



NDA 16-831/S-035

APR 5 2000

ICN Pharmaceuticals
Attention: Anil K. Hiteshi
Acting Director
3300 Hyland Avenue
Costa Mesa, CA 92626

Dear Mr. Hiteshi:

Please refer to your supplemental new drug application dated October 13, 1999, received October 18, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Efudex (Fluorouracil) Cream, 5%.

This supplemental new drug application provides for the addition of an alternate testing laboratory for QC testing for Efudex Cream, 5%.

We have completed the review of this supplemental application and it is approved.

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

If you have any questions, call Vicky Lutwak, Project Manager, at (301) 827-2020.

Sincerely yours,

WHD 4/15/00

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic and Dental
Drug Products, (HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-831/S-035

OCT 28

ICN Pharmaceuticals, Inc.
3300 Hyland Avenue
Costa Mesa, CA 92626

Attention: Anil K. Hiteshi, R.A.C.
Acting Director, Corp. Regulatory Affairs

Dear Mr. Hiteshi:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Efudex® (fluorouracil) Topical Cream, 5%

NDA Number: 16-831

Supplement Number: S-035

Date of Supplement: October 13, 1999

Date of Receipt: October 18, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on December 17, 1999 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Dermatologic and Dental Drug Products, HFD-540
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,


Mary J. Kozma-Fornaro
Supervisor, Project Management Staff
Division of Dermatologic and Dental
Drug Products, HFD-540
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Divf. 16-831

APR 3 2000

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls

NDA #: 16-831 CHEM.REVIEW #: 1 REVIEW DATE: March 8, 2000

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
SCM-035	13-OCT-99	18-OCT-99	19-OCT-99

NAME & ADDRESS OF APPLICANT: ICN Pharmaceuticals
3300 Hyland Avenue
Costa Mesa, CA 92626

Anil K. Hiteshi
Acting Director
Corporate Regulatory Affairs
(800) 548-5100

DRUG PRODUCT NAME:

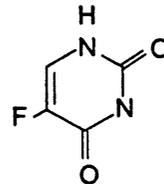
<u>Proprietary</u> :	Efudex
<u>Nonproprietary/USAN</u> :	Fluorouracil
<u>Code Names/ #'s</u> :	
<u>Chemical Type</u> :	
<u>Therapeutic Class</u> :	3 S

PHARMACOLOGICAL CATEGORY/INDICATION: multiple actinic
keratoses

<u>DOSAGE FORM</u> :	Cream
<u>STRENGTHS</u> :	5%
<u>ROUTE OF ADMINISTRATION</u> :	Topical
<u>DISPENSED</u> :	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

Molecular Formula:	C ₄ H ₃ FN ₂ O ₂
Molecular Weight:	130.1
CAS No.:	51-21-8



SUPPORTING DOCUMENTS: N/A

REMARKS/COMMENTS:

This CBE supplement was submitted to add an alternative laboratory for QC testing for the 5% Cream. The new facility is:

ICN Puerto Rico
Bo Mariana RD 909 Kilometer 1.1
Humacao, PR 00791931
CFN# 2650272

This facility has received an acceptable rating from OC. The EER is attached.

In further support of this supplement, an analytical transfer protocol was established. The purpose of the protocol was to ascertain that the tests/results performed/obtained at the new facility were identical to those at the old [approved] facility. A COA was submitted for the DP analyzed at the new facility. The COA indicated that the corresponding analytical methodology was successfully transferred to the new facility.

CONCLUSIONS & RECOMMENDATIONS:

The supplement is recommended for APPROVAL under section 505 of the FFD&C Act.

IS

W.C. Timmer, Ph.D.
Review Chemist

cc: Orig. NDA 16-831
HFD-540/Division File
HFD-540/PM/RBlay
HFD-540/Chem/WCTimmer
HFD-540/TeamLdr/WHDeCamp
filename: C:\WPWIN61\WPDOCS\CDER\SUPPLMNT\N16831-M.035

IS 4/2/00

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 16831/035	Priority: 3S	Org Code: 540
Stamp: 18-OCT-1999 Regulatory Due: 18-APR-2000	Action Goal:	District Goal: 14-MAR-2000
Applicant: ICN PHARMS	Brand Name: EFUDEX	
3300 HYLAND AVE	Established Name:	
COSTA MESA, CA 92626	Generic Name: FLUOROURACIL	
	Dosage Form: CRM (CREAM)	
	Strength: 5%	
FDA Contacts: V. LUTWAK (HFD-540)	301-827-2073	, Project Manager
W. TIMMER (HFD-540)	301-827-2048	, Review Chemist
W. DECAMP II (HFD-540)	301-827-2041	, Team Leader

Overall Recommendation:

ACCEPTABLE on 06-MAR-2000 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: **2650272**
ICN PUERTO RICO INC
BO MARIANA RD 909 KILOMETER 1.
HUMACAO, PR 007919731

DMF No:
AADA No:

Profile: **OIN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **06-MAR-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE RELEASE**
TESTER

RE: NDA 16-831/SCM-035

ICN Pharmaceuticals
3300 Hyland Avenue
Costa Mesa, CA 92626

Anil K. Hiteshi
Acting Director,
Corporate Regulatory Affairs
(800) 548-5100

Date of application: 13-OCT-99

Efudex Cream, 5%

The CBE supplement provides for:

- the addition of an alternate testing laboratory for QC testing ~~for QC release testing~~ of Efudex Cream, 5%

TS 4/4/00

TS 4/3/00