



MAR 20 2007

Lachman Consultant Services, Inc.  
Attention: Robert W. Pollock  
1600 Stewart Avenue  
Westbury, NY 11590

Docket No. 2006P-0267/CP1

Dear Mr. Pollock:

This is in response to your petition filed on June 26, 2006 requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Dextroamphetamine Sulfate Tablets, USP, 2.5 mg, 7.5 mg, 15 mg, 20 mg, and 30 mg. The listed drug products to which you refer in your petition are Dextrostat® (Dextroamphetamine Sulfate) Tablets, 5 mg and 10 mg, approved under NDA 84-051 held by Shire Richwood.

Your request involves a change in strengths from that of the listed drug products (i.e., from 5 mg and 10 mg to include a new lower strength of 2.5 mg, an intermediate strength of 7.5 mg, and new higher strengths of 15 mg, 20 mg, and 30 mg). The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug products.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The FDA finds that the change in strengths for the specific proposed drug products does not pose questions of safety or effectiveness because the uses, dosage form, and route of administration of the proposed drug products are the same as that of the listed drug products. In addition, the approved labeling of the reference listed drug, Dextrostat (dextroamphetamine sulfate) Tablets, indicates that for narcolepsy, the dosage range is from 5 mg to 60 mg per day given in divided doses depending on the individual response. Dextrostat is recommended to be given in two or three divided doses. In attention deficit disorder with hyperactivity, the dose ranges from 2.5 mg daily up to a maximum dose of 40 mg given in two or three divided doses depending upon the response. Therefore the new lower, intermediate and higher strengths of dextroamphetamine sulfate are supported by the approved labeling of the reference listed drug Dextrostat. FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug products.

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The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the FDA has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for the drug products to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug products to which you refer in your ANDA must be the same drug products upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Gary Buehler", with a stylized flourish at the end.

Gary J. Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research