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 28, 2013

OVERNIGHT COURIER 6/28/13

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 products, Griseofulvin Tablets, 187.5 mg and Griseofulvin Tablets, 375 mg, are 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 the drug products, Griseofulvin Tablets, 187.5 mg, and Griseofulvin Tablets, 375 mg, are suitable for submission as an ANDA. The reference-listed drug product (RLD), upon which this petition is based, is Gris-PEG® (Griseofulvin Ultramicrosize) Tablets USP, 250 mg, NDA 50-475 held by Pedinol. This approved NDA also provides for Gris-PEG® Tablets in a 125 mg dosage strength. Therefore, the petitioner seeks a change in strength (from 250 mg to 187.5 mg and 375 mg) from that of the listed drug product.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The reference listed drug, Gris-PEG® Tablets, 250 mg, held by Pedinol, is a tablet product containing 250 mg of griseofulvin ultramicrosize. See copy of the page from the current Electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Attachment 1). The proposed drug products also represent tablet dosage forms, but contain 187.5 mg of griseofulvin ultramicrosize and 375 mg of griseofulvin ultramicrosize, respectively. This petition is thus seeking a change in strength (from 250 to 187.5 mg, and from 250 mg to 375 mg) from that of the RLD. Please note that the proposed changes in strength represent a dosage strength that is clearly contemplated in the approved labeling for the RLD.

The current dosing instructions in the approved labeling of the RLD are as follows:

> "Gris-PEG® tablets may be swallowed whole or crushed and sprinkled onto 1 tablespoonful of applesauce and swallowed immediately without chewing.

> **Adults:** Daily administration of 375 mg (as a single dose or in divided doses) will give a satisfactory response in most patients with tinea corporis, tinea cruris, and tinea capitis. For those fungal infections more difficult to eradicate, such as tinea pedis and tinea unguium, a divided dose of 750 mg is recommended.
>
> **Pediatric Use:** Approximately 3.3 mg per pound of body weight per day of ultramicrosize griseofulvin is an effective dose for most pediatric patients. On this basis, the following dosage schedule is suggested: Children weighing 35-60 pounds 125 mg to 187.5 mg daily. Pediatric patients weighing over 60 pounds - 187.5 mg to 375 mg daily. Children and infants 2 years of age and younger - dosage has not been established. Clinical experience with griseofulvin in children with tinea capitis indicates that a single daily dose is effective. Clinical relapse will occur if the medication is not continued until the infecting organism is eradicated."

Thus, the 187.5 mg and 375 mg tablets would provide for greater flexibility in administration of the dose within the labeled dosing range, especially for pediatric patients, for which dosing by weight instructions are provided. The 187.5 and 375 mg strengths would obviate the need to crush the tablets and sprinkle onto applesauce prior to administration when those doses are prescribed for pediatric patients weighing over 60 pounds. Additionally, the 375 mg tablet strength would provide convenient one tablet dosing for adults requiring that dose. Providing the additional strengths of 187.5 mg and 357 mg will increase the healthcare practitioner's ability to titrate to the recommended doses while limiting the potential of adverse effects.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition. The uses, indications, warnings, and directions for use will remain the same as that of the RLD. Draft labeling for the proposed product is included in Attachment 2, and the RLD's approved labeling is provided in Attachment 3.

Therefore, the petitioner's request for the Commissioner to find that a change in strength from 250 mg to 187.5 mg, and from 250 mg to 375 mg, for Griseofulvin Tablets should raise no questions of safety or effectiveness, and the Agency should 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,

Christine Miller

Christine Miller, Pharm.D
Associate Director

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Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, accessed June 20, 2013
2. Draft Insert Labeling Proposed for Griseofulvin Tablets, 187.5 mg and 375 mg
3. Labeling for the RLD Gris-PEG® Tablets by Pedinol

cc: Martin Shimer (OGD)

Gris-PEG® is a registered trademark of Pedinol Pharmacal, Inc.

From: (516) 683-1881 Origin ID: RMEA
Westbury Office
LACHMAN CONSULTANT SERVICES
1600 STEWART AVE
SUITE 604
WESTBURY, NY 11590

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Division of Dockets Management
FDA, DHHS, HFA-305
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