-046:** Updates to the microbiology and renal impairment subsections of the package insert as well as minor editorial changes.

APPROVAL & LABELING

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

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 enclosed labeling with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, 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 this supplemental application, 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, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved Labeling

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
09/20/2014