DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-827/S-025

Schering Corporation
Attention: Mary Jane Nehring
Senior Director, Marketed Products, Support and Training
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated December 4, 2002, received December 6, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrisone (clotrimazole, USP and betamethasone dipropionate, USP) Cream, USP.

We acknowledge receipt of your submission dated March 26 (facsimile), 2003.

This supplemental new drug application provides for labeling revisions to the Carcinogenesis, Mutagenesis, Impairment of Fertility, and Usage in Pregnancy subsections and to add USP to the LOTRISONE® Cream brand name and the generic name clotrimazole and betamethasone diproprionate in the heading of the package insert and product information sheet.

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 (text for the package insert).

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 18-827/S-025. 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

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, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental 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 this page is the manifestation of the electronic signature.

/s/

John Kelsey
3/27/03 04:02:00 PM
for Dr. Wilkin