ANDA 75-598 July 24, 2000

L. Perrigo Company
Attention: Brian R. Schuster
515 Eastern Avenue
Allegan, MI 49010

Dear Sir:

This is in reference to your abbreviated new drug application dated March 8, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Minoxidil Topical Solution USP, 5% (for Men).

Reference is also made to your amendments dated November 15, 1999; May 26 and July 5, 2000.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug product is safe and effective for use as recommended in the submitted over-the-counter (OTC) labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. The listed referenced drug product (RLD) upon which you have based your application, Rogaine® Extra Strength for Men, 5%, by Pharmacia & Upjohn Co., is subject to a period of new product (NP) exclusivity. Therefore, final approval may not be made effective pursuant to 21 U.S.C. 355(j)(5)(D) of the Act until the NP exclusivity period has expired, i.e., November 14, 2000.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60 days (but not more than 90 days) prior to the date you believe your application will be eligible for final

approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing, and controls data as appropriate. In order to reactivate the file to provide for final approval of this application, an amendment should be submitted even if none of these changes were made. Please be advised that this amendment should provide final printed copies of all labels and labeling prior to final approval. The Agency reserves the right to request further changes in the labels and/or labeling based upon subsequent change to the approved labeling of the listed drug or upon further review of the application prior to approval. This amendment should be designated clearly as a MINOR AMENDMENT in your cover letter. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing (CGMPs) are subject to Agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction in to interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, your product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to November 14, 2000, you should amend your application accordingly.

Prior to submitting an amendment, please contact Ms. Elaine Hu, Project Manager, at (301) 827-5848, for further instructions.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research