DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-827/S-007
NDA 18-827/S-009
NDA 18-827/S-020
NDA 18-827/S-022

Schering Corporation 03 OCT 2001
Attention: Mary Jane Nehring
Senior Director, Marketed Products Support and Training, Worldwide Regulatory Affairs
2000 Galloping Hill Road
K-6-1/1600
Kenilworth, New Jersey 07033

Dear Ms. Nehring:

Please refer to your supplemental new drug applications dated March 28, 1990, received April 5, 1990, December 12, 1990, received December 21, 1990, June 27, 2000, received June 28, 2000, and October 4, 2000, received October 5, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrisone (clotrimazole and betamethasone dipropionate) Cream. Please also refer to our Approvable Letter dated June 25, 1991.

We acknowledge receipt of your submissions dated July 3 and September 30, 1991; June 9 and November 17 (two), 1994; July 28 and August 15, 2000; January 24, February 15, March 15 and 16, April 25, May 9, July 23, August 6, and 28, and September 12, 18, 21, 25 and 28 (facsimile), 2001.

Supplement 022 provides final pediatric study reports and a safety update in response to the Pediatric Written Request and supersedes S-007, S-009, and S-020.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

Please submit a supplemental application to NDA 20-010, Lotrisone (clotrimazole and betamethasone diproprionate) Lotion to allow for the use of the enclosed combined labeling to be used for that product also.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999).

Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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-022." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your commitment specified in the facsimile of your letter dated September 28, 2001, to implement the enclosed labeling within 3 months of approval.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632).

We note that you have fulfilled the pediatric study requirement at this time.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

Sincerely,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research