DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-010/S-003

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

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated October 23, 2001, received October 24, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrisone (betamethasone dipropionate and clotrimazole) Lotion.

We acknowledge receipt of your submission dated January 7, 2002.

This supplemental new drug application provides for revised labeling based on the approval of product labeling for Lotrisone Cream, NDA 18-827/S-007, S-009, S-020 and S-022 (letter dated October 3, 2001).

We have completed the review of this supplemental 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 (package insert and patient package insert submitted October 23, 2001, patient package insert submitted October 23, 2001).

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 20-010/S-003." 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 the 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/

Jonathan Wilkin

12/17/02 12:25:14 PM