



NDA 207131/S-003

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Ximena Semensato
Specialist, Regulatory Affairs
32650 N. Wilson Road, WG 1-3
Round Lake, IL 60073

Dear Ms. Semensato:

Please refer to your Supplemental New Drug Application (sNDA) dated April 21, 2016, received April 21, 2016 and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cefazolin Injection, for intravenous use.

This Prior Approval supplemental new drug application provides for revisions to the Prescribing Information (PI) as follows:

Section 11, DESCRIPTION, was revised to change the drug substance name from Cefazolin “injection” to Cefazolin sodium”. In addition, the molecular formula was revised and the word free “base” was replaced with free “acid”.

Section 16, HOW SUPPLIED/STORAGE AND HANDLING, was revised to update the National Drug Code (NDC). In addition, the product description was revised from “Supplied 12 bags per case” to “Supplied as 12 bags per carton.”

The PI was also revised to include replacement of the term “single-use” with “single-dose” and other minor editorial revisions.

The carton label was revised to make it consistent with the PI.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is 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 (text for the package insert), 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.

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 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton label, and your immediate-container label submitted on October 03, 2016, as soon as it is available, but no more than 30 days after it is printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 207131/S-003.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Fariba Izadi, Pharm.D., Regulatory Health Project Manager, at (301) 796-0563.

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(S):
Content of Labeling
Carton 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
10/11/2016