DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-501/S-024

Pfizer Consumer Healthcare
Pfizer Incorporated
Attention: Dina R. Russello
Director, Regulatory Affairs
201 Tabor Road
Morris Plains, New Jersey 07977

Dear Ms. Russello:

Please refer to your November 3, 2003, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rogaine for Men Regular Strength and Rogaine for Women (2% minoxidil) topical solution.

We acknowledge receipt of your submissions dated March 19, 2004 and June 4, 2004.

Your submission of June 4, 2004 constituted a complete response to our March 5, 2004 action letter.

This supplemental new drug application provides for an additional fragrance (with new labeling) for the Rogaine for Women topical solution.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 4, 2004.

You are reminded that the "**NEW!**" flag should be removed from the label within six months.

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 Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Charles Ganley
6/25/04 10:53:01 AM