021048_OriginalApproval_Package.pdf

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
21-048

Trade Name:

Generic Name: 17B-estradiol Transdermal System (E_2III TS)

Sponsor: Wyeth-Ayerst Laboratories, Inc.

Approval Date: September 20, 1999

Indications: Provides for the use of estradiol transdermal system 0.05, 0.075, and 0.1 mg per day for treatment of moderate to severe vasomotor symptoms associated with the menopause and treatment of vulvar and vaginal atrophy.

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APPLICATION NUMBER:

21-048

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Reviews / Information Included in this NDA Review.	
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Final Printed Labeling	X
Medical Review(s)	X
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	X
Statistical Review(s)	X
Microbiology Review(s)	X
Clinical Pharmacology/ Biopharmaceutics Review(s)	X
Administrative Document(s) and Correspondence	X

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APPLICATION NUMBER:

21-048

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-048

SEP 2 0 1999

Wyeth-Ayerst Research
Attention: Douglas Bitz
Director, US Regulatory Affairs
PO Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Bitz:

Please refer to your new drug application (NDA) dated November 20, 1998, received November 20, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 17ß-estradiol transdermal system, 0.05, 0.075, and 0.1 mg per day continuously for seven days.

We acknowledge receipt of your submissions dated January 7, March 15 and 24, August 5, September 16 and 20, 1999.

This new drug application provides for the use of estradiol transdermal system 0.05, 0.075, and 0.1 mg per day for treatment of moderate to severe vasomotor symptoms associated with the menopause and treatment of vulvar and vaginal atrophy.

We have completed the review of this application, as amended, 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 agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling (package insert and patient package insert submitted September 20, 1999, and immediate container and carton labels submitted November 20, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-048." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.
In addition, please submit three copies of the introductory promotional materials that you propose to

use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please note, if you choose to use a proprietary name for this product, the name and its use in the label must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

Please submit one market package of the drug product when it is available.

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

Sincerely,

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Archival NDA 21-048
HFD-580/Div. Files
HFD-580/D.Spell-LeSane
HFD-580/Reviewers and Team Leaders
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-103/ADRA (with labeling)
HFD-104/Peds/V.Kao (with labeling)
HFD-40/DDMAC (with labeling)
HFI-20/Press Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-21/ACS (with labeling) - for drug discussed at advisory committee meeting.
HFD-095/DDMS-IMT (with labeling)
HFD-170/C.Moody (if controlled substance)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: DSL/September 16, 1999
See concurance table page 4
final:Spell-LeSane 9.20.99
filename:

APPROVAL (AP)