DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-756/S-016

Dermik Laboratories
Attention: Jennifer Pavillard
Regulatory Affairs Manager
1050 Westlakes Drive
Berwyn, PA 19312

Dear Ms. Pavillard:

Please refer to your supplemental new drug application dated November 19, 2003, received November 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BenzaClin™ (clindamycin 1% and benzoyl peroxide 5% gel) Topical Gel.

We acknowledge receipt of your submissions dated July 29, 2004 and April 13, 2005.

Your submission of July 29, 2004, constituted a complete response to our May 20, 2004, action letter.

This supplemental new drug application provides for safety information in the Information for Patients, and Carcinogenesis, Mutagenesis, Impairment of Fertility sections of the package insert.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the labeling (package insert) submitted on July 29, 2004.

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

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-756/S-016**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, call Margo Owens, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan Wilkin, M.D.
Director
Division of Dermatologic and 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
4/28/05 03:53:22 PM
sign off for Dr. Jonathan Wilkin, Division Director