



NDA 20-834/S-003

Pharmacia Consumer Healthcare
Attention: Raymond Dann, Ph.D.
Director, U.S. Regulatory Affairs
100 Route 206 North
Peapack, New Jersey 07977

Dear Dr. Dann:

Please refer to your March 21, 2002, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rogaine for Men Extra Strength (5% minoxidil topical solution).

We also refer to your submission dated August 13, 2002. This amendment constituted a complete response to our July 12, 2002, action letter.

Supplement 003 provides labeling for 5% Rogaine in general accordance with the example for 2% minoxidil topical solution contained in FDA's February 2001 draft guidance document entitled, "Guidance for Industry - Labeling OTC Human Drug Products - Updating Labeling in ANDAs." In addition, you added new warnings and made other modifications to the product labeling.

We 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 enclosed labeling (immediate container and carton labels submitted August 13, 2002), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-834/S-003". 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2279.

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

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Charles Ganley
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