CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-021/S-005

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

Sponsor: ALZA Corporation

Approval Date: March 28, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-005

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APPLICATION NUMBER:

NDA 20-021/S-005

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-021/S-005

ALZA Corporation
Attention: Janne Wissel
Senior Vice President, Operations
1900 Charleston Road
P.O. Box 7210
Mountain View, California 94039-7210

Dear Ms. Wissel:

Please refer to your supplemental new drug application dated March 7, 2001, received March 9, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sudafed® 24 Hour/Efidac 24® (pseudoephedrine HCl) Extended Release Tablets, 240 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the use of pseudoephedrine hydrochloride produced using a modified synthesis process.

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 Babette Merritt, Project Manager for the Division of Over the Counter Drug Products, at (301) 827-2222.

Sincerely,

{See appended electronic signature page}

Charlotte Yaciw
Acting Chemistry Team Leader
Division of New Drug Chemistry III
Office of New Drug Chemistry
Center for Drug Evaluation and Research

/s/

Charlotte Yaciw
3/28/01 09:11:12 AM

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-005

CHEMISTRY REVIEW(S)

CHEMIST REVIEW
OF **SUPPLEMENT**

1. **ORGANIZATION HFD-560**
2. **NDA NUMBER:** 20-021
3. **SUPPLEMENT NUMBERS/DATES:** SCS-005
   Letter date: 3/7/2001
   Stamp date: 3/9/2001
   Due date: 9/9/2001
4. **AMENDMENTS/REPORTS/DATES:** none
   Letter date:
   Stamp date:
5. **RECEIVED BY CHEMIST:** 3/27/2001
6. **APPLICANT NAME AND ADDRESS:** Alza Corporation
   1900 Charleston Road
   P.O. Box 7210
   Mountain View, CA 94039-7210
7. **NAME OF DRUG:** Sudafed® 24 Hour Tablets; Efidac® Tablets
8. **NONPROPRIETARY NAME:** pseudoephedrine HCl
9. **CHEMICAL NAME/STRUCTURE:** see USP
10. **DOSAGE FORM(S):** tablet
11. **POTENCY:** 240 mg
12. **PHARMACOLOGICAL CATEGORY:** decongestant
13. **HOW DISPENSED:** OTC
14. **RECORDS & REPORTS CURRENT:** yes
15. **RELATED IND/NDA/DMF:** DMF ——— pseudoephedrine HCl); DMF ——— NDA 19-899/S009 (lead review for bundle)
16. **SUPPLEMENT PROVIDES FOR:** The use of pseudoephedrine HCl produced using a modified synthesis process.
17. **COMMENTS** CHANGES BEING EFFECTED IN 30 DAYS
    The pseudoephedrine HCl is provided by ———. This supplement is part of the ——"bundle" for a synthesis change in the ——— used in the synthesis of the pseudoephedrine HCl. See the lead review, NDA 19-899/S-009 which was approved on January 6, 2000. Alza has committed to placing the first batch of product manufactured using the new process material on stability.
18. **CONCLUSIONS AND RECOMMENDATIONS:** Issue an APPROVAL letter.
19. **REVIEWER NAME** **SIGNATURE** **DATE COMPLETED**
    Charlotte Yaciw 3/27/2001

Concurrence: Bonnie Dunn

Doc. ID: n20021_005.doc

/s/

Charlotte Yaciw
3/28/01 08:34:40 AM
CHEMIST

Bonnie Dunn
3/28/01 08:57:56 AM
CHEMIST

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-005

CORRESPONDENCE

7 March 2001

NDA 20-021, S-005
Volume 58.1

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation V (HFD-560)
Document Control Room
9201 Corporate Blvd
Rockville, MD 20850

Attention: Charles Ganley, M.D., Director
Division of Over the Counter Drug Products

Subject: **NDA 20-021 Sudafed® 24 Hour/Efidac 24® Pseudoephedrine (pseudoephedrine hydrochloride) extended release tablets Special Supplement – Changes Being Effected in 30 Days**

Dear Dr. Ganley:

In accordance with 21 CFR section 314.70, ALZA Corporation hereby submits a special supplement (S-005) to NDA 20-021 providing notice that our supplier of (+) – pseudoephedrine hydrochloride has submitted to the Agency a fully revised update of their drug master file (DMF——). As directed by the Agency, —— has informed us that we are obligated to submit a "Changes Being Effected in 30 Days" supplement to NDA 20-021 notifying the Agency of the update to DMF ——.

The additional information regarding this supplement and the stability commitment are provided in Appendix 1. Appendix 2 contains a copy of the DMF authorization letter.

ORIGINAL

ALZA CORPORATION 1900 CHARLESTON ROAD P.O. BOX 7210 MOUNTAIN VIEW CA 94039-7210 PHONE 650.564.5000 http://www.alza.com

A field copy of this supplement is provided to the FDA San Francisco District Office. ALZA hereby certifies that the field copy is a true copy of this supplement submitted in the NDA archival and review copies.

If you have any questions or comments regarding this submission, you may contact me at (650) 564-2524 or Tracy Lin at (650) 564-4135, or via fax at (650) 564-2581.

Sincerely,

Mirka Dunn

Mirka Dunn
Senior Director, Regulatory Affairs