DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-747/S-015
NDA 50-748/S-014

**SUPPLEMENT APPROVAL**

King Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc.
Attention: Mikhail Abarshalin
Senior Manager, Pfizer Essential Health
Global Regulatory Affairs Brands
235 East 42nd Street
New York, NY 10017-7555

Dear Mr. Abarshalin:

Please refer to your Supplemental New Drug Applications (sNDAs) dated December 17, 2015, received December 17, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SYNERCID I.V. (quinupristin and dalfopristin for injection).

These "Changes Being Effected" supplemental new drug applications provide for revisions to the Synercid U.S. Prescribing Information (PI) for conformance to 21 CFR §201.24 for labeling of systemic antibacterial drug products. Additionally, these supplemental applications provide for updates to the **CLINICAL PHARMACOLOGY** section, **Microbiology** subsection of the PI, including revisions to the susceptibility test interpretive criteria.

## APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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.

(1) Update the **REFERENCES** section to read as follows:

Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility testing. Twenty-seventh Informational Supplement, CLSI document M100-S27. Clinical Laboratory Standards Institute, 950 West Valley Rd., Suite 2500, Wayne, PA 19807, 2017.

(2) Revise the labeling date from March 2017 to June 2017.

**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 indicated, 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 indicated above approved in these supplemental applications, 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, Regulatory Project Manager, at (301) 796-0706.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: 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
06/16/2017