CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-813 / S-026

Trade Name: **Duragesic**

Generic Name: **Fentanyl Transdermal System**

Sponsor: **Alza Corporation**

Approval Date: **November 1, 2001**

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-813/S-026

Alza Corporation
1900 Charleston Road
P.O. Box 7210
Mountain View, CA 94039-7210

Attention: Janne Wissel
Sr. Vice President, Operations

Dear Ms. Wissel:

Please refer to your supplemental new drug application dated January 26, 2000, received January 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duragesic (fentanyl transdermal system).

This "Changes Being Effected" supplemental new drug application provides for changes to the 25, 50, 75, and 100 ug/h pouchstock.

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

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Sara Shepherd, Project Manager, at (301) 827-7430.

Sincerely,

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

/s/

Cynthia McCormick
11/1/00 05:16:07 PM

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LABELING

Inactive Ingredients: Hydroxyethyl cellulose, ethylene vinyl-acetate copolymer, silicone adhesive between polyester backings.

Dosage: For information for use, see accompanying product literature.

Apply immediately upon removal from pouch.
Do not store unpouched or above 77°F (25°C).

DO NOT USE IF SEAL ON POUCH IS BROKEN

KEEP OUT OF REACH OF CHILDREN

See patient instructions for disposal information.

Manufactured by:
ALZA Corporation
Mountain View, CA 94043

Distributed by:
JANSSEN PHARMACEUTICA INC.
Titusville, NJ 08560

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ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

Division of Anesthetic, Critical Care, and Addiction Drug Products

REGULATORY PROJECT MANAGER REVIEW

Application Number: NDA 19-813

Name of Drug: DURAGESIC (fentanyl transdermal system)

Sponsor: Alza Corporation

Material Reviewed

Submission Date(s): January 26, 2000 (SLR-026)

Receipt Date(s): January 27, 2000

Background and Summary Description: This is a Changes Being Effected supplement to update pouchstock. This was compared to the most recently approved pouchstock from Supplement S-018, approved on July 17, 1997.

Status Report

Reviews Completed: Sara E. Shepherd, RPM, October 29, 2000

Reviews Pending: none

RPM Review

Please note that a strikethrough indicates deletion and an underline indicates addition to the approved label

For the 25, 50, 75, and 100 ug/h pouchstocks:

Added the bolded statement "KEEP OUT OF REACH OF CHILDREN" to the back panel of the pouchstock.

This statement is consistent with the warnings in the package insert, patient insert and product carton.

Changed the ALZA Corporation address from "~~Palo Alto, CA 94304~~" to "Mountain View, CA 94043"

RECOMMENDATIONS

The changes to the pouchstock are acceptable.

_____

Regulatory Project Manager/Sara E. Shepherd, M.S.

_____

Supervisory Comment/Concurrence/Cathie Schumaker, R.Ph.

Cc: Original NDA 19-813
HFD-170/Div. Files
HFD-170/S. Shepherd
HFD-170/C. Schumaker

Drafted by: S. Shepherd, October 29, 2000
Initialed by: C. Schumaker 10/31/00
Final:
Filename: n19813026.doc