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March 31, 2000

Thomas K. Rogers, III, M.S.
Vice President, Regulatory Affairs

AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION

Mr. John Treacy
Advisors and Consultants Staff (HFD-21)
Food and Drug Administration
Center for Drug Evaluation and Research
5630 Fishers Lane
Rockville, MD 20857

2795 '00 APR 20 P2:30

Re: NDA 19-901/S028
Altace® (ramipril) Capsules
User Fee ID #: 3892
Cardio-Renal Advisory Committee – Briefing Package

Dear Mr. Treacy:

A Supplemental Application seeking approval of additional indications for Altace (ramipril) Capsules was submitted to FDA's Division of Cardio-Renal Drug Products on January 18, 2000. The Division Director, Dr. Raymond Lipicky, advised the firm that this submission will be considered by the Cardio-Renal Advisory Committee on May 1, 2000.

We are providing the enclosed Briefing Packages for distribution to members of the Committee and to FDA's reviewing Division. Under separate cover, we are also providing a copy of the package to Ms. Joan Standaert, Executive Secretary to the Committee. As indicated above, we believe that all of the materials provided herein are fully disclosable under the Freedom of Information Act.

The application is founded upon the results of the Heart Outcomes Prevention Evaluation (HOPE) Study conducted by the HOPE Study Investigators and reported in *The New England Journal of Medicine* and *The Lancet*. Briefing materials provided include a submission backgrounder, copies of the related published journal articles, study protocols, definitions for terms of adjudication, and proposed labeling as submitted to FDA.

Most of the documents included within the Briefing Package are also provided electronically on the accompanying disc. Please advise if you have questions or if we can be of further assistance in this matter.

Sincerely,
KING PHARMACEUTICALS, INC.

Thomas K. Rogers, III
Vice President Regulatory Affairs

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