

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-184

Microbiology Review(s)

FILED STU
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REVIEW FOR HFD-540
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 21-184
6 March 2000

MAR - 8 2000

A. 1. NDA 21-184

APPLICANT: Allergan, Inc.
2525 DuPont Drive
P.O. Box 19534
Irvine, CA 92623-9534

- 2. PRODUCT NAMES: Tazorac® 0.05% and 0.1%
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a topical cream.
- 4. METHODS OF STERILIZATION:
The product is not a sterile product but, is subject to microbial limits specifications.
- 5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for use in treatment of plaque psoriasis.

B. 1. DATE OF INITIAL SUBMISSION: 20 September 1999

- 2. DATE OF AMENDMENT: (none)
- 3. RELATED DOCUMENTS: _____
NDA 20-600, _____
- 4. ASSIGNED FOR REVIEW: 17 November 1999

REMARKS: The application provides for the manufacture of the product at the applicant's facility in Waco, Texas. The product is to be packaged in collapsible aluminum tubes in _____, 15 g, 30 g, and 60 g sizes. Benzyl alcohol at a concentration of 1% is used as the preservative.

D. CONCLUSIONS: The application is recommended for approval on the basis of microbiological quality of the drug product.

/S/

Paul Stinavage, Ph.D.

6 March 2000

PS 3/8/00

cc: Original NDA 21-184
HFD-540/K. Bhatt
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 6 March 2000
R/D initialed by P. Cooney

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