DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-747/S-011
NDA 50-748/S-009 & S-010

SUPPLEMENT APPROVAL

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

Dear Mr. Carrier:

Please refer to the following supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Synercid I.V. (quinupristin and dalfopristin for injection).

NDA#/Supplement #	Submission Dated	Submission Received
50-747/S-011	December 19, 2008	December 22, 2008
50-748/S-009	June 27, 2008	June 30, 2008
50-748/S-010	November 26, 2008	December 01, 2008

We acknowledge receipt of your amendments to NDA 50-747/S-011, dated January 22, 2009 and September 15, 2010, and your amendment to NDA 50-748/S-009 and S-010, dated November 08, 2010.

These "Prior Approval" supplemental new drug applications, as amended, provide for:

NDA 50-747/Supplement #011
The removal of the vancomycin-resistant *Enterococcus faecium* (VREF) indication.

NDA 50-748/Supplements #009 and #010
Revised labeling to remove the VREF indication, update pediatric dosing recommendations, and to describe better the protein binding for both quinupristin and dalfopristin.

As discussed, and agreed, at the teleconference held between representatives of your firm and the Division on July 19, 2010, the vancomycin-resistant *Enterococcus faecium* indication has been removed from the Synercid labeling because the submitted data failed to verify clinical benefit of the product for this treatment.

Additionally, as discussed in the November 5, 2010, telephone conversation with Dr. Susmita Samanta, Safety Project Manager, of this Division, and as submitted November 08, 2010, NDA 50-748, Supplements 009 and 010, have been further amended to include removal of the vancomycin-resistant *Enterococcus faecium* (VREF) indication to be consistent with the agreed upon labeling changes for NDA 50-747/S-011.

Therefore, these supplements are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text (label submitted November 08, 2010).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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, please contact Maureen Dillon-Parker, Regulatory Project Manager, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

WILEY A CHAMBERS
11/12/2010