DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-901/S-054
22-021/S-005

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 August 29, 2008 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.

These "Changes-Being-Effected" supplemental applications provide for additional information in the **PRECAUTIONS**/**Drug Interactions** section of the package insert as requested in our letter dated March 3, 2008.

These supplemental new drug applications provide for electronic labeling with the following revision:

1. Under the **PRECAUTIONS**/***Drug Interactions*** subsection, the following interaction has been added:

   Gold: Nitritoid reactions (symptoms include facial flushing, nausea, vomiting and hypotension) have been reported rarely in patients on therapy with injectable gold (sodium aurothiomalate) and concomitant ACE inhibitor therapy including ALTACE.

We also note the last revised labeling date has been updated to July 2008 for both Altace Capsules and Altace Tablets.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the electronic (SPL) labeling text submitted on August 29, 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Alisea Crowley, Pharm.D., RAC
Senior Regulatory Project Manager
(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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