CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-021/S-003

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

Sponsor: ALZA Corporation

Approval Date: May 9, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-003

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Chemistry Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Administrative Document(s)	
Correspondence	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-003

APPROVAL LETTER

NDA 20-021/S-003

MAY 9 1995

Ciba Self-Medication, Inc.
Mack Woodbridge II
581 Main Street
Woodbridge, NJ 07095

Attention: Russ Jones
Director, Regulatory Affairs

Dear Mr. Jones:

Please refer to your November 30, 1994 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Efidac 24 Pseudoephedrine (pseudoephedrine HCl) 240 mg extended release tablet.

The supplemental application provides for labeling changes including the change in the trade name from Efidac/24 to Efidac 24 Pseudoephedrine and to conform with the change to the Final Monograph for OTC Nasal Decongestants.

We have completed the review of this supplemental application including the submitted draft labeling and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on November 30, 1994.

Please submit fifteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FPL for approved supplemental NDA 20-021/S-003". Approval of this submission by FDA is not required before it is used.

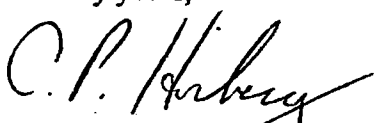
Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

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, please contact:

Koung Lee
Consumer Safety Officer
(301) 594-5712

Sincerely yours,



Charles P. Hoiberg, Ph.D.
Acting Director
Division of Oncology and
Pulmonary Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA 20-021
HFD-150/Div. files
HFD-150/CSchumaker/4-26-94
HFD-150/SJohnson/5-3-95
HFD-150/JJenkins/5-3-95
HFD-150/CSO/K.Lee
HFD-100
DISTRICT OFFICE
HF-2/medwatch (with labeling)
HFD-80 (with labeling)
HFD-240/S.Sherman (with labeling)
HFD-613 (with labeling - Only for applications with labeling.)

N:\N20021\S003.AP 5/8/95.
Drafted: KL/April 20, 1995 KL

Revised By: Cathie Schumaker/4-26-95
Final Type: Veronica Smith 5/8/95

APPROVAL OF SUPPLEMENT

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-003

APPROVED LABELING

LABELING Schumaker
NDA NO
REVIEWED BY
4/23/97

NDA 20-021
Efidac 24® Pseudoephedrine
(pseudoephedrine hydrochloride) extended release tablets

Print Mat
67028B

LABELING Schumaker
NDA NO. 20-021 RC'D 1/16/97
REVIEWED BY BY Gallassini 4/23/97

BS 4/22/97

ONCE DAILY

ORIGINAL FORMULA
NEW LABEL INFORMATION

EFIDAC 24®

PSEUDOEPHEDRINE

pseudoephedrine hydrochloride extended release tablets

24 HOUR RELIEF
- COLDS
- SINUS & ALLERGY CONGESTION

No Drowsiness

SIX DAYS RELIEF
6 TABLETS

6 TABLETS
6 DAY SIZE

EFIDAC 24®
PSEUDOEPHEDRINE

EFIDAC 24®
PSEUDOEPHEDRINE

3 00830 25093 5

68054A

NDC 0067-0250-93

EFIDAC 24 is a line of products specially formulated to provide relief for 24 hours with a one tablet, once daily dosage. Each EFIDAC 24 tablet releases an outer coating of medication immediately and then continuously to work by releasing medication at a precisely controlled rate for 24 hours of relief. EFIDAC 24 PSEUDOEPHEDRINE contains a nasal decongestant that provides relief without drowsiness.

ACTIVE INGREDIENT: Each EFIDAC 24 PSEUDOEPHEDRINE tablet contains a total of 240 mg pseudoephedrine hydrochloride, 60 mg immediate release and 180 mg controlled release.

INACTIVE INGREDIENTS: Cellulose, cellulose acetate, FD&C Blue #1, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, polyethylene glycol, polysorbate 80, povidone, sodium chloride, and titanium dioxide.

INDICATIONS: Provides temporary relief of nasal congestion due to the common cold, hay fever, or other upper respiratory allergies, and nasal congestion associated with sinusitis; reduces swelling of nasal passages; shrinks swollen membranes; relieves sinus pressure; and temporarily restores freer breathing through the nose.

DIRECTIONS: Adults and children 12 years of age and over: Take just one tablet with fluid every 24 hours. **DO NOT EXCEED ONE TABLET IN 24 HOURS.** SWALLOW EACH TABLET WHOLE; DO NOT DIVIDE, CRUSH, CHEW, OR DISSOLVE THE TABLET. The tablet does not completely dissolve and may be seen in the stool (this is normal). Not for use in children under 12 years of age.

