DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-834/S-009

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 dated November 29, 2004, received November 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Men's Rogaine® Extra Strength (5% minoxidil) topical solution.

We acknowledge receipt of your submission dated May 23, 2005. We also acknowledge receipt of your facsimile submission dated May 31, 2005. This submission was not reviewed for this action. You may incorporate this submission by reference in a future supplement to this NDA.

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 all products covered by this NDA.

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 and carton labels and patient package insert submitted on November 29, 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 20-834/S-009**." Approval of this submission by FDA is not required before the labeling is used.

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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