DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Alison M. Manhoff
King & Spalding L.L.P.
1700 Pennsylvania Avenue, N.W.
Washington, DC 20006-4708

Docket No. FDA-2006-P-0345
Legacy Docket No. 2006P-0084

Dear Ms. Manhoff:

This is in response to your petition filed on February 22, 2006, requesting permission to file an Abbreviated New Drug Application (ANDA) for Ramipril Tablets, 1.25 mg, 2.5 mg, 5 mg and 10mg. The listed drug to which you refer in your petition is Altace (ramipril) Capsules, 1.25 mg, 2.5 mg, 5 mg, and 10 mg (NDA 19-901, held by King Pharmaceuticals).

Your request involves a change in dosage form. We have reviewed your petition and have determined that it is now moot. On February 27, 2007, King Pharmaceuticals' NDA 22-021 was approved. NDA 22-021 is for Altace (ramipril) Tablets, 1.25 mg, 2.5 mg, 5 mg, and 10 mg. Because this product is approved and is designated as the reference listed drug for ramipril tablets, there is no need for a decision with respect to your petition on the identical product. You may submit an ANDA using NDA 22-021 as the basis of submission.

A copy of this letter will be placed on public display in the Division of Dockets Management, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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