WARNINGS: DO NOT EXCEED RECOMMENDED DOSAGE. If nervousness, dizziness or sleeplessness occur, discontinue use and consult a physician. Do not take this product for more than 7 days. If symptoms do not improve or are accompanied by fever, consult a physician. Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland, unless directed by a physician.

Rarely, tablets of this kind may cause bowel obstruction (blockage), usually in people with severe narrowing of the bowel (esophagus, stomach or intestine). If you have had obstruction or narrowing of the bowel, do not take this product without consulting your physician. Contact your physician if you experience persistent abdominal pain or vomiting. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

DRUG INTERACTION PRECAUTION: Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

Store in a dry place between 4° and 30°C (39° and 86°F).

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE BROKEN.

QUESTIONS ABOUT EFIDAC 24? Please write Consumer Affairs at the address below.

Distributed by: **Ciba Self-Medication, Inc.**
581 Main St., Woodbridge, NJ 07095

EFIDAC 24®
PSEUDOEPHEDRINE

6 TABLETS
6 DAY SIZE

9
521961
10/96

LABELING Schumaker
NDA NO. 20-021 RC'D 11/6/97
REVIEWED BY BGallaher 4/23/98

BG 4/23/98

ONCE DAILY

ORIGINAL FORMULA
NEW LABEL INFORMATION

EFIDAC 24®

PSEUDOEPHEDRINE

pseudoephedrine hydrochloride extended release tablets

24 HOUR RELIEF
- COLDS
- SINUS & ALLERGY CONGESTION

No Drowsiness

TWELVE DAYS RELIEF
12 TABLETS

12 TABLETS
12 DAY SIZE

EFIDAC 24®
PSEUDOEPHEDRINE

EFIDAC 24®
PSEUDOEPHEDRINE

3 0083-0250-78 2

68053A

NDC 0067-0250-78

EFIDAC 24 is a line of products specially formulated to provide relief for 24 hours with a one tablet, once daily dosage. Each EFIDAC 24 tablet releases an outer coating of medication immediately and then controlled rate for 24 hours of relief. EFIDAC 24 PSEUDOEPHEDRINE contains a nasal decongestant that provides relief without drowsiness.

ACTIVE INGREDIENT: Each EFIDAC 24 PSEUDOEPHEDRINE tablet contains a total of 240 mg pseudoephedrine hydrochloride, 60 mg immediate release and 180 mg controlled release.

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INDICATIONS: Provides temporary relief of nasal congestion due to the common cold, hay fever, or other upper respiratory allergies, and nasal congestion associated with sinusitis; reduces swelling of nasal passages; shrinks swollen membranes; relieves sinus pressure; and temporarily restores freer breathing through the nose.

DIRECTIONS: Adults and children 12 years of age and over: Take just one tablet with fluid every 24 hours. **DO NOT EXCEED ONE TABLET IN 24 HOURS.** SWALLOW EACH TABLET WHOLE. DO NOT DIVIDE, CRUSH, CHEW, OR DISSOLVE THE TABLET. The tablet does not completely dissolve and may be seen in the stool (this is normal). Not for use in children under 12 years of age.

WARNINGS: DO NOT EXCEED RECOMMENDED DOSAGE. If nervousness, dizziness or sleeplessness occur, discontinue use and consult a physician. Do not take this product for more than 7 days. If symptoms do not improve or are accompanied by fever, consult a physician. Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland, unless directed by a physician.

Rarely, tablets of this kind may cause bowel obstruction (blockage), usually in people with severe narrowing of the bowel (esophagus, stomach or intestine). If you have had obstruction or narrowing of the bowel, do not take this product without consulting your physician. Contact your physician if you experience persistent abdominal pain or vomiting. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

DRUG INTERACTION PRECAUTION: Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

Store in a dry place between 4° and 30°C (39° and 86°F).

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE BROKEN.

QUESTIONS ABOUT EFIDAC 24? Please write Consumer Affairs at the address below

Distributed by: **Ciba Self-Medication, Inc.**
581 Main St., Woodbridge, NJ 07095

EFIDAC 24®
PSEUDOEPHEDRINE

12 TABLETS
12 DAY SIZE

15
520351
08/96

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-003

LABELING REVIEW(S)

5

CSO Labeling Review April 21, 1995

NDA 20-021/S-003

Efidac 24 Pseudoephedrine (pseudoephedrine HCL 240 mg)
Sponsor: Ciba Self Medication Incorporated

Submission Date: November 30, 1994
Last Approved Labeling: December 15, 1992 (Approval of draft labeling)
May 5, 1993 (FPL Acceptable)
CSO: Koung Lee
Medical Officer: Susan Johnson

I have completed the review of the labeling supplement dated November 30, 1994 and it is identical to the draft labeling which the sponsor agreed to in their November 17, 1994 commitment. I have also compared it with the last approved labeling, which was when NDA 20-021 was approved, and it is identical except for the changes we requested. Please refer to the MOR and our September 23, 1994 telephone facsimile for details regarding the labeling changes.

