

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-834

APPROVAL LETTER



NDA 20834

NOV 14 1997

Pharmacia and Upjohn Consumer Healthcare
Attention: Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs
700 Portage Road
Kalamazoo, MI 49001-0199

Dear Dr. Dann:

Please refer to your new drug application dated February 28, 1997, received February 28, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rogaine Extra Strength for Men (minoxidil topical solution), 5%.

We acknowledge receipt of your submissions dated March 10, April 10 and 22, May 28, June 19, July 22 (two), 23, 28 and 29, August 4 (two), October 23 and 29, and November 3 and 13, 1997. The User Fee goal date for this application is February 28, 1998.

This new drug application provides for hair regrowth treatment for men.

We have completed the review of this application, including the submitted draft artwork labeling submitted on October 29 and November 13, 1997, 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 draft artwork labeling submitted on October 29 and November 13, 1997. Marketing the product with FPL that is not identical to this draft artwork labeling may render the product misbranded and unapproved new drug.

Please note that as agreed on November 13, 1997, the change on the Consumer Booklet cover for "5% Minoxidil Topical Solution", to be added as part of the statement of identity preceding "Hair Regrowth Treatment", can occur with the second printing of the Consumer Booklet.

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 20-834. Approval of this submission by FDA is not required before the labeling is used.

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

In addition, please submit three copies of the introductory promotional material that you propose to use for these products. 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 inserts 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.

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If you have any questions, please contact Mary Jean Kozma-Fornaro, Supervisor, Project Management, at (301) 827-2020.

Sincerely yours,

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

Debra L. Bowen
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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cc:

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HFD-540/Div. files/w.label

HFD-560/Div Files/w.label

HFD-540/CSO/M.J.Kozma-Fornaro/w.label

HFD-540/Huene/w.label

HFD-540/Hathaway/w.label

HFD-540/Avalos/w.label

HFD-540/Wilkin/w.label

HFD-540/Jacobs/w.label

HFD-540/DeCamp/w.label

HFD-002/ORM (with labeling)

HFD-105/Office Director/w.label

HFD-101/L.Carter/w.label

HFD-830/ONDC Division Director/w.label

DISTRICT OFFICE

HF-2/Medwatch (with labeling)

HFD-92/DDM-DIAB (with labeling)

HFD-40/DDMAC/Lechter(w/labeling)

HFD-613/OGD (with labeling)

HFD-735/DPE (with labeling)

HFD-560/OTC/Bowen (with labeling)

HFD-560/OTC/Aurecchia/Katz/Wright/Rejali/Cook/w. Label for all

HFI-20/Press Office (with labeling)

HFD-021/ACS (with labeling)

Drafted by: mjkf/October 27, 1997/20834ap

final: 11/13/97

APPROVAL (AP)