



NDA 50-605/S-051
NDA 50-672/S-037

SUPPLEMENT APPROVAL

GlaxoSmithKline
c/o GlaxoSmithKline Intellectual Property (no.2) Ltd. England
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 June 8, 2018, received June 8, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- CEFTIN (cefuroxime axetil) tablets 250 mg and 500 mg [NDA 50-605]
- CEFTIN (cefuroxime axetil) for oral suspension 125 mg/5 mL and 250 mg/5 mL [NDA 50-672]

These supplemental applications propose revisions to the prescribing information (PI) in order to comply with the requirements of the Pregnancy and Lactation Labeling Rule (PLLR) [21 CFR 201.57(c)(9)(i) through (iii)]. Additionally, the PI has been revised in accordance with section 3044 of the 21st Century Cures Act (511A FD&C Act) and the Agency letter of February 8, 2018, regarding the susceptibility test interpretive criteria and associated test methods and quality control standards. Minor editorial changes have also been made throughout the PI.

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 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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}

Dmitri Iarikov, MD, PhD
Deputy 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
04/25/2019 10:40:31 AM