DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-568/S-008

Dermik Laboratories
Attn: Jennifer Phillips, Pharm.D.
1050 Westlakes Drive
Berwyn, PA 19312

Dear Dr. Phillips:

Please refer to your supplemental new drug application dated December 31, 2003, received January 2, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dermatop® Ointment (prednicarbate ointment), 0.1%.

We acknowledge receipt of your submissions dated December 31, 2003, January 26, 2004, February 3, 2004, February 20, 2004, March 31, 2004 and May 24, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change in the composition of (b)(4)----------of Dermatop Ointment. (b)(4)-------- a proprietary(b)(4)---------- ---------- incl udes an (b)(4)---------- (b)(4)-- Specifically, the change in composition of (b)(4)---------- (b)(4)----------with propyl gallate. In addition, this supplement provides for revised labeling for Dermatop Ointment to reflect the internationally recognized nomenclature for (b)(4)-------

In a telephone conference between you and representatives of the Division of Dermatologic and Dental Drug Products on January 22, 2004, the Agency requested a revision to the labeling for Dermatop (prednicarbate ointment) Ointment, 0.1%, to include all ingredients contained in (b)(4)------- Your submission dated January 26, 2004, provides for a revision to the labeling for Dermatop Ointment to include all ingredients contained in (b)(4)--------

We completed our review of this supplemental new drug application. This supplement is approved.

As a condition of the approval of this supplement, we remind you of your postmarketing study commitment agreed upon both during the May 17, 2004, teleconference with representatives from this Division and in your submission dated May 24, 2004. These commitments are listed below.

Description of Commitments:

1. Contact sensitization (not less than 200 evaluable subjects)

Protocol Submission:	by January 31, 2005
Study Start:	by January 31, 2005
Final Report Submission:	by June 30, 2005

2. Photoallergenicity (not less than 50 evaluable subjects)

   Protocol Submission: by January 31, 2005
   Study Start: by January 31, 2005
   Final Report Submission: by June 30, 2005

3. Phototoxicity (not less than 30 evaluable subjects)

   Protocol Submission: by January 31, 2005
   Study Start: by January 31, 2005
   Final Report Submission: by June 30, 2005

These studies should be blinded and conducted with formulation vehicle and the marketed formulation. Propyl gallate is the only change in the composition for Dermatop Ointment 0.1%; therefore, if there is no absorption in the UVA, UVB, or visible light spectra for propyl gallate, then phototoxicity and photoallergenicity studies may be waived.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

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

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

Sincerely,

{See appended electronic signature page}

Jonathan Wilkin, M.D.
Division Director
Division of Dermatologic and 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/

Stanka Kukich
7/2/04 02:34:40 PM
Signing off for Dr. Wilkin, Division Director