DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-901/S-040 & 041

King Pharmaceuticals, Inc.
Attention: Ms. Felicia Bullock
501 Fifth Street
Bristol, Tennessee 37620

Dear Ms. Bullock:

Please refer to your supplemental new drug applications dated December 20, 2002 (S-040) and February 11, 2003 (S-041) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Altace (ramipril) 1.25, 2.5, 5 and 10 mg Capsules.

We acknowledge receipt of your submissions dated March 19 and May 27, 2004.

Your submission of May 27, 2004 constituted a complete response to our March 10, 2004 action letter.

These "Changes Being Effected" supplemental new drug applications provide for changes to the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the labeling based on information from post-marketing surveillance reports.

We 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 printed labeling (FPL) dated on May 27, 2004.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 contact:

Alisea Sermon, Pharm.D.
Regulatory Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-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

10/15/04 03:24:48 PM