

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

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

0218 6 JUN 14 09:06

June 13, 2006

OVERNIGHT COURIER 6/13/06

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

**AMENDMENT TO CITIZEN PETITION 2005P-0406/CP1
ADDITION OF 25 MG STRENGTH**

Dear Sir or Madam:

On September 30, 2005 the undersigned submitted, on behalf of a client, a petition to request that the Commissioner of Food and Drugs make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Benzphetamine Hydrochloride Capsules, 50 mg. This amendment revises that request to also include a 25 mg capsule strength.

A. Action Requested

After further review of the directions for use of the reference-listed drug product, the petitioner amends its requests that the Commissioner of Food and Drugs make a determination that a Benzphetamine Hydrochloride Capsule, 50 mg drug product is suitable for submission as an ANDA to also include a 25 mg strength capsule. The reference-listed drug (RLD) product upon which this petition amendment is based is Didrex[®] (Benzphetamine Hydrochloride) Tablets, 50 mg, the same RLD, as sited in the original petition.

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 or strength 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 tablet to a capsule, is designed to provide a more convenient dosage form for those adult patients that find it difficult to swallow tablets. According to the labeling of the reference-listed drug products, the suggested dosage range of Didrex[®] is "25 mg to 50 mg one to three times a day". The package insert for Didrex[®] (Benzphetamine Hydrochloride Tablets, 50 mg) was provided with the original petition. The dosage for the proposed product is consistent with the labeling of the RLD product and with the addition of the 25 mg strength proposed in this amendment. The proposed product will provide all available doses that may be obtained from the currently approved and scored (bisected) 50 mg tablet.

2005P-0406

In summary, the proposed change in dosage form from that of the reference-listed drug (i.e., a change from a tablet to a capsule for both a 25 mg and 50 mg product) will not affect the product's safety or efficacy. The indication remains 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 revised proposed labeling for Benzphetamine Hydrochloride Capsules, 25 mg and 50 mg, is included as **Attachment A**. Labeling for the proposed product will be consistent with the approved labeling for Didrex[®] (Benzphetamine Hydrochloride Tablets, 50 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 Benzphetamine does not appear on the historical list of drugs for which additional information may produce benefits in the pediatric population.

Based on the use and nature of the RLD, the proposed change in dosage form to a capsule from a tablet will not make the product any more likely to be used in pediatric patients. In addition, the limitations of use, i.e., 12 years of age and older, described in the labeling of the RLD make it unlikely that the proposed product would be used in a substantial number of pediatric patients other than those for which the product is currently indicated. Current available IMS data show that an average of about 138 prescriptions / month were dispensed to pediatric patients, which is a total of about 1656 prescriptions **per year**. While these data do not break out the number of prescriptions by age (range from 10 – 19 years), it is assumed that most are related to pediatric patients for whom this drug is labeled, i.e., patients from 12 years of age or older. However, even if some of all of the prescriptions are written for patients below 12 years of age, it appears that it is a small percentage of the 1656 prescriptions IMS reported and is far below the 50,000-prescription threshold cited in previous FDA documents, as a barometer to determine if the product would likely be used in a significant number of pediatric patients.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Benzphetamine Hydrochloride Capsules, both 25 mg (subject of this amendment) and 50 mg (as requested in the original petition).

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), the 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
Senior Vice President

RWP/pk

Attachment A: Proposed Insert Labeling for Benzphetamine Hydrochloride Capsules, 25 mg and 50 mg

cc: Cecelia Parise (Office of Generic Drugs)
Leo Zadecky (Office of Generic Drugs)

M24P6164