Based on the recommendation of the medical officer, and my review of the labeling, this labeling supplement should be approved.

4-21-95
Koung Lee, CSO

cc: Orig. NDA 20-021
HFD-150/CSchumaker
HFD-150/KLee
HFD-150/SJohnson
HFD-150/JJenkins

4-25-95

N:\N20021\LABELING.CSO

APR 9 1997

Project Manager Labeling Review Date: April 4, 1997

NDA:	20-021/S-003
Drug:	Efidac 24 (pseudoephedrine hydrochloride)
Sponsor:	ALZA
Submission Date:	January 15, 1997
Receipt Date:	January 16, 1997
Project Manager:	Beverly Gallauresi
Medical Officer:	Susan Johnson

I have completed the review of the FPL submitted on January 15, 1997, and it is **not** identical to the draft labeling submitted on November 30, 1994; therefore, prior to an ACKNOWLEDGE AND RETAIN letter being issued to the sponsor, the M.O. should review the changes as listed below.

1. The front label of the carton container submitted has the addition "SIX DAYS RELIEF" for the 6 tablet carton container, and " TWELVE DAYS RELIEF" on the 12 tablet carton container.

2. Although this change may be added in the next annual report, it is noted that the distributor name has been changed from " CIBA Consumer Pharmaceuticals" to CIBA Self-Medication, Inc."

Beverly Gallauresi
Project Manager

cc:
Orig. NDA
Division Files
HFD-570/CSchumaker/
HFD-570/BGallauresi/
HFD-570/SJohnson/
HFD-570/RMeyer/

4/9/97 4/9/97 4/9/97

N:\N20021la.003

n:\hdel\20021s-003\pml 97-04-04.Rev

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-003

MEDICAL REVIEW(S)

3

MEDICAL OFFICER REVIEW MAY 9 1995

NDA#: 20-021 (SLR-003)
SPONSOR: ALZA Pharmaceuticals / CIBA Consumer Pharmaceuticals
PRODUCT NAME: Efidac/24, now Efidac Pseudoephedrine
DATE OF SUBMISSION: November 30, 1994
DATE OF REVIEW: December 15, 1994
MATERIAL SUBMITTED: Brand Name and Labeling Changes.

REVIEW OF SUBMISSION

The sponsor has provided a draft labeling which includes revisions required by the agency. The most significant changes are the conversion of the tradename from Efidac/24 to Efidac Pseudoephedrine and the warning that nervousness, drowsiness and sleeplessness can occur at normal doses. Although it was not mentioned in the cover letter, the active ingredients section has been modified to include a specification of the amount of pseudoephedrine which is contained in the immediate release coat and the sustained release core. The sponsor has identified that the packaging runs beginning February - March 1995 will use the new labeling.

RECOMMENDED REGULATORY ACTION

Final printed labeling will be submitted as it becomes available, but the supplement is approvable.

Susan S. Johnson, Pharm.D.
Medical Officer

cc: NDA 20-021
HFD-150/SJOHNSON
HFD-150/KLEE

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-003

CORRESPONDENCE

MACK WOODBRIDGE II
581 MAIN STREET
WOODBRIDGE, NJ 07095
TEL. (908) 602-6600
FAX (908) 602-6612

ORIGINAL

CIBA
CONSUMER
PHARMACEUTICALS

NDA NO. 20 021 REF. NO. 003
NDA SUPPL FOR SUB

NDA 20-021
EFIDAC/24® (pseudoephedrine hydrochloride) 240 mg

November 30, 1994

Center for Drug Evaluation and Research
Office of Drug Evaluation I
Division of Oncology and Pulmonary Drug Products
HFD-150
1451 Rockville Pike
Rockville, MD 20852

Attention: Charles Hoiberg, Ph.D., Acting Director
Division of Oncology and Pulmonary Drug Products

Re: Supplemental New Drug Application - Labeling Changes

Dear Dr. Hoiberg:

In accordance with 21 CFR 314.70 (b)(3), we respectfully submit a supplemental application to NDA 20-021 regarding changes to the labeling for EFIDAC/24® (pseudoephedrine hydrochloride 240 mg).

