LACHMAN CONSULTANT SERVICES, INC.
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October 1, 2003

OVERNIGHT COURIER 10/1/03

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug product, Clonazepam Oral Solution, 1 mg / 5 mL is suitable for consideration in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Clonazepam Oral Solution, 1 mg / 5 mL is suitable for submission as an ANDA. The reference listed drug (RLD) product upon which this petition is based is Klonopin® Tablets (clonazepam) available in strengths of 0.5 mg, 1 mg and 2 mg. Klonopin® Tablets are approved under NDA 17-533 and are manufactured by Roche. A copy of the appropriate page (3-92) of the Approved Drug Products with Therapeutic Equivalence Evaluations 23rd edition that lists the approval is provided in Attachment 1. The petitioner thus seeks a change in the dosage form (from a tablet to oral solution) from that of the reference-listed drug and a change in strength (from tablets containing either 0.5 mg, 1 mg or 2 mg to a 1 mg / 5 mL strength oral solution from which each of the recommended doses in the approved labeling of the RLD can be achieved).

B. Statement of Grounds

The RLD product, Klonopin®, is currently available in a tablet dosage form comprising strengths of 0.5 mg, 1 mg, and 2 mg per tablet. The proposed drug product is consistent with the currently approved RLD product's labeling with the exception of the dosage form and directions for administration (because the proposed product is an oral solution). The proposed product will provide an alternate dosage form that may prove to be more easily administered to patients that have difficulty in swallowing a tablet, prefer an oral solution over a tablet or who, due to their illness or age, may not be physically able to swallow a tablet. The proposed product will also provide the physician the option of providing the patient a single drug product from which titration to the appropriate dose can be achieved by merely varying the volume of drug administered.

The petition is thus seeking a change in the dosage form (from tablet to oral solution) and a change in strength (from tablets containing 0.5 mg, 1 mg and 2 mg to an oral solution in a strength of 1 mg / 5 mL) from that of the reference listed drug product. The oral solution will be supplied with an

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appropriately calibrated delivery device to assist the patient in measuring the specific dose as dictated by the prescribing practitioner.

Copies of the labeling of the reference listed drug product upon which this petition is based and draft labeling for the proposed product are included in Attachments 2 and 3, respectively. The proposed labeling is the same as the approved RLD labeling with the exception of changes allowed because the manufacturer of the proposed product differs from that of the RLD and those changes that would be necessitated by the change in dosage form and strength requested in this petition. There are no changes in the doses recommended, the indications, or conditions of use from that of the RLD's labeling.

Therefore, the petitioner requests that the Commissioner find that a change in dosage form from a tablet to an oral solution and a change in strength from tablets containing 0.5 mg, 1 mg and 2 mg to an oral solution containing 1 mg / 5 mL (from which all recommended doses can be achieved) for this proposed product raises no questions of safety or effectiveness, and the Agency should therefore approve the petition.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

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 RPC

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RWP/pk

Attachments:
- Attachment 1: Approved Drug Products with Therapeutic Equivalence Evaluations 23rd Edition, page 3-92
- Attachment 2: Klonopin Tablets Approved Labeling
- Attachment 3: Draft Labeling for the Proposed Clonazepam Oral Solution Product Subject of this Petition

cc: Martin Shimer (Office of Generic Drugs)

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