DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-901/S-052
22-021/S-001

King Pharmaceuticals, Inc.
Attention: Ms. Karen C. Baker
501 Fifth Street
Bristol, TN 37620

Dear Ms. Baker:

Please refer to your supplemental new drug applications dated September 10, 2007 submitted under section 505(b)(1), NDA 19-901 and section 505(b)(2), NDA 22-021 of the Federal Food, Drug, and Cosmetic Act for Altace (ramipril) 1.25, 2.5, 5, and 10 Capsules and Altace (ramipril) 1.25, 2.5, 5 and 10 mg Tablets respectively.

We acknowledge receipt of your submissions dated April 8 and July 11, 2008.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the **WARNINGS** and **PRECAUTIONS** sections of the labeling based on a recently published article regarding the use of ACE inhibitors during the first trimester of pregnancy.

We have completed our review of these supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final SPL labeling submitted on July 11, 2008.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Alisea Crowley, Pharm.D, Regulatory Project Manager, at (301) 796-1144.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Norman Stockbridge

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