DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-376/S-056
NDA 17-598/S-039

King Pharmaceuticals, Inc.
Attention: Tom W. Der
Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Der:

Please refer to your supplemental new drug applications dated March 19, 2004, received March 22, 2004 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

> NDA 17-376/S-056 Septra® (trimethoprim/sulfamethoxazole) Tablets and DS Tablets, and;
> NDA 17-598/S-036 Septra® (trimethoprim/sulfamethoxazole) Suspension

We also acknowledge receipt of your submissions dated January 27, 2005, received January 28, 2005. These submissions constitute a complete response to our November 9, 2004 action letter.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, with the editorial revisions listed below:

1. The statement added to the CLINICAL PHARMACOLOGY section should be relocated to the end of the section, preceding the Microbiology subsection.

2. In the Geriatric Use subsection, under PRECAUTIONS, the word “increase” should be changed to “increased” in the first sentence of the second paragraph.

3. Under REFERENCES, the Varoquaux, O, *et al.* paper should be added as number 3.

The final printed labeling (FPL) must be identical to the enclosed labeling and include the editorial revisions listed above. These revisions are terms of the approval of these applications.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 17-376/S-056 and NDA 17-598/S-039**." 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 the respective NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
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 J. Chistopher Davi, Regulatory Project Manager, at (301) 827-2217.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD, Director
Division of Anti-Infective and Ophthalmology Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Labeling Submitted January 27, 2005

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

/s/

Lillian Gavrilovich

7/28/05 05:04:46 PM