EFIDAC/24 was approved on December 15, 1992, and is part of a family of controlled release cold/allergy products under various stages of approval. NDA #19-746, EFIDAC 24 Chlorpheniramine, was most recently approved by your division (November 18, 1994). During the chlorpheniramine product's review, concerns were raised regarding the use of the base trade name EFIDAC 24® for this family of products. Through several correspondences and clarifications during the approval process for NDA 19-746, the trade name issue for the family of products was, in part, clarified. As agreed during the chlorpheniramine negotiations, this labeling supplement provides for several changes, including a name change, as outlined below and as specified in a telefax received September 23, 1994 from Dr. Susan Johnson, Medical Reviewer (see Attachment A). We informally responded to the 9/23/94 telefax on October 4, 1994 and are therefore incorporating the described changes provided at that time by means of this supplement.

1) A change in trade name from EFIDAC/24® to EFIDAC 24® PSEUDOEPHEDRINE

2) A banner on the front panel which will state "Original Formula" and "New Label Information;" the "New Label Information" portion of the banner will be removed after a 6 month period.

3) The Drug Interaction Precaution section will be revised to conform with the Final Monograph for OTC nasal decongestants and will read:

> **"Drug Interaction Precaution:** Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product."

4) The wording for a portion of the Warnings section of the labeling will be modified to comply with the Final Monograph for OTC nasal decongestants and will read: **"WARNINGS: DO NOT EXCEED RECOMMENDED DOSAGE.** If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a physician."

5) Removal of the "Upper Respiratory Allergies" bullet from the principal display panel for added clarity between the chlorpheniramine and pseudoephedrine products (not requested in the 9/23/94 telefax).

Enclosed herein as Attachment B are copies of the current and revised carton and blister for the EFIDAC 24® PSEUDOEPHEDRINE product. Please note that only copies of the 6 tablet labeling are provided since the only difference between the 6 tablet and 12 tablet package is in the number of tablets supplied.

As referenced in our 11/17/94 letter to Dr. Susan Johnson concerning the chlorpheniramine application, these changes to the pseudoephedrine product labeling will appear in packaging runs of EFIDAC 24 PSEUDOEPHEDRINE beginning February-March, 1995. Fifteen final printed cartons for each SKU will be submitted as soon as they become available.

If you have any questions or comments, please do not hesitate to contact the undersigned at (908) 602-6706.

Sincerely,

CIBA Consumer Pharmaceuticals
Division Of Ciba-Geigy Corporation

Vincent De Stefano
Manager, Regulatory Affairs

Attachments:
A - FDA fax dated 9/23/94 from Susan Johnson, Pharm.D. (HFD-150)
B - Current and revised labeling for EFIDAC24® PSEUDOEPHEDRINE

Memorandum of Telephone Facsimile Correspondence

Date: September 23, 1994

To: Leonard Fantasia
Vice President, Scientific Affairs
CIBA Consumer Pharmaceuticals

Through: John Jenkins, M.D.
Pulmonary Group Leader
Division of Oncology and Pulmonary Drug Products

From: Susan Johnson, Pharm.D.
Medical Reviewer
Division of Oncology and Pulmonary Drug Products

Subject: Clinical Comments for NDA 19-746 and NDA 20-021

We are providing the attached information via telephone facsimile for your convenience, to expedite the progress of your drug development program. This material should be viewed as unofficial correspondence. Please feel free to contact me if you have any questions regarding the contents of this transmission.

Susan S. Johnson, Pharm.D.
Medical Officer
Division of Oncology and Pulmonary
Drug Products

We have completed the clinical portion of the review will require that the following corrections be made to the labels of Efidac 24 Pseudoephedrine and Efidac 24 Chlorpheniramine prior to approval of NDA 19-746.

The following comments are provided regarding NDA 20-021 for Efidac 24 Pseudoephedrine.

1. Insomnia has been described in approximately one third of the nearly 1,000 adverse event reports submitted to the agency since the initiation of distribution of Efidac 24 Pseudoephedrine in June, 1993. We consider this to be a clinically significant signal that the drug is associated with the event. In addition, we feel that it is rational that if the formulation can be expected to produce therapeutic effects throughout a 24 hour interval, it can be expected to produce adverse effects throughout that period as well. Patients can not titrate dosing to avoid this effect, so in this instance we feel that it is necessary to deviate from the OTC monograph labeling for decongestant products and require a statement which indicates that sleeplessness may occur at normal doses.

   The wording for the Warnings section of the labeling should be modified to read "WARNINGS: DO NOT EXCEED RECOMMENDED ____

2. The banner on front panel of the package should state "Original ________ Formula". The words "________________________".
   should also appear on the front of the package, preferably in the banner.

3. The Drug Interaction Precaution section should be revised to conform with the final OTC monograph for nasal decongestants which was published in August, 1994.

