

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-600

MICROBIOLOGY REVIEW(S)

J C ✓ Higley

**CONSULTATIVE REVIEW TO HFD-540
DIVISION OF MEDICAL IMAGING, SURGICAL,
and DENTAL DRUG PRODUCTS; HFD-160
MICROBIOLOGIST'S REVIEW OF NDA**

AUG 9 1995

August 9, 1995

A. 1. NDA 20-600

APPLICANT: Allergan, Inc.
P.O. Box 19534
2525 Dupont Drive
Irvine, CA 92713-9534 USA

2. PRODUCT NAMES: Tazarotene
AGN 190168
Ethyl 6-[(4,4-dimethylthiochroman-6-yl)ethyl]nicotinate

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
Topical Gel. It is packaged in collapsible aluminum tubes, in 10 gram, 30 gram, and 100 gram sizes containing either 01% or 0.05% Tazarotene gel.

4. METHODS OF STERILIZATION:
None. The drug product is a gel preserved with 1.0% (w/w) benzyl alcohol.

5. PHARMACOLOGICAL CATEGORY:
For the topical treatment of plaque psoriasis and the topical treatment of acne.

B. 1. DATE OF INITIAL SUBMISSION: June 16, 1995

2. RELATED DOCUMENTS:

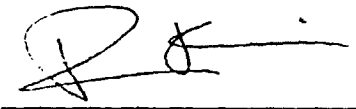
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3. AMENDMENT DATE: June 28, 1995. This amendment to the pending NDA submission was submitted as information for the microbiology review.


4. **ASSIGNED FOR REVIEW: July 5, 1995**

C. **REMARKS:** The NDA 20-600 provides for Tazarotene, a non-sterile and preserved topical gel formulation, for use in cases of plaque psoriasis and acne. An amendment to the original NDA submission was provided by the sponsor for the microbiology review. This amendment contains information also found in the original submission.

D. **CONCLUSIONS:** The NDA 20-600 for Tazarotene is approvable pending resolution of certain microbiology issues.

 8/9/95

Patricia F. Hughes, Ph.D.
Review Microbiologist

 8/9/95

cc: Original NDA 20-600
HFD-160/Consult File
HFD-160/P.F.Hughes/8/9/95
HFD-540/Division File
HFD-540/CSO
HFD/Rev.Chemist/J. Holmes

Drafted by P.F.Hughes, 08/9/95
R/D initialed by P. Cooney, 08/9/95

