



NDA 50655/S-023

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Melissa I. Klesch
Manager, Global Regulatory Affairs
25212 W. Illinois Route 120, RLT-10
Round Lake, IL 60073

Dear Ms. Klesch:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 26, 2014, submitted under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nafcillin Injection, USP in Plastic Container (PL2040).

This “Prior Approval” supplemental new drug application provides for changes to the **Microbiology** subsection of the **CLINICAL PHARMACOLOGY** section to update the susceptibility test interpretive criteria, changes to the **WARNINGS** section regarding hypersensitivity (anaphylactic) reactions, and editorial changes in the **Pregnancy** subsection of the **PRECAUTIONS** section of the label.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below and indicated in the enclosed labeling.

REFERENCES

1. Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth* ^{(b) (4)} *-Informational Supplement*, CLSI document M100-S2 ^{(b) (4)} *[2015]*, ^{(b) (4)} *-Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA, 2014.*

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 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 includes 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).

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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure:
Package Insert

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
04/03/2015