The following comments should be relayed to the sponsor regarding NDA 19-746 for Efidac 24 Chlorpheniramine.

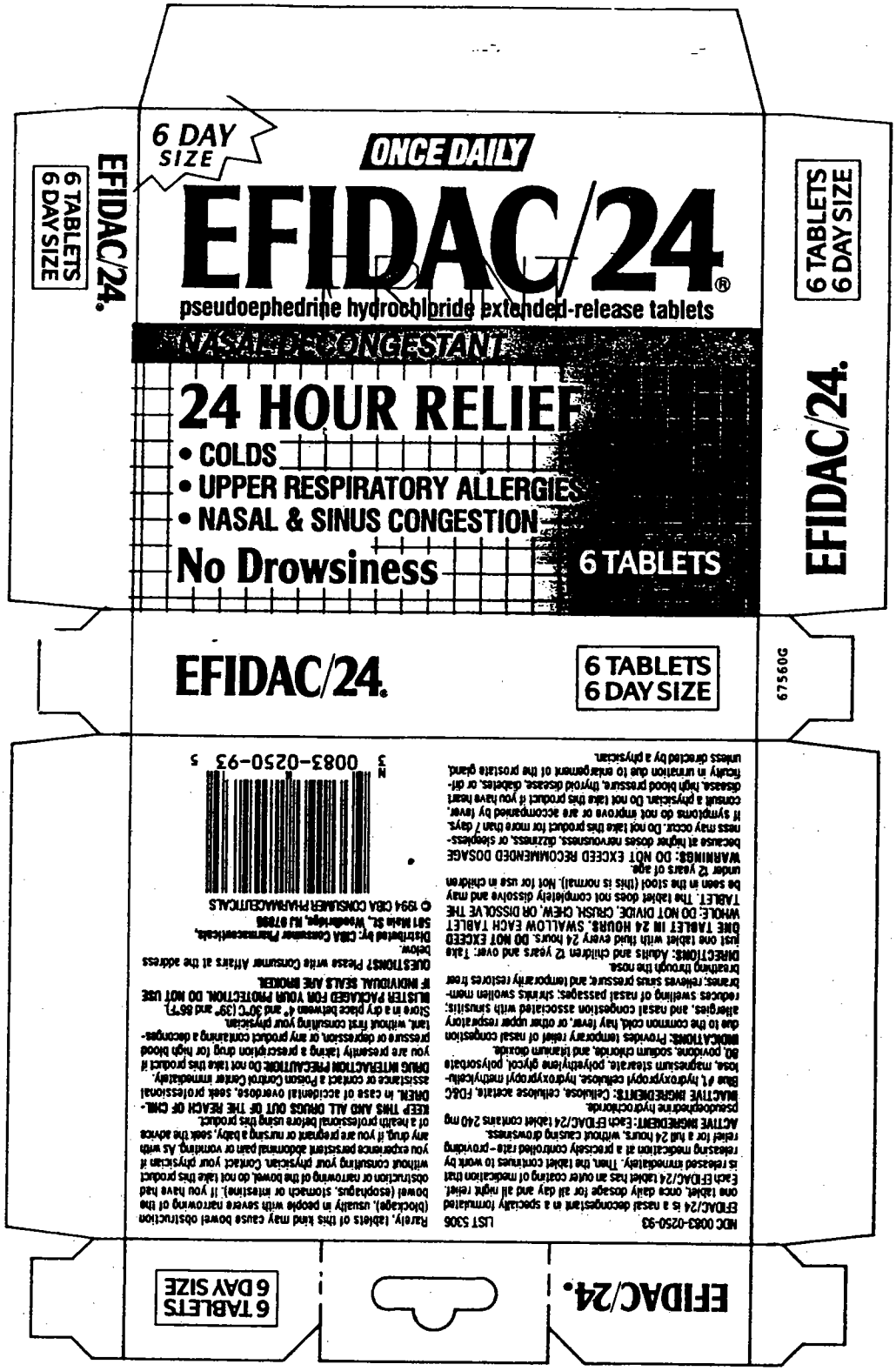
4. The proposed banner which states "________________________" is unacceptable because it does not distinguish the Efidac 24 Chlorpheniramine product from the Efidac 24 Pseudoephedrine product. As clearly stated on the front panel of both packages, both products can be used to treat upper respiratory allergies. Our specific intent in requesting the addition of the banner was to make consumers aware that there were now two Efidac 24 formulations which are used to treat different symptoms. The banner should state "New Antihistamine Formula".

5. Changes should be made in the Warnings section so that it reads "May cause drowsiness which may persist for 24 hours after dosing."

