

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
21-184/S-001**

Approval Letter



NDA 21-184/S-001

OCT 11 2001

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

Dear Dr. Rumbaugh:

Please refer to your supplemental new drug application dated December 8, 2000, received December 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tazorac® (tazarotene) Cream, 0.1%.

We acknowledge receipt of your submissions dated January 19 and 31; February 1, and April 24, 2001 and October 10, 2001.

This supplemental new drug application provides for the use of Tazorac (tazarotene) Cream, 0.1%, for acne vulgaris.

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

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

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 21-184/S-001." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing commitments specified in your submission dated October 11, 2002.

These commitments are listed below.

- 1.) A commitment to revise within 90 days, the tazarotene gel label with a labeling supplement to NDA 20-600, to include relevant information on tazarotene gel data which has been submitted to NDA 21-184/S-001.

If needed, submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

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.

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 the pediatric study requirement for this action on this application.

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

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

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314.80 and 314.81.

If you have any questions, please call Kalyani Bhatt, Project Manger, at 301-827-2020.

Sincerely,

(See appended electronic signature page)

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