DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-155/S-039

King Pharmaceuticals, Inc.
Attention: Tom W. Der
Director, Regulatory Affairs
501 Fifth Street
Bristol, Tennessee 37620

Dear Mr. Der:

Please refer to your supplemental new drug application dated November 24, 2003 received November 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chloromycetin Sodium Succinate (chloramphenicol sodium succinate for injection, USP).

This application is 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 and October 18, 2004.

This supplemental application provides for a "Geriatric Use" subsection.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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, HFD-410
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).

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 827-2120.

Sincerely,

{See appended electronic signature page}

Janice Soreth, MD
Division Director
Division of Anti-Infective and Ophthalmology 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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