CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-021/S-002

Name: Efidac/24 (Pseudoephedrine HCl) Extended Release Tablets, 240 mg

Sponsor: ALZA Corporation

Approval Date: May 21, 1993

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-002

CONTENTS

Reviews / Information Included in this Review	
Approval Letter	X
Approvable Letter(s)	
Final Printed Labeling	
Labeling Review(s)	
Medical Review(s)	
Chemistry Review(s)	X
Statistical Review(s)	
Microbiology Review(s)	
Administrative Document(s)	
Correspondence	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-002

APPROVAL LETTER

MAY 21 1993

NDA 20-021/S-002

Alza Corporation
P.O. Box 10950
950 Page Mill Road
Palo Alto, CA 94303-0802

Attention: Harriet Benson
Vice President, Regulatory Affairs

Gentlemen:

Please refer to your supplemental new drug application dated January 29, 1993 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Efidac/24 (Pseudoephedrine HCl) Extended Release Tablets.

We also acknowledge your additional communications dated March 16, 1993, May 11, 1993 and May 18, 1993 amending the supplemental application.

The supplemental application provides for an alternate facility to package the drug product. The facility is ——— located at ———. The tablets are shipped in bulk from Vacaville California to ———. The same blister packaging materials used in Alza's Vacaville CA facility are also used by ———

We have completed our review of the supplemental application and it is approved. We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for approved new drugs.

Sincerely yours,

Guirag Poochikian, Ph.D.
Supervisory Chemist
Division of Oncology and
Pulmonary Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CC:
NDA 20-021/S-002
HFD-150/Division File
HFD-150/GKPoochikian
HFD-150/MCTheodorakis MCTheodorakis 5/20/93.
HFD-150/CSchumaker
R/D Init. by: LNg for GPoochikian/5-19-93
F/T by: DEFoxx/5-20-93
DOC.\ALZA\20021-02.SLA GP 5/20/93

APPROVAL

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-002

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW	Organization FDA/ HFD-150	NDA Number 20-021
Name and Address of Applicant: Alza Corporation 950 Page Mill Road, P.O. Box 10950 Palo Alto, CA 94303-0802 tel.: 415-494-5022, fax: 415-494-5050 Attention: Dr. Harriet Benson		**AF Number** **Supplement Number** **Date** S-002 1/29/93
Name of Drug Efidac/24 Extended Release Tablets	**Nonproprietary Name** Pseudoephedrine HCl Extended Release Tablets	**Amendment & dates** 3/16/93 5/11/93 5/18/93
Supplement Provides for an alternate packager of the drug product. The packager is [redacted] located at [redacted]. The same blister packaging materials used in Alza's Vacaville CA facility are also used by		**Related INDs, NDAs and DMF**
Pharmacological Category	**How Dispensed** Rx | OTC x	
Dosage Form: Extended Release Tablets	**Potency:** 240 mg/tablet	
Chemical Name and Structure See USP (XXII) p. 1186.		**Records & Reports Current** yes no **Reviewed** yes no

COMMENTS:
See page 2.

CONCLUSIONS and RECOMMENDATIONS:
It is recommended that approval be granted to this supplemental application.

CC:
NDA 20-021/S-002
HFD-150/Division File
HFD-150/MTheodorakis
HFD-150/GPoochikian
HFD-150/CSO
R/D Init. by: SN for GP 5/19/93
F/T by:MCT/
DOC.\ALZA\20021-02.SUP

REVIEWER NAME	SIGNATURE	DATE COMPLETED
Michael C. Theodorakis Ph.D.	MTheodorakis	5/18/93

Distribution: Original Jacket Reviewer Division File

12. RELATED INDs, NDAs, DMFs:

DMF ——— Type I, ———————, facilities, personnel, equipment.

