DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-022/S-004

Dermik Labroatories
Attn: Gary Feiss, M.S.
Head, Clinical Development, Regulatory Affairs/Compliance
1050 Westlakes Drive
Berwyn, PA 19312

Dear Mr. Feiss:

Please refer to your supplemental new drug application dated June 4, 2004, received June 7, 2004, 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 August 10, August 16 and December 1 (facsimile), 2004.

This supplemental new drug application provide for revised labeling to reflect the final study results for contact sensitization.

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

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 the requirements for an approved NDA set forth under 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.
Division 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
12/3/04 03:12:26 PM
sign off for Dr. Jonathan Wilkin, Division Director