DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-605/S-048
NDA 50-672/S-034

SUPPLEMENT APPROVALS

GlaxoSmithKline
Attention: Linda Rebar, Director, Global Regulatory Affairs
Mail Code RN 0420
2301 Renaissance Boulevard
King of Prussia, PA 19301

Dear Ms. Rebar:

Please refer to your Supplemental New Drug Applications (sNDAs) dated July 8, 2015, received July 8, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- CEFTIN (cefuroxime axetil) Tablets, 125 mg, 250 mg and 500 mg
- CEFTIN (cefuroxime axetil powder for oral suspension) 125 mg/5mL and 250 mg/5mL

These supplemental applications, submitted as "Changes Being Effected", provide for corrections to Table 4, titled 'Dosing in Adults with Renal Impairment', to reinstate text that was inadvertently omitted from the final labeling when NDA 50-605/S-046 and NDA 50-672/S-032 (Physician's Labeling Rule conversions) were approved on June 26, 2015.

APPROVAL & LABELING

We have completed our review of these supplemental applications and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below:

- A horizontal line separating **HIGHLIGHTS** from the **Table of Contents** has been added in accordance with 21CFR 201.57(d)(2). The Revision Date at the end of the Highlights has been updated to read 8/2015.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 revisions described above and 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes 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, 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: Content of 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
08/26/2015