DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-138/S-222
NDA 50-138/S-223
NDA 50-141/S-218
NDA 50-141/S-219

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

Dear Mr. Carrier:

Please refer to your supplemental new drug applications dated May 15, 2001 (NDAs 50-138/S-222 and 50-141/S-218) and September 27, 2001 (NDAs 50-138/S-223 and 50-141/S-219), received May 16, 2001 and September 28, 2001, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bicillin® CR and Bicillin® CR 900/300 (Penicillin G Benzathine and Penicillin G Procaine Injectable Suspension, USP) (NDA 50-138) and Bicillin® LA (Penicillin G Benzathine Injectable Suspension) (NDA 50-141). We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated April 19, 2002.

These "Changes Being Effected" supplemental new drug applications provide for safety changes and revisions to the immediate container and carton labels in response to the Medication Error review.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted April 19, 2002, immediate container and carton labels submitted April 19, 2002).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-138/S-222, 50-138/S-223, 50-141/S-218, 50-141/S-219." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

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

Please submit one market package of the drug product when it is available.

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, 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 this page is the manifestation of the electronic signature.

/s/

Janice Soreth

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