DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-901/S-035

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

Dear Ms. Bullock:

Please refer to your supplemental new drug application dated January 9, 2002, received January 10, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Altace (ramipril) Capsules 1.25, 2.5, 5.0 and 10.0 mg.

We acknowledge receipt of your submissions dated July 3 and 9, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for King Pharmaceuticals, Inc. in Bristol Tennessee as a alternate manufacturing/testing/packaging site for the 2.5 mg, 5.0 mg and 10.0 mg strengths of Altace Capsules.

We have completed the review of this supplemental application, and it is approved.

Please submit final printed labeling (FPL) for Altace identical to the submitted draft labeling in your next annual report. Please note that the dissolution acceptance criterion for this product is Q =(b)(4 (i.e., at stage 1, each of the 6 units tested is (b)(4)-----) in 30 min. for both release and shelf life. The revised dissolution specifications should be submitted in your next annual report.

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, call Ms. Sandra L. Birdsong, Regulatory Health Project Manager, at (301) 594-5312.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar

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