DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-543/S-014

Schering Corporation
Attention: Isidoro Perez
Vice President, Worldwide Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Mr. Perez:

Please refer to your supplemental new drug application, NDA 19-543/S-014, dated July 23, 2002, received July 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ELOCON® (mometasone furoate) Ointment, 0.1%.

Your supplement provides for support of the proposed revision to the labeled drug product storage conditions.

We have completed the review of this supplemental application, and have concluded that the information presented in the cited submission is adequate to support the changes made to the statement of storage conditions for the drug product.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). The approved change in the storage conditions should also be incorporated on the carton and container labels as appropriate with the next printing.

Please submit the copies of final printed labeling (FPL) electronically 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, the submission should be designated "FPL for approved supplements NDA 19-543/S-014." Approval of this submission by FDA is not required before the labeling is used.

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,

{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

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

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