CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-184

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 21-184

SEP 29 2000

Allergan
Attention: Trudy Rumbaugh, M.D.
Director, Global Regulatory Affairs, Retinoids
2525 Dupont Drive,
P.O. Box 19534
Irvine, California 92623-9534

Dear Dr. Rumbaugh:

Please refer to your new drug application NDA dated September 30, 1999, received September 30, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAZORAC ® (tazarotene) Cream, 0.05% and 0.1%.

We acknowledge receipt of your submissions dated September 30, 1999, February 3, March 7 and 22, April 7, May 5 and 15, June 7, July 25 and 27, and September 1 and 13, 2000.

This new drug application provides for the use of TAZORAC® (tazarotene) Creams, 0.05% and 0.1%, for the indication of plaque psoriasis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that these drug products are 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, text for the patient 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 21-184." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please 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 plaque psoriasis is not prevalent in the population from birth to 11 years and tazarotene cream would not represent a substantial therapeutic benefit over existing anti-psoriatic therapies. The Agency grants you a partial waiver for pediatric psoriasis studies for the age group between birth and 11 years of age, under 21 CFR 314.55(c)(4). The Agency further allows you to defer submission of information for patients between 12 and 17 years of age, under 21 CFR 314.55(b)(2). We remind you of your Phase 4 commitment specified in the facsimile of your letter dated September 26, 2000, to submit safety information, including the effects on epiphyses, for tazarotene creams in the treatment of psoriasis in patients between 12 and 17 years of age, by September 30, 2001.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity, you should submit a "Proposed Pediatric Study Request" (PPSR). We recommend that you submit the PPSR within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

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 Kalyani Bhatt at 301-827-2020.

Sincerely,

/S/

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

APPEARS THIS WAY
ON ORIGINAL

Enclosure