CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-788

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-788

DEC 19 1997

Merck Research Laboratories
Attention: Robert E. Silverman, M.D., Ph.D.
Senior Director, Regulatory Affairs
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Dr. Silverman:

Please refer to your new drug application dated December 20, 1996, received December 20, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Propecia, (finasteride tablets) Tablets, 1 mg.

We acknowledge receipt of your submissions dated January 3, 15 (three), 24 (two), 29, and 31, February 14 (two), March 4, 5 , 6 (two), 7, 10, and 21, April 8, 14, 18, 23, 24, and 29, May 13, June 6, 13, 18, and 20, July 8, August 11, September 12, 17, 23, 25, 26, and 30, October 10, and 22, November 5, 10, 11, 19 (two), and 20, and December 2, 8, 10, 12, 15, 16, and 19, 1997. The User Fee goal date for this application is December 20, 1997.

This new drug application provides for the treatment of male pattern hair loss (androgenetic alopecia) in **MEN ONLY**.

We have completed the review of this application, including the submitted draft labeling, 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 approved 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 approved labeling text. Marketing the product with FPL that is not identical to this enclosed approved labeling text may render the product misbranded and an unapproved new drug.

Additionally, we note your December 19, 1997, commitment to change the representation of the generic name and strength on cartons and labels, to be consistent with the package insert at the next printing.

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 "FINAL PRINTED LABELING" for approved NDA 20-788. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We acknowledge your Phase 4 Commitments specified in your submission dated December 19, 1997. The commitments are stated below:

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 Commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material 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 material and the package insert directly to:

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

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.

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, please contact Susan Kummerer, M.S., Project Manager, at (301) 827-2022.

Sincerely yours,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
Original NDA 20-788 (with labeling)
HFD-540/Div. files (with labeling)
HFD-540/Wilkin (with labeling)
HFD-540/Kozma-Fornaro (with labeling)12/19/97
HFD-540/CSO/S.Kummerer (with labeling)
HFD-540/Ko (with labeling)
HFD-540/Hathaway (with labeling)12/19/97
HFD-540/Avalos (with labeling)
HFD-540/Walker (with labeling)
HFD-540/Jacobs (with labeling)12/19/97
HFD-540/DeCamp (with labeling)JH for WDC 12/19/97
HFD-880/Kumi/Bashaw (with labeling)DB 12/19/97
HFD-725/Srinivasin/Freidlin (with labeling)12/19/97
HFD-002/ORM (with labeling)
HFD-105/Office Director (with labeling)
HFD-101/L.Carter (with labeling)
HFD-830/ONDC Division Director (with labeling)
DISTRICT OFFICE (with labeling)
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
HFI-20/Press Office (with labeling)
HFD-021/ACS (with labeling)
HFD-580/Rarick/Hirsch/Pauls (with labeling)
Drafted by: Kummerer/12-11-97/revised 12-17-97/N20788.ap2
Initialed by:MJKF/12/19/97
final: 12/19/97

APPROVAL (AP)
PHASE 4 COMMITMENTS