DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-501/S-020
NDA 19-501/S-025

Pharmacia and Upjohn, A Pfizer Company
Attention: Dina R. Russello, Director
Global Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Ms. Russello:

Please refer to your supplemental new drug application (S-025) dated December 20, 2004, received December 22, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Men's Rogaine® Regular Strength and Women's Rogaine® (2% minoxidil) topical solutions.

We acknowledge receipt of your submissions dated May 23 and June 7, 2005.

This supplemental new drug application proposes the inclusion of the phrase "#1 Dermatologist Recommended Brand" within a "seal" graphic on the Principal Display Panels (PDPs) for unscented Men's Rogaine®, and both scented and unscented Women's Rogaine® products.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container, carton labels, and patient package insert submitted on December 20, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-501/S-025.**" Approval of this submission by FDA is not required before the labeling is used.

We also refer to your supplemental new drug application (S-020) dated March 20, 2002, received on March 25, 2002. This application (S-020) provided for labeling in ***Drug Facts*** format with new warnings and other modifications to the product label and package insert for Men's Rogaine® and Women's Rogaine® (2% minoxidil) topical solutions. The approved draft labeling for application S-025 incorporates the changes proposed under S-020 and the revisions required in our February 3, 2003, approvable letter for S-020. Supplemental application S-020 is hereby superseded by the approval for application S-025. Supplemental application S-020 will be closed and retained in our files.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,

{See appended electronic signature page}
Curtis Rosebraugh, M.D., M.P.H.
Acting Division Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Curtis Rosebraugh

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