DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-747/S-014
NDA 50-748/S-013

**SUPPLEMENT APPROVAL**

King Pharmaceuticals, Inc.
Attention: Will Vogt
Manager, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Vogt:

Please refer to your Supplemental New Drug Applications (sNDAs) dated November 16, 2011, received November 17, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Synercid (quinupristin and dalfopristin for injection)

These "Prior Approval" supplemental new drug applications provides for changes in the CLINICAL PHARMACOLOGY section, Microbiology subsection, *in vitro* susceptibility test interpretive criteria and quality control parameters for susceptibility testing information. Specifically, these supplements request the addition of *Streptococcus pneumoniae* (ATCC 49619) to the quality controls section under Susceptibility Test Methods Dilution Techniques and the Diffusion Techniques.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below as agreed to in the email communication of January 12, 2012.

1. In reference to the MIC and disk diffusion interpretive criteria tables please change *Staphylococcus* spp. to *Staphylococcus aureus* and *Streptococcus* spp. to *Streptococcus pyogenes*.

2. In the quality control tables please add a note to *Streptococcus pneumoniae* ATCC 49619 that it is used when testing *Streptococcus pyogenes.*

3. Please add the following reference: Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility testing. CLSI document M100-S22. CLSI, 950 West Valley Rd., Suite 2500, Wayne, PA 19807, 2012.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions listed, the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions listed above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## REPORTING REQUIREMENTS

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 Project Manager, at (301) 796-0706.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, M.D., MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling

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

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/s/

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SUMATHI NAMBIAR
01/13/2012