NDA 20-021
EFIDAC/24®(pseudoephedrine HCl 240 mg)
Extended Release Tablets

CIBA Consumer Pharmaceuticals

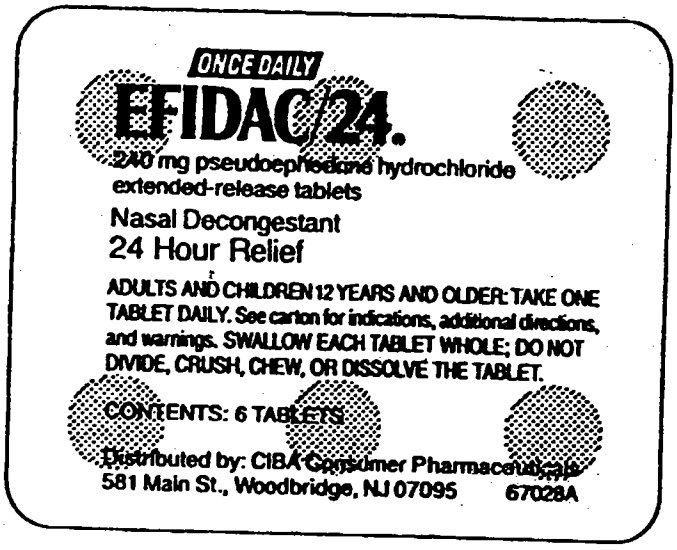
Current Carton Copy



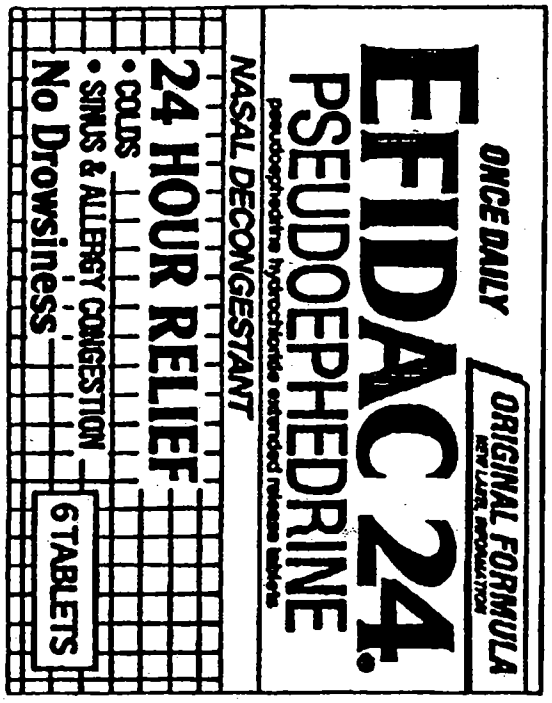
NDA 20-021
EFIDAC/24®(pseudoephedrine HCl 240 mg)
Extended Release Tablets

CIBA Consumer Pharmaceuticals

Current
Blister Copy



Revised Carton Copy



Revised Carton Copy

EFIDAC 24 PSEUDOEPHEDRINE
NDC 0000-0000-00 List 0000
EFIDAC 24 is a line of products specially formulated to provide relief for 24 hours with a one tablet, once daily dosage. Each EFIDAC 24 tablet releases an outer coating of medication immediately and then continues to work by releasing medication at a precisely controlled rate for 24 hours of relief. EFIDAC 24 PSEUDOEPHEDRINE contains a nasal decongestant that provides relief without drowsiness.
ACTIVE INGREDIENT: Each EFIDAC 24 PSEUDOEPHEDRINE tablet contains a total of 240 mg pseudoephedrine hydrochloride, 60 mg immediate release and 180 mg controlled release.
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INDICATIONS: Provides temporary relief of nasal congestion due to the common cold, hay fever, or other upper respiratory allergies, and nasal congestion associated with sinusitis; reduces swelling of nasal passages; shrinks swollen membranes; relieves sinus pressure; and temporarily restores freer breathing through the nose.
DIRECTIONS: Adults and children 12 years of age and over: Take just one tablet with fluid every 24 hours. DO NOT EXCEED ONE TABLET IN 24 HOURS. SWALLOW EACH TABLET WHOLE; DO NOT DIVIDE, CRUSH, CHEW OR DISSOLVE THE TABLET. The tablet does not completely dissolve and may be seen in the stool (this is normal). Not for use in children under 12 years of age.
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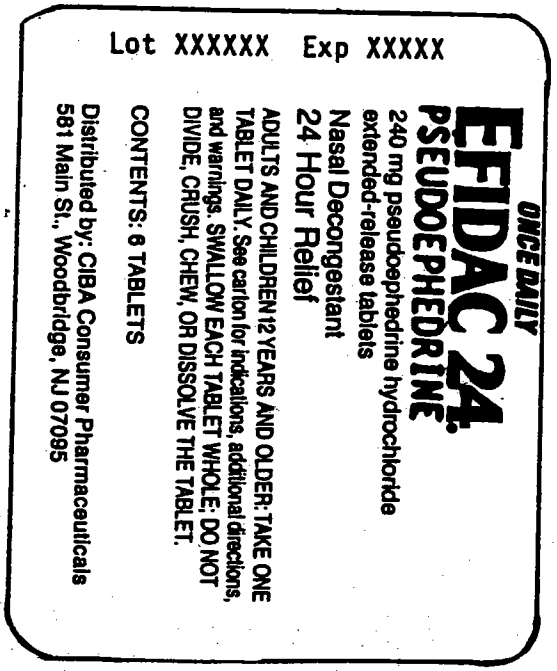
DRUG INTERACTION PRECAUTION: Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

