

NDA 16-831/S-030

Betty C. Holland
Senior Manager
Drug Regulatory Affairs
Hoffmann-La Roche, Inc.
Roche Dermatologics
340 Kingsland Street
Nutley, New Jersey 07110

MAR 4 1993

Dear Ms. Holland:

Please refer to your supplemental New Drug Application (NDA) dated September 23, 1992,, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Efudex (fluorouracil) Topical Solution and Creams.

The supplemental application provides for revisions and directions for testing for Efudex Topical Cream, 5%.

We have completed our review of this supplemental application and it is approved effective as of the date of this letter.

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

/S/ 3/1/93

Wilson H. De Camp, Ph.D.
Supervisory Chemist
Division of Anti-Infective Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc: Orig: NDA 16-831/S-030
HFD-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/Browder
HFD-521/Cook
HFD-520/Mokhtari-Rejali
init. by SUPVCHEM/2/26/93
td:3/1/93/n16831.s30

/S/ 3/12/93

APPROVED



Food and Drug Administration
Rockville MD 20857

Date OCT 2 1992

NDA No. 16-831

Roche Dermatologics
340 Kingsland Street
Nutley, NJ 07110-1199

Attention: Betty C. Holland

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Efudex Topical Solutions and Cream

NDA Number: 16-831

Supplement Number: S-030

Date of Supplement: September 23, 1992

Date of Receipt: September 30, 1992

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control, Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

IS/
Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drug Evaluation and Research

NDA SUPPLEMENT REVIEW

FEB 26 1993

CHEMIST'S REVIEW	1. ORGANIZATION DAIDP (HFD-520)	2. NDA NUMBER 16-831
3. NAME & ADDRESS OF APPLICANT Hoffman-La Roche Roche Dermatologics 340 Kingsland Street Nutley, NJ 07110		4. AF NUMBER
		5. SUPPLEMENT(s) NUMBER(s) DATE(s)
6. NAME OF DRUG Efudex Topical Solution	7. NONPROPRIETARY NAME 5-Fluorouracil	9/23/92
8. SUPPLEMENT(s) PROVIDES FOR: SCS-030 for revision to the specifications and directions for testing for Efudex Topical Cream, 5%.	9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES None	
10. PHARMACOLOGICAL CATEGORY Chemotherapeutic	11. HOW DISPENSED XXX Rx OTC	12. RELATED IND/NDA/DMF(s)
13. DOSAGE FORM(s) Topical Solutions and Cream	14. POTENCY(ies) 2% & 5% 5%	
15. CHEMICAL NAME AND STRUCTURE USP		Yes No
17. COMMENTS SPECIAL SUPPLEMENT--CHANGES BEING EFFECTED ON OCTOBER 1, 1992.		

The following revisions to the specifications and directions for testing for Efudex Topical Cream, 5% are provided:

18. **CONCLUSIONS AND RECOMMENDATIONS:**

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 16-831

HFD-520

HFD-520/MO/Sanders

HFD-520/Browder

HFD-520/CSO/Cook

HFD-520/Mokhtari

HFD-520/WHDeCamp:R/D initialed

IS/
[Handwritten initials]

19.

REVIEWER

NAME

SIGNATURE

DATE COMPLETED

Nahid Mokhtari-Rejali, Ph.D.

1/19/92

IS/

DISTRIBUTION

ORIGINAL JACKET

REVIEWER

DIVISION FILE