

April 29, 1998

Apotex USA, Inc.
U.S. Agent for: Nu-Pharm Inc.
Attention: Marcy Macdonald
1641 Barclay Blvd.
Buffalo Grove, IL 60089

Dear Madam:

This is in reference to your abbreviated new drug application dated July 8, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Minoxidil Topical Solution, 2% (for Men and Women).

Reference is also made to your amendments dated November 3, 1997, and March 9 and April 24, 1998.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Minoxidil Topical Solution, 2% to be bioequivalent to the listed drug (Rogaine® Topical Solution 2% of Pharmacia and Upjohn Co.).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research