NDA 20-908

Novo Nordisk Pharmaceuticals
Attention: Barry Reit, Ph.D.
Vice President, Regulatory Affairs
100 Overlook Center, Suite 200
Princeton, NJ 08540-7810

MAR 26 1999

Dear Dr. Reit:

Please refer to your new drug application (NDA) dated May 28, 1998, received June 4, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VAGIFEM™ (17-β-estradiol) 25 μg, vaginal tablets.

We acknowledge receipt of your submissions dated July 9, October 21 and 22, November 25, December 7 and 10, 1998, January 7, 13 and 14, February 24 and 26, and March 3, 4, 17, 18, 19 (2), 23, 24 (2) and 25 (2), 1999.

This new drug application provides for the use of VAGIFEM™ (17-β-estradiol) for the relief of postmenopausal atrophic vaginitis due to estrogen deficiency.

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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert dated March 24, 1999, and the immediate container and carton labels dated May 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 NDA 20-908." 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 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/ 3/26/99

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

Enclosure

cc:
Archival NDA 20-908
HFD-580/Div. Files
HFD-580/J.Mercier
HFD-580/Rarick/Mann/Slaughter/Allen/Bennett/Rhee/Mitra/Kammerman/Elashoff/Parekh/Haidar/Madani
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/March 24, 1999
Initialed by:
final:
filename: 20908AP.WPD

APPROVAL (AP)