DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-022/S-003

Dermik Labroatories
Attn: Jennifer W. Phillips, Pharm.D.,
Director, Regulatory Affairs
1050 Westlakes Drive
Berwyn, PA 19312

Dear Dr. Phillips:

Please refer to your supplemental new drug application dated June 27, 2003, received June 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Penlac™ Nail Lacquer (ciclopirox) Topical Solution, 8%.

We acknowledge receipt of your submission dated December 22, 2003 (facsimile).

This supplemental new drug application provides for revisions to the PRECAUTIONS Section, Pediatric Use Sub-section of labeling.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-022/S-003." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, 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

Enclosure

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

/s/

Stanka Kukich
12/22/03 01:00:48 PM
signing for Jonathan Wilkin, Division Director