



NDA 50-605-S-052  
NDA 50-672-S-038

## 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 (sNDA) dated and received February 24, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA	Product Name	Dosage form
NDA 50605 - S-052	CEFTIN (cefuroxime axetil) tablets	250 mg and 500 mg
NDA 50672 - S-038	CEFTIN (cefuroxime axetil) for oral suspension	125 mg/5 mL and 250 mg/5 mL

These Changes Being Effected (CBE) supplemental new drug applications provide for revisions to the following sections of the prescribing information (PI): **ADVERSE REACTIONS (6)** section, **Postmarketing Experience (6.2)** subsection to include the statement under the Immune System Disorders subheading that “acute myocardial ischemia with or without myocardial infarction may occur as part of an allergic reaction.”

In addition, *Clostridium difficile* was replaced with *Clostridioides difficile* throughout the PI.

### **APPROVAL & LABELING**

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

## **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 FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information,), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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 these supplemental applications, 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).

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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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-Infectives  
Office of Infectious Diseases  
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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**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.**

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/s/

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DMITRI IARIKOV  
03/05/2021 09:54:18 AM