CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-021/S-006

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

Sponsor: ALZA Corporation

Approval Date: October 24, 2001

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APPLICATION NUMBER:

NDA 20-021/S-006

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APPLICATION NUMBER:

NDA 20-021/S-006

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-021/S-006

Alza Corporation
Attention: Janne Wissel
Senior Vice President, Operations
1900 Charleston Road
P. O. Box 7210
Mountain view, CA 94039-7210

Dear Ms. Wissel:

Please refer to your supplemental new drug application dated July 18, 2001, received July 18, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sudafed 24 hour/Efidac 24 Pseudoephedrine Tablets (pseudoephedrine hydrochloride extended release tablets), 240 mg.

This supplemental new drug application provides for modification of the approved drug release specifications.

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, at (301) 827-2222.

Sincerely,

{See appended electronic signature page}

John Smith, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

John Smith
10/24/01 07:37:11 AM

APPEARS THIS WAY
ON ORIGINAL

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APPLICATION NUMBER:

NDA 20-021/S-006

ADMINISTRATIVE DOCUMENTS

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: October 16, 2001

From: Bart. Ho, Reviewing Chemist, HFD-550, Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products

To: Dennis Bashaw, Division of Pharm. Eval. – III

NDA No: 20-021/S-006 (Pseudoephedrine HCl Sustained Release Tablets)

Applicant: Alza

Subject: Dissolution Specifications

Reasons for the consult:

Revision of Dissolution Specification, 0 – 24 hours:

Currently approved	Currently proposed
—%	—%

Review Chemist Comments:

Please provide your comments in regard to Firm's proposed revision

BioPharm's Recommendation:

Yes The revised dissolution specification is acceptable.

No The revised dissolution specification is not acceptable

Dennis: Please give your concurrence in the signature comments area of DFS.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bartholomew Ho
10/16/01 02:13:49 PM
CHEMIST

Dennis Bashaw
10/23/01 05:04:11 PM
BIOPHARMACEUTICS

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-021/S-006

CORRESPONDENCE

July 18, 2001

NDA 20-021, S-006

Volume 59.1

NDA NO. 20-021 REF. NO. 006

NDA SUPPL FOR SCS

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

Subject: **NDA 20-021 Sudafed® 24 Hour/Efidac 24® Pseudoephedrine (pseudoephedrine hydrochloride) extended release tablets (OROS® pseudoephedrine HCl) Prior Approval Supplement**

Dear Dr. Ganley:

In accordance with 21 CFR section 314.70, ALZA Corporation hereby submits a prior approval supplement (S-006) to NDA 20-021 requesting modification of the approved drug release specifications for ALZA's OROS® pseudoephedrine HCl extended release tablets.

Information regarding this supplement is provided in the Appendix 1. Appendix 2 contains copies of letters from ALZA Corporation to the FDA concerning this issue. Appendix 3 contains a reference article.

ORIGINAL

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.

ALZA claims a categorical exclusion from preparation of an environmental assessment under 21 CFR 25.31(a). The requested action is for approval of an NDA supplement for a revised drug release specification. Approval of the supplement is not expected to increase the use of the active moiety. To the best of the applicant's knowledge, no extraordinary circumstances exist.

If you have any questions or comments regarding this submission, you may contact me at (650) 564-2519 or Peter Quigley at (650) 564-2769, or via fax at (650) 564-2581.

Sincerely,

Elizabeth A. Clark

Elizabeth (Betty) A. Clark
Director, Regulatory Affairs