DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-756/S-007

Dermik Laboratories, Inc.
Attention: Robert W. Babilon
Senior Manager, Regulatory Affairs
1050 Westlakes Drive
Berwyn, PA 19312

Dear Mr. Babilon:

Please refer to your supplemental new drug application dated February 12, 2002, received February 14, 2002, submitted under Section 505(b) of the Federal Food, Drug, and Cosmetic Act for BenzaClin (clindamycin phosphate, 1% and benzoyl peroxide, 5%) Topical Gel.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a 50-gram packaging size for BenzaClin Topical Gel with changes to its polypropylene resin and minor labeling changes.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

Under the HOW SUPPLIED AND COMPOUNDING INSTRUCTIONS Section of the Package Insert, the 50-gram container was added to the table listing the 25-gram container. In addition, the following paragraph had minor changes as follows: (1) the second sentence is changed to read, "Add 5 mL of purified water . . . ", (2) the fourth sentence of that paragraph is changed to read, "BenzaClin Topical Gel (as constituted) can be stored at room temperature . . ", and (3) the Net Wt. is changed to add 50-grams (after reconstitution) to the label.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted February 12, 2002, immediate container and carton labels submitted February 12, 2002). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-756/S-007." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Dermatologic & Dental Drug Products 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, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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

Please submit one market package of the drug product when it is available.

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, call Mary Jean Kozma-Fornaro, Supervisor, Project Management, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products,
(HFD-540)
DNDC III, Office of New Drug Chemistry
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/

Wilson H. DeCamp
8/9/02 10:56:53 AM
approved