Store in a dry place between 4° and 30°C (39° and 86°F).
BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE BROKEN.

QUESTIONS ABOUT EFIDAC 24? Please write Consumer Affairs at the address below.
Distributed by: CIBA Consumer Pharmaceuticals, 581 Main St., Woodbridge, NJ 07095

Revised Blister Copy



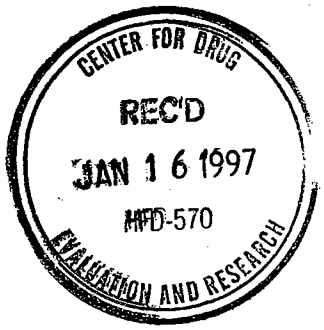
alza

ORIGINAL
SUPPL AMENDEMENT SLR-003 FA

January 15, 1997

NDA 20-021
Volume Number 46.1

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation II
Attention: Document Control Room
HFD-570
5600 Fishers Lane
Rockville, MD 20857



Attention: John K. Jenkins, M.D., Director
Division of Pulmonary Drug Products

Subject: Annual Report for NDA 20-021 Efidac 24® Pseudoephedrine (pseudoephedrine hydrochloride) extended release tablets

Final Printed Labeling for approved supplement NDA 20-021/S-003

Dear Dr. Jenkins:

In accordance with 21 CFR 314.81, ALZA Corporation is submitting the Annual Report for NDA 20-021 Efidac 24® Pseudoephedrine (pseudoephedrine hydrochloride) extended release tablets for the period of December 15, 1995 to October 14, 1996. The reporting period was shortened for administrative purposes. The next reporting period will be from October 15, 1996 through October 14, 1997.

In addition, we are submitting fifteen copies of the final printed labeling (FPL) for approved supplement NDA 20-021/S-003.

If you have any questions or comments regarding this submission, please contact me at (415) 237-2524 or via facsimile at (415) 237-2581.

