

KING & SPALDING LLP

0391 '06 FEB 22 P3 '09

February 22, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

CITIZEN PETITION

A. Action Requested

King & Spalding LLP submits this petition to request that the Food and Drug Administration (FDA) declare abbreviated new drug applications (ANDAs) may be filed for 1.25 mg, 2.50 mg, 5 mg, and 10 mg Ramipril *Tablets* similar to Altace (Ramipril) Capsules, 1.25 mg, 2.50 mg, 5 mg, and 10 mg.

We are aware that two substantially identical petitions were received by FDA on November 14 and 21, 2005 and assigned, respectively, to Docket Nos. 2005P-0460 and 2005P-0472. **We respectfully request that FDA respond simultaneously, and in a manner designed to reach all petitioners on the same day, to this petition and the previously filed petitions.** Such equal treatment is necessary to allow fair opportunity for all interested and prepared firms to submit ANDAs that may qualify for 180-day market exclusivity or other benefit accruing to first ANDA filers.¹

B. Statement of Grounds

1. Basis for Dosage Form Change

FDA has approved Ramipril Capsules in strengths of 1.25 mg, 2.50 mg, 5 mg, and 10 mg for the treatment of hypertension and certain cardiovascular conditions. See New Drug

¹ We are aware that, in some instances, a citizen petitioner may receive FDA's response to a petition one or more days before the response is made publicly available at the Division of Dockets Management (*i.e.*, before other interested persons could know about it). The sponsor of Altace® Capsules has listed in the Orange Book at least one patent covering the approved drug product (*see* Attachment 1). That being the case, there is a very real possibility that a first ANDA filer may be eligible for 180-day exclusivity and the very substantial advantage from being able to file an ANDA on the earliest possible date.

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Application (NDA) 19-901. Ramipril Capsules in those approved strengths are the reference listed drugs for the corresponding-strength tablet products proposed in this petition.

The petition requests a change from the reference listed drugs in *dosage form only*: *i.e.*, change from capsules to tablets. The proposed drug products would contain the same active ingredient, comprise the same dosage strengths, be intended for the same route of administration, and bear the same labeling (except for permitted differences) as the reference products. The change in dosage form would *not* affect the site of absorption, but rather would simply provide a dosage form that is more convenient for, or preferred by, some patients. Comparative bioavailability data will be submitted in the ANDA to establish appropriate rate and extent of absorption of the tablet products.

The Federal Food, Drug, and Cosmetic Act and FDA regulations permit the submission of ANDAs for drug products that differ in dosage form compared to a listed drug. 21 U.S.C. § 355(j)(2)(C); 21 C.F.R. §§ 314.93, 5.10. FDA has approved a number of ANDA suitability petitions seeking comparable dosage form change from capsules to tablets. *See, e.g.*, Docket No. 1999P-4958 (approval of petition to submit ANDA for doxycycline tablets).

2. Labeling Information

In accordance with 21 C.F.R. § 314.93(d), the following labeling information and comparisons are attached to this petition:

1. An annotated copy of the current prescribing information for the reference listed drugs, Altace® Capsules 1.25 mg, 2.50 mg, 5 mg, and 10 mg is Attachment 2. The annotations identify specific portions of the proposed products' labeling that would vary from the reference listed drugs' approved prescribing information.
2. Draft prescribing labeling for the proposed products, which would be the same as that of the corresponding reference products except for permitted deviations (including the description of the dosage form and related administration information). The draft package insert for proposed Ramipril Tablets is Attachment 3.

3. Pediatric Assessment

We are aware that the Pediatric Research Equity Act of 2003 amended the Federal Food, Drug, and Cosmetic Act to require that certain drug applications seeking approval of a new dosage form include "data ... that are adequate (i) to assess the safety and effectiveness of the ... product for the claimed indications in all relevant pediatric subpopulations; and (ii) to support dosing and administration for each pediatric subpopulation for which the ... product is safe and effective." 21 U.S.C. § 355c(a)(2). We assume that the pediatric assessment requirement would be applied to this suitability petition.

King & Spalding requests that FDA fully waive any pediatric assessment requirement relative to this petition. The agency has affirmatively waived pediatric study for certain uses of the reference listed drug (*see* Attachment 4); furthermore, the reference listed drug sponsor announced in 2003 that it had undertaken a Phase IV study to assess safety and effectiveness of the RLD in pediatric subjects (*see* Attachment 5). The latter study report is anticipated to be submitted to FDA in response to the agency's outstanding written request for pediatric review. Hence, no pediatric assessment would be reasonably required here.

C. Environmental Impact

In accordance with 21 C.F.R. § 25.31, neither an environmental assessment nor an environmental impact statement is required in support of this petition.

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information will not be submitted unless requested by the Commissioner following review of this petition.

E. Certification

The undersigned representative of King & Spalding certifies that to her best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information that are known to be unfavorable to the petition.

Sincerely,



Alison M. Manhoff

Admitted to practice in California only

Attachments

cc: Arianne Camphire, Pharm.D.
Mr. Leo Zadecky