



NDA 50-138/S-235  
NDA 50-141/S-232

**SUPPLEMENT APPROVAL**

King Pharmaceuticals, Inc.  
a subsidiary of Pfizer, Inc.  
Attention: William C. Vogt  
Regulatory Affairs Manager, Worldwide Safety & Regulatory  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Mr. Vogt:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received May 22, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 50-138/S-235, Bicillin C-R (penicillin G benzathine and penicillin G procaine) Injectable Suspension  
NDA 50-141/S-232, Bicillin L-A (penicillin G benzathine) Injectable Suspension

We acknowledge receipt of your amendment dated December 13, 2013.

The December 13, 2013, submission constituted a complete response to our August 23, 2013, action letter.

These "Prior Approval" supplements propose to revise the **DOSAGE AND ADMINISTRATION** section, **Method of Administration** subsection, regarding the site for intramuscular administration.

**APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. They are 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 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 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, 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:  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SUMATHI NAMBIAR  
04/25/2014