



NDA 050655/S-018

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Mary Beth Esche
Associate Director, Global Regulatory Affairs – Medical Products
1620 Waukegan Road, MPGR-AL
McGaw Park, Illinois 60085

Dear Ms. Esche:

Please refer to your supplemental New Drug Application (sNDA) dated April 21, 2008, received April 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nafcillin Injection, USP, in Plastic Galaxy Container, PL 2040.

We also acknowledge receipt of your amendments dated June 14, October 26, and November 02, 2011. The June 14, 2011 submission constituted a complete response to our July 29, 2010, action letter.

This “Prior Approval” supplement provides for revisions to the **CLINICAL PHARMACOLOGY** section, **Microbiology** subsection, regarding the *in vitro* susceptibility test interpretive criteria (breakpoints) and the quality control parameters for *in vitro* susceptibility testing listed in the package insert as requested in our letter of January 6, 2008.

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, submitted on October 26, 2011.

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 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 these supplemental applications, 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, MD, Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

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
11/09/2011