DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-834/S-011

Pfizer Consumer Healthcare
Attention: Dina Russello
Director, Regulatory Affairs
201 Tabor Road
Morris Plain, NJ 07950

Dear Russello:

Please refer to your supplemental new drug application dated March 10, 2006, received March 13, 2006, 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 submissions dated July 20 and September 1, 2006.

This supplemental new drug application proposes labeling for the Prevail Brand of Hair Care Products co-package.

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 (outer carton (clamshell) front panel submitted September 1, 2006, minoxidil package insert submitted July 20, 2006, and outer carton (clamshell) back panel, minoxidil inner carton, minoxidil immediate container label, shampoo label, shampoo conditioner combination label, conditioner label, and mousse label submitted March 10, 2006), 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-011**." 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 LCDR Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Drug 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/

Andrea Segal

9/12/2006 04:13:42 PM