DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-747/S-008
NDA 50-748/S-008

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

Dear Mr. Carrier:

Please refer to your supplemental new drug applications dated May 13, 2008, received May 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Synercid I.V. (quinupristin and dalfopristin for injection).

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for revisions to the **WARNINGS** and **PRECAUTIONS** sections regarding *Clostridium difficile* associated diarrhea (CDAD).

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text. Please note the addition of the subsection heading "**Information for Patients**", in the **PRECAUTIONS** section of the labeling.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 50-747/S-008 and NDA 50-748/S-008."

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
5600 Fishers Lane, Suite 12B05
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 Maureen Dillon-Parker, Chief, Project Management Staff/Regulatory Health Project Manager, at (301) 796-0706.

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

Enclosure – Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kathrine Laessig
6/18/2008 10:55:28 AM