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

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

June 23, 2006

OVERNIGHT COURIER 6/23/06

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 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 ("the FDC 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 Dextroamphetamine Sulfate Tablets, USP in strengths of 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs make a determination that Dextroamphetamine Sulfate Tablets, 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg, are suitable for submission as an ANDA. The reference-listed drug product upon which this petition is based is Dextrostat® (Dextroamphetamine Sulfate) Tablets, approved in 5 mg and 10 mg dosage strengths, NDA Number 84-051, held by Shire Richwood. (See Orange Book Listing in Attachment C.) Please note that the approved 5 mg RLD is a scored tablet and the 10 mg RLD is double scored. This petition is submitted for a change in dosage strength from that of the referenced drug product.

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 strength from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application. This petition requests a change in the strength for the proposed drug from that of the reference-listed drug.

According to the approved labeling of the reference-listed drug product, Dextrostat® (dextroamphetamine sulfate) Tablets, 5 mg and 10 mg, the starting dosage for the management of Narcolepsy and Attention Deficit Disorder with Hyperactivity is listed in the following table:

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DOSAGE	
Narcolepsy	Usual dose 5 mg to 60 mg per day in divided doses, depending on the individual patient response.
Attention Deficit Disorder with Hyperactivity	Not recommended for pediatric patients under 3 years of age.
	In pediatric patients from 3 to 5 years of age, start with 2.5 mg daily, by tablet; daily dosage may be increased in increments of 2.5 mg at weekly intervals until optimal response is obtained.
	In pediatric patients 6 years of age and older, start with 5 mg once or twice daily; daily dosage may be increased in increments of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 mg per day.

The proposed package insert for the Dextroamphetamine Sulfate Tablets USP, 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg is consistent with the reference-listed drug labeling. These strengths are within the treatment ranges described in the reference-listed drug labeling and are clearly contemplated doses based on the titration schedule and dosing recommended in the RLD. The availability of the additional strengths will make it easier for physicians to titrate patients to the appropriate dose without requiring the breaking of tablets, and in many cases, will permit dosing with a single tablet, where patients previously had to rely upon multiple tablets to obtain the desired dose. These factors may improve compliance and patient convenience with prescribed dosing regimens.

In summary, the proposed change in strength of Dextroamphetamine Sulfate Tablets from that of the reference-listed drug (i.e., a change from 5 mg and 10 mg to include strengths of 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg) will not raise questions in safety and efficacy of the proposed product. The indication remains unchanged, and the proposed dosing is consistent with dosing recommendations in the labeling of the approved reference-listed drug product's labeling. Therefore, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The proposed product will differ from the listed drug only in dosage strength. The indications, route of administration, intended patient population, and recommendations for use will remain the same as for the Dextrostat® Tablet product. Therefore, there should be no question regarding the safety and or efficacy of the proposed strengths of Dextroamphetamine Sulfate Tablets USP, 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg requested in this petition. The proposed strengths are within the treatment ranges described in the reference-listed drug labeling.

The package insert for Dextrostat® is provided in Attachment A of this petition. The draft package insert for the proposed Dextroamphetamine Sulfate, 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg Tablets is provided in Attachment B.

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 Pollock
PK

Robert W. Pollock
Senior Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

RWP/pk

Attachments:

A. Dextrostat® (Dextroamphetamine Sulfate 5 mg or 10 mg Tablets) Insert Labeling
B. Draft Insert Labeling for Proposed Drug Product
C. Approved Drug Products with Therapeutic Equivalence Evaluations, 25th Edition

cc: Leo Zadecky, Office of Generic Drugs

M24P6174