

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-813 / S-025

Trade Name: Duragesic

Generic Name: Fentanyl Transdermal System

Sponsor: Alza Corporation

Approval Date: November 1, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-813 / S-025

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	X
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-813 / S-025

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-813/S-025

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 December 2, 1999, received December 3, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duragesic (fentanyl transdermal system).

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

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 05:46:48 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-813 / S-025

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).

For your convenience in recording narcotic use,

INITIAL/DATE

1. _____ 2. _____ 3. _____

4. _____ 5. _____

NSN#6505-01-335-9391

For questions concerning this product please call the Janssen One to One™ Customer Action Center at 1-800-JANSSEN (1-800-526-7736) 8 A.M. to 8 P.M. EST, Monday through Friday.

Manufactured by:
ALZA Corporation
Mountain View, CA 94043
© JPPLP 1999

Distributed by:
JANSSEN PHARMACEUTICA INC.
Titusville, NJ 08560



JANSSEN
PHARMACEUTICA

DURAGESIC® 25µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

NDC 50458-033-05

Five (25µg/h) Systems

DURAGESIC® 25µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

In vivo delivery of 25µg/h fentanyl for 72 hours

NOT FOR ACUTE OR POSTOPERATIVE USE

Each transdermal system contains:
2.5 mg fentanyl and 0.1ml alcohol USP

DO NOT USE IF SEAL ON POUCH IS BROKEN

KEEP OUT OF REACH OF CHILDREN

Rx only



JANSSEN
PHARMACEUTICA

DURAGESIC® 75µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

NDC 50458-035-05

Five (75µg/h) Systems

DURAGESIC® 75µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

In vivo delivery of 75µg/h fentanyl for 72 hours

NOT FOR ACUTE OR POSTOPERATIVE USE

Each transdermal system contains:
7.5 mg fentanyl and 0.3ml alcohol USP

DO NOT USE IF SEAL ON POUCH IS BROKEN

KEEP OUT OF REACH OF CHILDREN

Rx only



JANSSEN
PHARMACEUTICA

**FOR USE IN
OPIOID TOLERANT
PATIENTS**

DURAGESIC® 100µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

NDC 50458-036-05

Five (100µg/h) Systems

DURAGESIC® 100µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

In vivo delivery of 100µg/h fentanyl for 72 hours

NOT FOR ACUTE OR POSTOPERATIVE USE

Each transdermal system contains:
10mg fentanyl and 0.4ml alcohol USP

DO NOT USE IF SEAL ON POUCH IS BROKEN

KEEP OUT OF REACH OF CHILDREN

Rx only



JANSSEN
PHARMACEUTICA

FOR USE IN
OPIOID TOLERANT
PATIENTS

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-813 / S-025

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): December 2, 1999 (SLR-025)

Receipt Date(s): December 3, 1999

Background and Summary Description: This is a Changes Being Effected supplement to update the product carton. This was compared to the most recently approved carton 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 cartons:

Deleted ~~“WARNING: MAY BE HABIT FORMING”~~

Revised: ~~“Caution: Federal law prohibits dispensing without a prescription”~~ to “Rx only”

Added the bolded statement “KEEP OUT OF REACH OF CHILDREN” to the front panel of the carton.

Revised the statement on the back of the carton directing patient inquiries from
“~~For questions concerning this product please call the Janssen Customer Action
Center~~” to “For questions concerning this product please call the Janssen One to
One Customer Action Center.....”

NOTE: This statement was not on the carton approved July 17, 1997 (S-018).

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

Updated the carton code numbers

RECOMMENDATIONS

The changes to the cartons 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:

Final:

Filename: n19813025.doc

/s/

Sara Shepherd
11/1/00 08:28:32 AM
CSO

Cathie Schumaker
11/2/00 08:22:15 AM
CSO