

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

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

February 8, 2005

OVERNIGHT COURIER 2/8/05

Division of Dockets Management
Food and Drug Administration
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

Pursuant to 21 CFR 10.20 and 10.30, Lachman Consultant Services, Inc., is submitting this petition on behalf of a client under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act to request that the Commissioner of the Food and Drug Administration make a determination that an Abbreviated New Drug Application may be submitted for Hydrochlorothiazide Tablets, 12.5 mg to an approved Abbreviated New Drug Application (ANDA).

A. Action Requested

The petitioner requests the Commissioner of the Food and Drug Administration make a determination that Hydrochlorothiazide Tablets, 12.5 mg, is suitable for submission in an ANDA. The listed drug product on which this petition is based is Hydrochlorothiazide Tablets, 100 mg (IVAX Pharmaceuticals). The listing of Hydrochlorothiazide Tablets, 100 mg, is found on the World Wide Web at <http://www.fda.gov/cder/ob/default.htm>, the electronic Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the Orange Book). A copy of the listing is included as Attachment 1. Therefore, the petitioner seeks to introduce a lower strength (12.5 mg) tablet from that of the listed drug product strength (100 mg).

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in strength from a listed drug provided the FDA has approved a petition that proposed the filing of such an application. This petition involves an introduction of a new strength for the proposed drug from that of the listed drug. The reference-listed drug (RLD), on which this petition is based, is Hydrochlorothiazide Tablets, 100 mg, manufactured by IVAX Pharmaceuticals. The proposed drug product differs only in strength from the reference-listed drug. The RLD is marketed as a tablet form containing 100 mg of Hydrochlorothiazide. The proposed drug product represents the same dosage form and route of administration as the RLD. Additionally, the proposed strength will be a direct, dose proportional scale down of a proposed formulation for Hydrochlorothiazide 25 mg, 50 mg and 100 mg Tablets, consistent with the approved strengths of the RLD and the applicant plans to provide an appropriate demonstration of bioequivalence in its ANDA submission.

2005P-0060

CPI

The RLD, Hydrochlorothiazide, is currently approved for marketing as 25 mg, 50 mg and 100 mg tablets. In addition, there is another Hydrochlorothiazide product in capsule form that is approved at a 12.5 mg strength.

The proposed drug product offers an alternate strength of Hydrochlorothiazide Tablets (12.5 mg) for use by patients for the indications approved in the RLD.

The approved labeling for Hydrochlorothiazide Tablets states that the usual adult dose for edema is 25 mg to 100 mg daily as a single or divided dose. For control of hypertension, the usual initial dose in adults is 25 mg daily given as a single dose and the dose may be increased to 50 mg daily given as a single or two divided doses. The usual pediatric dosage for control of diuresis and control of hypertension is 0.5 to 1 mg per pound (1 to 2 mg/kg) per day in a single or two divided doses, not to exceed 37.5 mg per day in infants up to 2 years of age or 100 mg per day in children 2 to 12 years in age. In infants less than 6 months of age, doses up to 1.5 mg per pound (3 mg/kg) per day in two divided doses may be required.

The strength of the proposed tablet is clearly contemplated in the approved labeling of the listed product. The proposed 12.5 mg tablet strength will provide the ability to titrate patients that may require doses in between the currently approved 25 mg, 50 mg and 100 mg tablets allowing adjustment of dosage levels as necessary without requiring the patient to have to break existing tablets, a task that may prove especially difficult and frustrating for the elderly or infirmed. Also, since the labeling of the RLD suggests that the usual dosing may be given as a single or divided dose, the 12.5 mg product could provide a convenient product for patients for whom the physician determines would require 25 mg given in divided doses.

Therefore, the petitioner's request for the Commissioner to find that an introduction of a new 12.5 mg tablet strength for Hydrochlorothiazide Tablets should raise no questions of safety or effectiveness, and the Agency should approve the petition.

A copy of the reference-listed drug labeling is included in Attachment 2. Draft labeling for the proposed product is included in Attachment 3. The proposed drug product represents the same uses, dosage, and indications as those for the reference-listed drug.

C. Environmental Impact

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.3(b), economic impact information is to be submitted only when requested by the Commissioner. The petitioner will promptly provide such information if so requested.

E. Certification

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

Respectfully Submitted,



Robert W. Pollock 
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

RWP/pk

- Attachments: 1. Approved Drug Products with Therapeutic Equivalence Evaluations listing
for 100 mg Hydrochlorothiazide Tablets
2. Reference-listed Drug Labeling
3. Proposed Draft Labeling

cc: Emily Thakur (Office of Generic Drugs)

A10P5039