CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-472/S-001

Trade Name: Estring 2 mg

Generic Name: estradiol vaginal ring

Sponsor: Pharmacia and Upjohn Company

Approval Date: 05/16/2000

Indications: For the treatment of urogenital symptoms associated with post-menopausal atrophy of the vagina (such as dryness, burning, pruritus and dyspareunia) and/or the lower urinary tract (urinary urgency and dysuria).

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APPLICATION NUMBER:

NDA 20-472/S-001

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APPLICATION NUMBER:

NDA 20-472/S-001

APPROVAL LETTER

NDA 20-472/S-001

MAY 16 2000

Pharmacia & Upjohn
Attention: Daniel G. Chirby, M.Sc.
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Chirby:

Please refer to your supplemental new drug application (NDA) dated December 3, 1996, received December 4, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Estring (estradiol vaginal ring) 2 mg.

This supplemental new drug application provides for:

Final printed carton labeling that reflects the Company's name change and logo from Pharmacia Inc. to Pharmacia & Upjohn.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (carton labels submitted December 3, 1996). Accordingly, the application is approved effective on the date of this letter.

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 Dornette Spell-LeSane, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Susan Allen, MD

Susan Allen M.D., M.P.H. 5/15/00
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Archival NDA 20472
HFD-580/Div. Files
HFD-580/D.Spell-LeSane
HFD-580/Allen/Slaughter/van der Vlugt/Rhee/Lin/Jordan/Raheja/Kammerman/Rumble
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-103/ADRA (with labeling)
HFD-104/Peds/V.Kao (with labeling)
HFD-104/Peds/T.Crescenzi (with labeling)
HFD-40/DDMAC (with labeling)
HFI-20/Press Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-095/DDMS-IMT (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: dsl/March 16, 2000
Initialed by: Colangelo for Rumble, 3.24.00/Lin, 3.28.00/Rhee, 3.28.00/Mann, 4.3.00/Allen, 4.3.00/ van der Vlugt, 4.7.00/Slaughter, 4.12.00
final: Spell-LeSane, 5.2.00
filename: APFA.DOC

ACKNOWLEDGE (ACK)/APPROVAL (AP)

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APPLICATION NUMBER:

NDA 20-472/S-001

LABELING

MADE IN SWEDEN
Manufactured by:
Ferring AB
Malmö, Sweden

For:
Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA

Printed in Sweden by
BERGSTENS
HELSINGBORG
97-12-19

NDC 0013-2150-36

Pharmacia
&Upjohn

101071197
1 unit

Estring®
Vaginal Ring

estradiol vaginal ring

2 mg

1 unit

Estring® Vaginal Ring
estradiol vaginal ring 2 mg

CAUTION: Federal law prohibits dispensing without prescription.

LOT:
EXP:

USUAL DOSAGE: Before administration read package insert for complete prescribing and product information.

DISPENSER: This carton contains information intended for the patient. This information is to be provided to the patient with each package dispensed.

Keep out of reach of children.

DO NOT USE IF SEAL ON POUCH IS BROKEN.

Store at controlled room temperature 15° to 30°C (59° to 86°F).

Each vaginal ring contains 2 mg estradiol, USP.
The inactive components are silicone polymers and barium sulfate.
7.5 µg/24 hrs of estradiol is released over 90 days.

Pharmacia&Upjohn

N 3 0013-2150-36 0

81 33 08

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APPLICATION NUMBER:

NDA 20-472/S-001

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

NDA 20-472/S-001
ESTRING
Carton Labeling

APR 12 2000

Date of submission: December 3, 1996
Date submission reviewed: March 16, 2000

The purpose of this supplement is to revise the carton labeling to reflect the sponsor's name change from Pharmacia Inc. to Pharmacia & Upjohn. This change in the Logo was submitted for the Physician Package Insert and the Patient Package Insert February 14, 1999, and approved December 10, 1998.

This supplement provides for:

A change in the Logo on the external Carton Labeling.

This is acceptable.

Proposed Regulatory Action (MO to complete)

☒ Approved
☐ Approvable
☐ Not Approved

PM signature — Date 3/28/00

Medical Officer Signature — Date 4/7/00

Team Leader Signature — Date 4/12/00

Deputy Director Signature — Date 4/12/00

Archival NDA 20-472
HFD-580/Div. Files
HFD-580/D.Spell-LeSane
HFD-580/Mann/Slaughter/Price/Rhee/Raheja/Jordan/Parekh/Rumble

LABEL REVIEW

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-472/S-001

OCT 29 1996

Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

Attention: Jan E. Baker
Regulatory Manager
U.S. Market Company-Regulatory Affairs

Dear Ms. Baker:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Estring (estradiol vaginal ring) 2 mg

NDA Number: 20-472

Supplement Number: S-001

Date of Supplement: October 18, 1996

Date of Receipt: October 21, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on December 20, 1996 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation II
Attention: Document Control Room 17B-20
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Lana Pauls
Chief, Project Management Staff
Division of Reproductive and Urologic
Drug Products, HFD-580
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-472/S-001
HFD-580/Div. Files
HFD-580/CSO/Moore

SUPPLEMENT ACKNOWLEDGEMENT