



NDA 50-475/S-046

Pedinol Pharmacal, Inc.
Attention: Harry Gordon, Ph.D.
Regulatory Consultant
30 Banfi Plaza North
Farmingdale, NY 11735

Dear Dr. Gordon:

Please refer to your supplemental new drug application dated August 13, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gris-PEG[®] (griseofulvin ultramicrosize) Tablets, 125 mg and 250 mg.

This special supplemental new drug application changes being effected provides for the addition of "erythema multiforme – like drug reactions" to the ADVERSE REACTIONS section.

We completed our review of this supplemental new drug application, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on August 13, 1996. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

In the DESCRIPTION section, please harmonize the listings in both dosage form descriptions, using "povidone" as the appropriate USAN name for polyvinylpyrrolidone at the next printing of the package insert and report the change in the Annual Report.

If a letter communicating important information about this drug product (i.e. a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be necessary.

If you have any questions, call Frank Cross, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{ See appended electronic signature page }

Jonathan K. Wilkin, M.D.

Director

Division of Dermatologic & Dental Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Jonathan Wilkin
nulldate