



NDA 50138/S-231  
NDA 50141/S-226

**SUPPLEMENT APPROVAL**

King Pharmaceuticals, Inc.  
Attention: L. Diane Pierce  
Manager, Regulatory Affairs  
501 Fifth Street  
Bristol, TN 37620

Dear Ms. Pierce:

Please refer to your supplemental new drug applications dated October 2, 2007, received October 3, 2007 (NDA 50141), and December 11, 2007, received December 12, 2007 (NDA 50138), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bicillin<sup>®</sup> L-A Injectable Suspension (penicillin G benzathine) (NDA 50-141), and Bicillin<sup>®</sup> C-R (penicillin G benzathine and penicillin G procaine injectable suspension) (NDA 50-138).

We acknowledge receipt of your submissions dated November 25, 2009.

These “Changes Being Effected in 30 days” supplemental new drug applications provide for revisions to **WARNINGS** and **PRECAUTIONS/Information for Patients** subsections regarding *C. difficile*.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on November 25, 2009.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Susmita Samanta, M.D., Regulatory Project Manager, at 301-796-0803.

Sincerely,

*{See appended electronic signature page}*

Katherine Laessig, M.D.  
Deputy Director  
Division of Anti-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50138	SUPPL-231	KING PHARMACEUTICA LS INC	BICILLIN-CR
NDA-50141	SUPPL-226	KING PHARMACEUTICA LS INC	BICILLIN (PENICILLIN G BENZATHINE) L-A I

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/s/

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KATHERINE A LAESSIG  
12/18/2009