CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 50-756

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-756

Dermik Laboratories, Inc.
Attention: Kim Forbes-McKean, Ph.D.
Senior Director, Product Development and Commercialization
1050 Westlakes Drive
Berwyn, PA 19312

Dear Dr. Forbes-McKean:

Please refer to your new drug application (NDA) dated April 9, 1998, received April 10, 1998, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for BenzaClin (clindamycin 1% and benzoyl peroxide 5% gel) Topical Gel.

Please refer to our action letter dated April 1, 1999.

We acknowledge receipt of your submissions dated June 29, July 7, August 4, September 20, and October 17, 2000. Your submission of June 29, 2000, received June 30, 2000, constituted a complete response to our April 1, 1999, action letter.

This new drug application provides for the use of BenzaClin (clindamycin 1% and benzoyl peroxide 5% gel) Topical Gel for the treatment of acne vulgaris.

We have completed the review of this application, as amended, 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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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

We remind you of your post marketing commitments specified in your facsimile dated December 20, 2000. You have agreed to submit the following protocols within 9 months of the approval of this application:

1. To conduct a dermal carcinogenicity study and a study on the effects on UV-induced skin carcinogenicity. These studies should be completed and submitted within 4 years of the approval of this application.

2. To conduct a study in patients with acne vulgaris designed to assess the degree of systemic absorption of clindamycin under maximal use conditions (i.e. maximizing the amount applied, surface area involved, and frequency of application consistent with the approved package insert). Such a study should be done under multiple dosing conditions and include a representative range of ages of both sexes. This *in vivo* pharmacokinetic study should be completed and submitted within 18 months of approval of this application.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your post marketing commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these post marketing commitments must be clearly designated "Post Marketing Commitments."

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving pediatric studies below the age of 12 years, because acne is not prevalent in the population from birth to 11 years, and this product would not represent a substantive therapeutic benefit as an acne therapy for that population. There are sufficient data to determine efficacy and safety down to and including age 12 years. The Agency grants you a partial waiver for pediatric acne studies for the age group between birth and 11 years of age, under 21 CFR 314.55(c)(4)

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 submit 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, Maryland 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, please call Kevin Darryl White, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

APPEARS THIS WAY
ON ORIGINAL

cc:
Archival NDA 50-756
HFD-540/Div. Files
HFD-540/White (with labeling) 11.17.00
HFD-540/Kozma-Fornaro (with labeling) 11.17.00
HFD-540/Wilkin (with labeling)
HFD-540/Walker (with labeling) 11.17.00
HFD-540/Huene (with labeling)
HFD-540/DeCamp (with labeling) 11.21.00
HFD-540Vidra (with labeling) 11.21.00
HFD-540/Jacobs (with labeling) 11.17.00
HFD-540Mainigi (with labeling)
HFD-540/Bashaw (with labeling) 11.21.00
HFD-540/Al-Osh (with labeling)
HFD-540/Thomson (with labeling)
HFD-520/A. Sheldon/Marsik (with labeling)
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-105/ADRA (with labeling)
HFD-104/Peds/V.Kao (with labeling)
HFD-104/Peds/T.Crescenzi (with labeling)
HFD-42/DDMAC (with labeling)
HFI-20/Press Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-095/DDMS-IMT (with labeling)
HFD-093/DDMS-IST (with labeling)
HFD-830/DNDC Division Director (with labeling)
DISTRICT OFFICE

Drafted by: KDW 11-17-00 02:45pm
Initialed by:
Final:
Filename: NDA 50-756 BenzaClin AP 11-20-00

APPROVAL (AP)