

LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE, WESTBURY, NY 11590

(516) 222-6222 • FAX (516) 683-1887

November 11, 2005

OVERNIGHT COURIER 11/11/05

Division of Dockets Management
Food and Drug Administration, HFD-305
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned, on behalf of a client, submits this petition in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 355(j)(2)(C), and 21 C.F.R. §§ 10.20, 10.30, and 314.93 to request that the Commissioner of Food and Drugs make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Ramipril Tablets, 1.25 mg, 2.5 mg, 5 mg and 10 mg.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs make a determination that Ramipril Tablets, 1.25 mg, 2.5 mg, 5 mg and 10 mg drug products are suitable for submission in an ANDA. The reference-listed drug (RLD) product upon which this petition is based is Altace® (ramipril) Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg. The listing reference drug product's NDA Number 19-901, which is held by King Pharmaceuticals, appears in the electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations 25th Edition (accessed November 11, 2005). A copy of that listing is provided in **Attachment A**. This petition thus requests a change in the dosage form from capsules to tablets.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in dosage form from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application.

The proposed change in dosage form, from a capsule to a tablet, is designed to provide a more convenient dosage form for those patients that find it difficult to swallow capsules or who prefer a tablet dosage form.

The package insert for the RLD, Altace® (ramipril) Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg, is provided in **Attachment B** of this petition. The strengths, dosage, indications, usage, warnings and precautions for the proposed product are the same as that described in the approved RLD's labeling.

In summary, the proposed change in dosage form from that of the reference-listed drug (i.e., a change from a capsule to a tablet), will not affect the product's safety or efficacy. The indications remain unchanged and the proposed dosing is the same as the dosing recommendations in the approved labeling for the reference-listed drug. Therefore, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The proposed labeling for Ramipril Tablets, 1.25 mg, 2.5 mg, 5 mg and 10 mg is included as **Attachment C**. Labeling for the proposed product will be consistent with the approved labeling for Altace[®] (ramipril) Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg.

Pediatric Waiver Request

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 that amended the Federal Food Drug and Cosmetic Act to provide the Agency authority to require drug firms to study certain drugs in pediatric patients if the Agency felt that such study would provide beneficial health data for that patient population. The act also provides a provision for a waiver from such requirement if:

(iii) the drug or biological product;

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric studies be granted for the approval of this petition to permit a subsequent ANDA filing. The drug product, ramipril, does appear on the historical list of drugs for which additional information may produce benefits in the pediatric population. However, as indicated on the CDER web page, the innovator has received a written request from the Agency for the conduct of pediatric studies. While no pediatric exclusivity appears to have yet been granted, given the nature of the market of this product, it must be assumed that the studies that were subject to the request have either been initiated or completed and not yet assessed by the Agency. In addition, there are at least two other ACE inhibitor sponsors that have received written requests, have conducted the requested pediatric studies and were granted pediatric exclusivity. Therefore, it is not likely that duplication of studies requested from the innovators will add anything to the knowledge base for pediatric patients and this petition requesting a change in dosage form from capsule to tablet should be granted a waiver under PREA.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Ramipril Tablets, 1.25 mg, 2.5 mg, 5 mg and 10 mg.

C. Environmental Impact

According to 21 C.F.R. § 25.31(a), this petition qualifies for a categorical exemption from the requirement to submit an environmental assessment.

D. Economic Impact Statement

According to 21 C.F.R. § 10.30(b), petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

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

Respectfully submitted,



Robert W. Pollock *pk*
Senior Vice President
Lachman Consultant Services, Inc.
1600 Stewart Ave
Westbury, NY 11590

RWP/pk

- Attachment A: Electronic Orange Book, Accessed November 11, 2005
- Attachment B: Approved insert labeling for Altace[®] (ramipril) Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg
- Attachment C: Proposed insert labeling for Ramipril Tablets, 1.25 mg, 2.5 mg, 5 mg and 10 mg

cc: Arianne Camphire (Office of Generic Drugs)

T10P5315