

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
20-748

MICROBIOLOGY REVIEW

O. Cintron

REVIEW FOR HFD-540
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW NO. 3 OF NDA 20-748

OCT 5 1999

September 23, 1999

A 1. NDA 20-748

APPLICANT: Galderma Laboratories Inc.
3000 Alta Mesa Blvd., Suite 300
Fort Worth, Texas 76133

2. PRODUCT NAMES: Differin™ (adapalene cream) Cream, 0.1%
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Cream, for topical application to the skin, provided in 15 gm and 45 gm laminate tubes. Rx
4. METHOD(S) OF STERILIZATION: Nonsterile drug
5. PHARMACOLOGICAL CATEGORY: Topical treatment of acne vulgaris
6. DRUG PRIORITY CLASSIFICATION: 3S

B. 1. DATE OF INITIAL SUBMISSION: July 16 , 1997

2. AMENDMENTS:

February 2, 1998-Review #2
September 7, 1999-Subject of Review #3

3. RELATED DOCUMENTS:

IND

NDA 20-338 Differin (adapalene solution) Solution,
0.1%

NDA 20-380 Differin (adapalene gel) Gel, 0.1%

4. ASSIGNED FOR REVIEW: September 17, 1999

C. REMARKS:

The amendment of September 7, 1999 responds to the FDA Not Approvable letter dated July 9, 1998.

D. CONCLUSIONS: The submission is recommended for approval based on the microbial quality of the subject drug. Specific comments are provided in "E. Review Notes".

LS
Vivian Greenman

cc: Orig. NDA 20-748
HFD 160/Consult File
HFD 540/CSO/Olga Cintron
drafted by: V. Greenman
R/D init. by PCooney
PC #: NDA20748.MR3

1
LS

10-5-99

Redacted 1

pages of trade

secret and/or

confidential

commercial

information

Redacted 10

pages of trade

secret and/or

confidential

commercial

information

540

DEC 12 1997

REVIEW FOR HFD-540
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW NO. 1 OF NDA 20-748

December 11 , 1997

1. NDA 20-748

APPLICANT: Galderma Laboratories Inc.
3000 Alta Mesa Blvd., Suite 300
Fort Worth , Texas 76133

2. PRODUCT NAMES: Differin™ (adapalene cream) Cream, 0.1%
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Cream, for topical application to the skin, provided in 15 gm and 45 gm laminate tubes.
Rx
4. METHOD(S) OF STERILIZATION: Nonsterile drug
5. PHARMACOLOGICAL CATEGORY: Topical treatment of acne vulgaris
6. DRUG PRIORITY CLASSIFICATION:

B. 1. DATE OF INITIAL SUBMISSION: July 16 ,1997

2. DATE OF AMENDMENT: N/A

3. RELATED DOCUMENTS:

IND _____

NDA 20-338 Differin (adapalene solution) Solution, 0.1%
NDA 20-380 Differin (adapalene gel) Gel, 0.1%

4. ASSIGNED FOR REVIEW: July 25, 1997

C. REMARKS:

The subject drug is one of three topical adapalene dosage forms sponsored by the applicant, Galderma Laboratories, and indicated for treatment of acne vulgaris. The following related NDAs were approved on May 31, 1996:

NDA 20-338 Differin Solution , 0.1%
NDA 20-380 Differin Gel, 0.1%

Galderma Laboratories is a subsidiary of Galderma S.A., Levallois Perret, France.

- D. CONCLUSIONS: The submissions are not recommended for approval on the basis of microbial quality of the subject drug. Specific comments are provided in "E. Review Notes" and "Microbiologist's Draft of Letter to Applicant".**

LS

Vivian Greenman

LS

cc: **Orig. NDA 20-748**
HFD 160/Consult File
HFD 540/CSO/Olga Cintron
drafted by: V. Greenman
R/D init. by PCooney

Redacted 7

pages of trade

secret and/or

confidential

commercial

information