



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 22021/S-006

**SUPPLEMENT APPROVAL**

King Pharmaceuticals, Inc.  
Attention: Felicia A. Bullock  
Senior Director, Regulatory Affairs  
501 Fifth Street  
Bristol, TN 37620

Dear Ms. Bullock:

Please refer to your supplemental new drug application dated August 12, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Altace (ramipril) 1.25, 2.5, 5, and 10 mg Tablets.

We also refer to our supplement request letter issued July 1, 2009.

This "Prior Approval" supplemental new drug application proposes revisions to the Precautions section of the package insert.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on August 12, 2009.

**PROMOTIONAL MATERIALS**

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see

page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (*i.e.*, a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

**REPORTING REQUIREMENTS**

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:

Michael Monteleone, M.S.  
Regulatory Health Project Manager  
(301) 796-1952

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, Pharm.D.  
Deputy Director for Safety  
Division of Cardiovascular and Renal Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure  
Content of Labeling

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

-----  
NDA-22021

-----  
SUPPL-6

-----  
KING  
PHARMACEUTICA  
LS INC

-----  
ALTACE (RAMIPRIL)

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

/s/  
-----

MARY R SOUTHWORTH  
11/20/2009