



NDA 050638/S-016

**SUPPLEMENT APPROVAL**

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

Dear Ms. Esche:

Please refer to your Supplemental New Drug Application (sNDA) dated August 11, 2011, received August 15, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Penicillin G Potassium Injection, USP.

We acknowledge receipt of your amendment dated April 9, 2012.

The April 9, 2012, submission constituted a complete response to our September 21, 2011, action letter.

This "Prior Approval" labeling supplement proposes to update the Microbiology subsection of the package insert, *in vitro* susceptibility test interpretive criteria (breakpoints) and quality control parameters for *in vitro* susceptibility testing sections.

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 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 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, 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

Enclosure: 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  
04/16/2012