DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-154/S-023

Pharmacia & Upjohn Company
Attention: Ms. Rebecca K. Tong
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Ms. Tong:

Please refer to your supplemental new drug application dated September 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Loniten (minoxidil) 2.5 and 10 mg Tablets.

We acknowledge receipt of your submission dated April 15, 2002. Your submission of April 15, 2002 constituted a complete response to our February 13, 2002 action letter.

This supplemental new drug application provides for electronic final printed labeling revised to add a Geriatric Use subsection to the PRECAUTIONS section as follows:

> 10. Geriatric Use
>
> Clinical studies of LONITEN Tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

In addition the following revisions were noted under the HOW SUPPLIED section:

1. Reference to bottles of 500 has been deleted.

2. The storage statement has been changed from:

   Store at controlled room temperature 15^0 to 30^0 C (59^0 to 86^0 F).

   To:

   Store at controlled room temperature 20^0 to 25^0 C (68^0 to 77^0 F) [see USP].

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling included in your April 15, 2002 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Ms. Zelda McDonald, Regulatory Health Project Manager, at (301) 594-5333.

Sincerely,

{See appended electronic signature page}

Douglas C.Throckmorton M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Doug Throckmorton

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