17. COMMENTS:

a. The alternate packager is ——————— located at ——————— ———————————————. The tablets are shipped in bulk from Vacaville California to ——————————— The same blister packaging materials used in Alza's Vacaville CA facility are also used by ———————.

b. An EER request was issued on ——— for ———————. The facility was found to be acceptable on ———.

c. The bulk tablets are shipped from Vacaville CA to ———————. The tablets ——— are packaged ———————————————

d. [redacted]

e. The following lots were manufactured at Alza in Vacaville CA, packaged at ——————————— and placed on stability at Alza:

Lot No.	Storage Conditions	Period of Storage (months)	Container
91-1389:	30°C	6	blister package
	37°C/75% RH	3	
	40°C	3	
91-1392:	30°C	6	blister package
	37°C/75% RH	3	
	40°C	3	
91-1396:	30°C	6	blister package
	37°C/75% RH	3	
	40°C	3	

The limited stability data indicate that the drug product packaged at ——————— was stable over the period tested. Based on these data and on data submitted previously for the facility of Vacaville, it is recommended that the same expiration dating period be granted for the drug product packaged at ———————.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

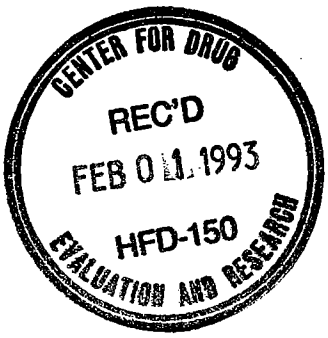
NDA 20-021/S-002

CORRESPONDENCE

alza

NDA NO. 20021 REF. NO. 002

NDA SUPPL FOR SCM



NDA 20-021
Volume 21.1

January 29, 1993

Center for Drug Evaluation and Research
Office of Drug Evaluation I, HFD-150
Document Control Room 9B-23
5600 Fishers Lane
Rockville, MD 20857

Attention: Gregory P. Burke, M.D., Ph.D., Director
Division of Oncologic and Pulmonary Drug Products

Subject: EFIDAC/24® pseudoephedrine hydrochloride (240 mg):
Supplemental New Drug Application - Alternate Packaging Site
EXPEDITED REVIEW REQUESTED

Dear Dr. Burke:

In accordance with 21 CFR 314.70 (b)(2)(vi) we are submitting a supplemental new drug application to use an alternate packaging site for EFIDAC/24® pseudoephedrine hydrochloride (240 mg). We request that ———— located on ———— be approved as an alternative packaging site for EFIDAC/24. Currently EFIDAC/24 is manufactured and packaged at ALZA Corporation's approved facility in Vacaville, California.

The EFIDAC/24 product will continue to be manufactured by ALZA Corporation using the currently approved manufacturing procedure. The finished tablets will be tested by ALZA in accordance to the approved Quality Standard and only acceptable finished product will be shipped in bulk to ——— packaging facility. At ——— the bulk finished tablets will be visually inspected and blister packaged using the packaging materials currently approved for use by ALZA Corporation.

Three commercial sized production lots were sampled, packaged at ——— and placed on stability. Three (3) month accelerated data and six (6) month room temperature data for three (3) lots of EFIDAC/24 packaged at ———— are provided in Attachment 1. These lots will continue to be monitored at the specified time points. At least one lot each year thereafter will be placed on stability and monitored. Our stability commitment is provided in Attachment 2.

Our commitment for expiration dating is provided in Attachment 3. Attachment 4 contains the DMF Authorization letter from ———— authorizing the FDA full reference to ——— DMF No.———

alza

An expedited review is requested because ALZA Corporation is currently the single approved packaging source for this product. We may be facing capacity constraints as demand for this product exceeds that anticipated. This additional packaging site, will allow greater flexibility in scheduling, provide for increased production and provide an essential back-up in case of any unforeseen problems at ALZA corporation.

If you need any additional information, please feel free to contact me at (415) 494-5022 or via facsimile at (415) 494-5050.

Sincerely,

Harriet Benson, Ph.D.

Harriet Benson, Ph.D.
Vice President
Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date February 1, 1993

NDA No. 20-021

ALZA Corporation
950 Page Mill Road
Palo Alto, California
94304

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Pseudoephedrine Hydrochloride (240 mg)

NDA Number: 20-021

Supplement Number: SCM-002

Date of Supplement: January 29, 1993

Date of Receipt: February 1, 1993

All communications concerning this NDA should be addressed as follows:

National Center for Drugs and Biologics(HFN-150)
Attention: Document Control Room 17B-28
5600 Fishers Lane
Rockville, MD 20857

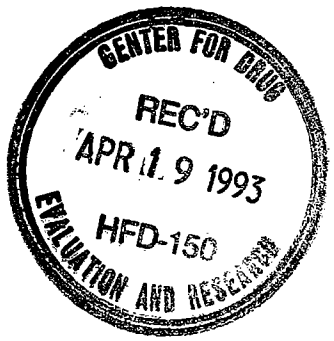
Nancy Crane

for: Supervisory Consumer Safety Officer
Division of Oncology and Radiopharmaceutical
Drug Products
National Center for Drugs and Biologics

