DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-812

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 new drug application (NDA) dated March 23, 2005, received March 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Men's Rogaine (5% minoxidil) Topical Aerosol.

We acknowledge receipt of your submissions dated April 28, May 11, 24 and 25, June 8, July 8 and 19, August 23 and 26; September 2, October 11 (2), 13 and 26, November 30, and December 22, 2005 (2), and January 12, 13 and 18 (3), 2006.

This new drug application provides for the use of Men's Rogaine (5% minoxidil) Topical Aerosol for the nonprescription treatment of androgenic alopecia of the vertex of the scalp.

We have completed our review of this application, as amended. It 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 (consumer package insert, outer carton PDP, immediate container label, outer carton Drug Facts label (except for the inside left of the label) submitted on January 18, 2006, and the outer carton Drug Facts label containing only the inside left of the label submitted on January 18, 2006), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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 NDA 21-812**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We reference the waiver granted on November 10, 2005 for the pediatric study requirement for the entire pediatric population (under 18 years of age) for this application.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print, to the Division of Nonprescription Clinical Evaluation.

Please submit one market package of the drug product when it is available.

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}
Stanka Kukich, M.D.
Acting Director
Division of Dermatology and Dental Products
Office of New Drugs
Center for Drug Evaluation and Research

{See appended electronic signature page}
Andrea Leonard-Segal, M.D., M.S.
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Stanka Kukich
1/20/2006 03:03:42 PM

Andrea Segal
1/20/2006 03:07:20 PM