CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION:NDA 20-538/S-006

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Statistical Review(s)			X	
Microbiology Review(s)			X	
Clinical Pharmacology Biopharmaceutics Review(s)	X			
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Correspondence	X			

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Approval Package for:

Application Number: NDA 20-538/S-006

Trade Name: Estradiol Transdermal System

Generic Name:

Sponsor: Menorest Manufacturing, Inc.

Approval Date: January 8, 1999

Indication: Provides for a new formulation with various strengths based on surface area difference.

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Application Number: NDA 20-538/S-006

APPROVAL LETTER

NDA 20-538/S-006

Menorest Manufacturing, Inc.
Attention: David Lucking
Senior Director, Medical and Regulatory Affairs
11960 S.W. 144th Street
Miami, FL 33186

JAN 8 1999

Dear Mr. Lucking:

Please refer to your supplemental new drug application dated August 18, 1997, received August 19, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Estradiol Transdermal System.

We acknowledge receipt of your submissions dated March 19, June 26, September 15, and October 28, 1998 .

This supplemental new drug application provides for a new formulation with various strengths based on surface area difference.

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

The final printed labeling (FPL) must be identical to the submitted draft labeling except for the proprietary name (package insert submitted and, patient package insert submitted October 28, 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 supplement NDA 20-538/S-006." Approval of this submission by FDA is not required before the labeling is used.

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, it should conform to the specifications under 21 CFR 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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

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 Jennifer Mercier, Project Manager, at (301) 827-4260.

Sincerely,

/S/ (for L. Rarick)

1-9-99

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

cc:
Archival NDA 20-538
HFD-580/Div. Files
HFD-580/J.Mercier/Rarick/Mann/Price/Rhee/Mitra/Jarugula/Parekh
HFD-103/BCollier
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-102/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-21/ACS (with labeling) - for drug discussed at advisory committee meeting.
HFD-95/DDMS (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: jm/January 8, 1999
Initialed by:
final:
filename: 20538S6A.WPD

APPROVAL (AP)