FORM FDA 3217e (6/83)

☆ GPO : 1983 O - 408-424

NDA SUPPL AMENDMENT
S cm 002 (Bc)



NDA 20-021
Volume 23.1

March 16, 1993

Center for Drug Evaluation and Research
Office of Drug Evaluation I, HFD-150
Document Control Room 9B-23
5600 Fishers Lane
Rockville, MD 20857

Attention: Gregory P. Burke, M.D., Ph.D., Director
Division of Oncologic and Pulmonary Drug Products

Subject: EFIDAC/24® pseudoephedrine hydrochloride (240 mg):
Amendment to our Supplemental New Drug Application - Packaging for Bulk Shipment to Alternative Packaging Site

Dear Dr. Burke:

We are submitting an amendment to our alternative packaging site supplement (Volume 21.1) submitted to the FDA on January 29, 1993 for EFIDAC/24® pseudoephedrine hydrochloride (240 mg). This supplement requested ——— ——— located in ——— to be approved as an alternative packaging site for EFIDAC/24. Currently EFIDAC/24 is manufactured and packaged at ALZA Corporation's approved facility in Vacaville, California.

As previously mentioned the EFIDAC/24 product will continue to be manufactured by ALZA Corporation using the currently approved manufacturing procedure. The finished tablets will be tested by ALZA in accordance with the approved Quality Standard and only acceptable finished product will be shipped in bulk to ——— packaging facility.

The bulk shipment will consist of approximately ——— of systems packaged in

ORIGINAL

ALZA CORPORATION, 950 PAGE MILL ROAD, P.O. BOX 10950, PALO ALTO, CA 94303-0802 (415) 494-5000 TELEX 345526

alza

Once at —— the bulk finished tablets will be visually inspected and blister packaged using the packaging materials currently approved for use by ALZA Corporation.

If you need any additional information, please feel free to contact me at (415) 494-5022 or via facsimile at (415) 494-5050.

Sincerely,

Harriet Benson, Ph.D.

Harriet Benson, Ph.D.
Vice President
Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

Scm 002 (BC)

NDA SUPPL AMENDMENT

NDA 20-021

May 11, 1993

Center for Drug Evaluation and Research
Office of Drug Evaluation I, HFD-150
Document Control Room 9B-23
5600 Fishers Lane
Rockville, MD 20857

Attention: Michael Theodorakis, Chemist
Division of Oncologic and Pulmonary Drug Products

Subject: EFIDAC/24® pseudoephedrine hydrochloride (240 mg):
Requested Information (————————)

Dear Mr. Theodorakis:

The following is in response to your request for additional information regarding our alternate packaging site supplement (Volume 21.1 and Volume 23.1) for EFIDAC/24® pseudoephedrine hydrochloride (240 mg).

[redacted]

If you need any additional information, please feel free to contact me at (415) 494-5022 or via facsimile at (415) 494-5050.

Sincerely,

Harriet Benson

Harriet Benson, Ph.D.
Vice President
Regulatory Affairs

Size of — composition of — cert. of analysis. ~~Specs~~ configuration.

ORIGINAL

NDA 20-021

May 18, 1993

Center for Drug Evaluation and Research
Office of Drug Evaluation I, HFD-150
Document Control Room 9B-23
5600 Fishers Lane
Rockville, MD 20857

Attention: Michael Theodorakis, Chemist
Division of Oncologic and Pulmonary Drug Products

Subject: EFIDAC/24® pseudoephedrine hydrochloride (240 mg):
Requested Information (————————)

Dear Mr. Theodorakis:

The following is in response to your request for additional information regarding our alternate packaging site supplement (Volume 21.1 and Volume 23.1) for EFIDAC/24® pseudoephedrine hydrochloride (240 mg).

As mentioned in my facsimile of 11 May, the ———————— is supplied by ———————. Attached is the product specification sheet provided by ——— In addition attached are the technical specifications and material safety data sheet for the ——— material supplied by ———.

If you need any additional information, please feel free to contact me at (415) 494-5022 or via facsimile at (415) 494-5050.

Sincerely,

Mirka Dunn for

Harriet Benson, Ph.D.
Vice President
Regulatory Affairs