DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-605/S-049
NDA 50-672/S-035

SUPPLEMENT APPROVALS

GlaxoSmithKline
Attention: Linda Rebar
Director, Global Regulatory Affairs
1250 South Collegeville Road
P.O. Box 5089, Mail Code UP4400
Collegeville, PA 19426-0989

Dear Ms. Rebar:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 20, 2016, received October 20, 2016, 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 [NDA 50-605]
- CEFTIN (cefuroxime axetil powder for oral suspension) 125 mg/5mL and 250 mg/5mL [NDA 50-672]

These "Prior Approval" supplemental new drug applications provide for removal of the indication Secondary Bacterial Infections of Acute Bronchitis (SBIAB) from the **INDICATIONS AND USAGE**, **DOSAGE AND ADMINISTRATION, ADVERSE REACTIONS** and **CLINICAL STUDIES** sections of the package insert. These revisions have been submitted in response to the Agency's October 3, 2016, Prior Approval Supplement Request letter.

These revisions are necessary to furnish information needed for the safe use of these drugs, as the Agency no longer grants the indication of SBIAB.

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 RECENT MAJOR CHANGES subsection is to be added to the HIGHLIGHTS OF PRESCRIBING INFORMATION Section, per § 21 CFR 201.57 (a)(5).

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 editorial revision listed 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 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: 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
11/22/2016