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U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

D1178B

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Richard Strauss, R.Ph.
President
Pedinol Pharmacal, Inc.
30 Banfi Plaza, North
Farmingdale, NY 11735

February 10, 1997

Ref: 38-NYK-97

Dear Mr. Strauss:

This letter is written in reference to the marketing and distribution of Pedi-Dri Topical Powder by your firm. Our review of the labeling for this product finds that it contains nystatin 100,000 U.S.P. units per gram as the active ingredient, and is represented and suggested as useful in treating fungal infections of the feet caused by Candida species.

Based on its formulation and intended uses, we regard Pedi-Dri to be an antibiotic drug product within the meaning of Section 507(a) of the Federal Food, Drug, and Cosmetic Act ("the Act") and subject to the provisions of Section 507. It is misbranded within the meaning of Section 502(l) in that it is, or purports to be, or is represented to be an antibiotic drug and no certificate or release has been issued pursuant to Section 507 and the drug product is not exempted by regulations promulgated under Section 507(c) or (d). Consequently, the continued marketing of Pedi-Dri, or any other antibiotic drug product you may market and distribute without the required certificate or release, constitutes a violation of Section 502(l) of the Act.

This letter does not represent a comprehensive review of all the products your firm may market and distribute. It is your responsibility to ensure that all of your firm's products are in compliance with all of the requirements of the Act and its implementing regulations.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific actions taken to correct the noted violations, including an explanation of each step being

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taken to prevent recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is fluid and cursive, with a large initial "C" and a long, sweeping tail that ends in a sharp point.

Charles W. Sedgwick
Acting District Director