DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 17-376/S-058
17-598/S-040
18-452/S-025

King Pharmaceuticals, Inc.
Attention: L. Diane Pierce
Manager, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Ms. Pierce:

Please refer to your supplemental new drug applications dated January 30, 2007, received February 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA 17-376, Septra® Tablets, and Septra® DS Tablets (S-058)
NDA 17-598, Septra® Suspension (S-040)
NDA 18-452, Septra® I.V. (S-025)

These "Changes Being Effected" supplemental new drug applications provide for revisions to the package inserts to include the language required in the final rule, **Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use** (68 FR 6062, February 6, 2003).

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling submitted on January 30, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* For administrative purposes, designate these submissions "**FPL for approved supplement NDAs 17-376/S-058, 17-598/S-040 and 18-452/S-025**." Approval of these submissions by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 J. Christopher Davi, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}
Katherine A. Laessig, MD
Deputy Division Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on January 30, 2007

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
3/11/2008 11:21:36 AM