Sincerely,

Mirka Dunn

Mirka Dunn
Director, Regulatory Affairs

314.81(B)(2)(iii) LABELING

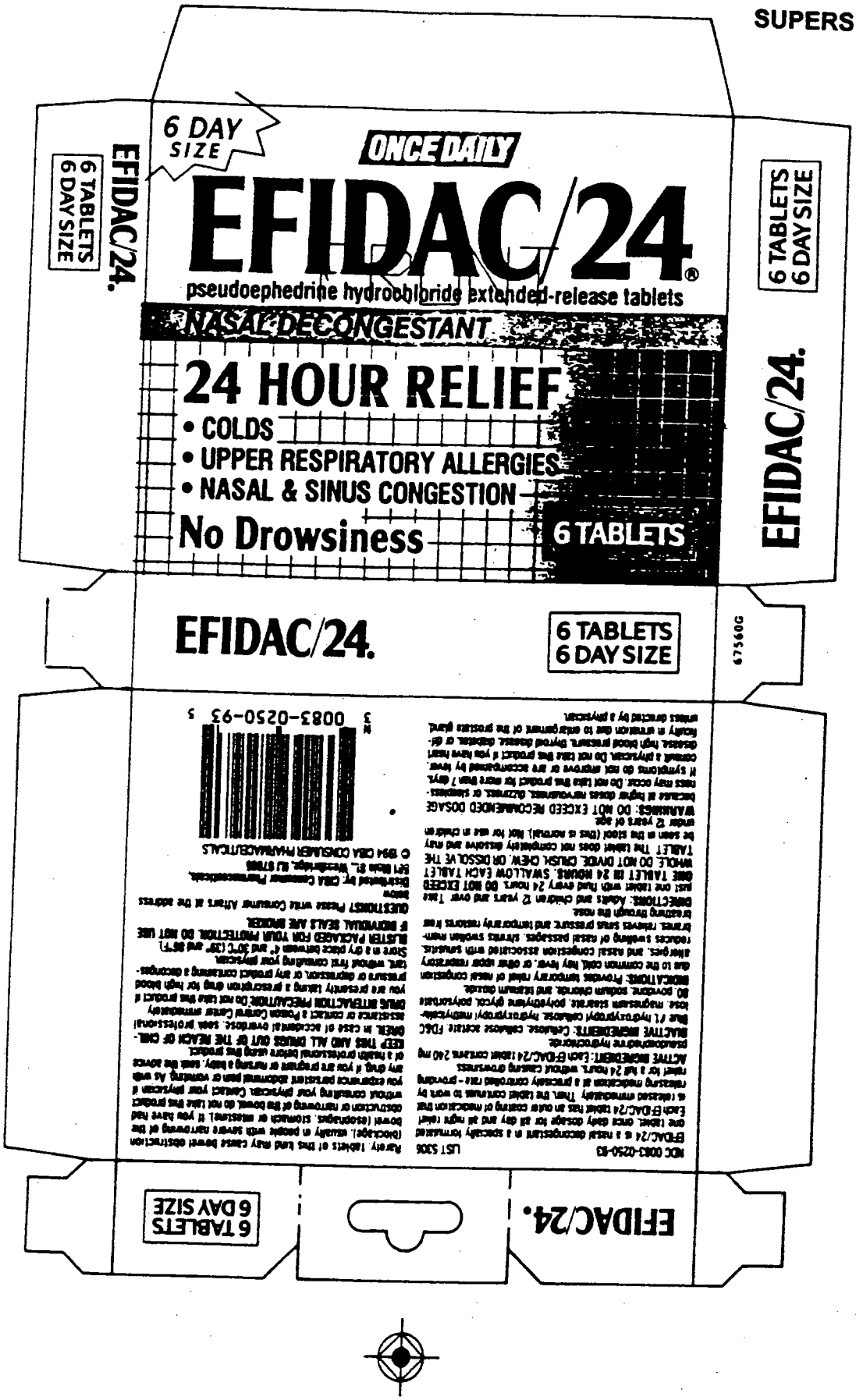
Provided are superseded editions of the product labeling (cartons) and the blister (print mat) which were in use at the beginning of the reporting period. Also included are the current labeling and blister which are the subject of approved supplement S-003; submitted to NDA 20-021 on November 30, 1994 by Ciba Self-Medication, Inc. (previously CIBA Consumer Pharmaceuticals). As requested in the approval letter for supplement S-003, we are submitting fifteen copies of the final printed labeling (FPL) in the archival copy of this submission. Ten of the fifteen copies of the cartons are mounted; all the blister labels are mounted.

Below is a listing of the attached product labeling (cartons) and the blister (print mat) included in this section.

Product Labeling (Carton)	Code No.	Status
6 tablet carton	67560G	Superseded
12 tablet carton	67561G	Superseded
6 tablet carton	68054A	New/Included ✓
12 tablet carton	68053A	New/Included ✓

Blister (print mat)	Code No.	Status
6 and 12 tablet print mat	67028A	Superseded
6 and 12 tablet print mat	67028B	Revised/Included ✓

SUPERSEDED



NDA 20-021/S-003

APR 24 1997

Alza Corporation
950 Page Mill Road
P.O. Box 10950
Palo Alto, CA 94303-5000

Attention: Mirka Dunn
Director, Regulatory Affairs

Dear Ms. Dunn:

We acknowledge the receipt of your January 15, 1997 submission containing final printed labeling in response to our May 9, 1995 letter approving your supplemental new drug application for Efidac 24 Pseudoephedrine (pseudoephedrine HCL) 240 mg Extended Release Tablet.

We have reviewed the labeling that you have submitted in accordance with our May 9, 1995 letter, and we find it acceptable.

Sincerely yours,

John K. Jenkins, M.D.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-021
HFD-570/Div. Files
HFD-570/CSchumaker/04-15-97
HFD-570/BGallauresi/04-15-97 4/22/97
HFD-570/SJohnson/04-15-97
HFD-570/RMeyer/04-15-97
HF-2/Medwatch (with labeling)
HFD-102/Office Director (with labeling)
HFD-40/DDMAC (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
HFD-560/OTC (with labeling)

R/D BY: BGallauresi/04-11-97
F/T BY: LSlaybaugh/04-22-97

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4/22/97

final:

ACKNOWLEDGE AND RETAIN (AR)

4/23/97