



NDA 50-138/S-228

King Pharmaceuticals, Inc.
Attention: Greg Carrier
Vice President, Regulatory Affairs
501 Fifth Street
Bristol, Tennessee 37620

Dear Mr. Carrier:

Please refer to your supplemental new drug applications dated October 6, 2004, received October 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bicillin[®] C-R and Bicillin[®] C-R 900/300 (Penicillin G Benzathine and Penicillin G Procaine Injectable Suspension, USP). We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

The purpose of this "Changes Being Effected" labeling supplement is to incorporate the statement "NOT FOR THE TREATMENT OF SYPHILIS" on the cartons and syringe labels for all Bicillin[®] C-R products. In addition, the background color of the cartons has been changed from a white background to a pale shade of the color of the title color, to distinguish Bicillin[®] C-R (pale green background) and Bicillin[®] C-R 900/300 (pale purple background) from the cartons for Bicillin[®] L-A, which retains the previous white background.

We have completed our review of this application and it is approved, effective on the date of this letter.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.

Director

Division of Anti-Infective Drug Products

Office of Drug Evaluation IV

Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Lillian Gavrilovich
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