ANDA 75-357 July 30, 1999

L. Perrigo Company
Attention: Brian R. Schuster
117 Water Street
Allegan, MI 49010

Dear Sir:

This is in reference to your abbreviated new drug application dated April 13, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Minoxidil Topical Solution USP, 2% (for Men) and Minoxidil Topical Solution USP, 2% (for Women).

Reference is also made to your amendments dated February 18, May 19, July 9, and July 27, 1999.

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 USP, 2% (for Men) and your Minoxidil Topical Solution USP, 2% (for Women) to be bioequivalent to the listed drug (Rogaine® for Men and Rogaine® for Women, respectively, 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
Office of Generic Drugs
Center for Drug Evaluation and Research