

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 50-782

APPROVAL LETTER

Food and Drug Administration
Rockville MD 20857

NDA 50-782

NOV 27 2000

Target Research Associates
Attention: Robert J. McCormack, Ph.D.
Vice President, Regulatory Affairs
554 Central Avenue
New Providence, NJ 07974

Dear Dr. McCormack:

Please refer to your new drug application (NDA) dated January 27, 2000, received January 27, 2000, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Tradename (clindamycin phosphate) Topical Gel, 1%.

We acknowledge receipt of your submissions dated February 28 and 29 (2), March 24, April 26 and 28 (2), May 16 and 25, July 17, 20 and 31, August 16 and 21, September 6, 14 and 18, October 9 and 31, and November 8, 15, 17, 20, 21 (2), and 22, 2000.

This new drug application provides for the use of Tradename (clindamycin phosphate) Topical Gel, 1%, for once a day 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.

According to "Guidance for Industry, Changes to an Approved NDA or ANDA," dated November 1999, you will need to submit a labeling supplement for alternative options for tradename. The reporting category for a tradename qualifies as a major change requiring a prior approval supplement per 21CFR 314.70(b)(3).

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 50-782." Approval of this submission by FDA is not required before the labeling is used.

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 note that you have requested a waiver for pediatric studies on neonates, infants and children, because acne is not prevalent in the population from birth to 11 years, and clindamycin phosphate would not represent a substantive therapeutic benefit as an acne therapy for that population. 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 in print. Please submit one copy to this Division and two copies of both the promotional material 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 Indira Kumar, Regulatory 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

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/s/

Jonathan Wilkin
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APPEARS THIS WAY
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