DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-796/S-008 & S-015

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 applications, NDA 19-796/S-008, dated July 18, 1997, received July 22, 1997, and S-015, dated September 14, 2001, received September 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ELOCON® (mometasone furoate) Lotion, 0.1%.

We acknowledge receipt of your submissions dated November 28, 2000; April 30, and May 9, 2001 (S-008), and March 22 and 27 (S-015), July 15 (facsimile) and 17 (facsimile), 2002.

Supplement 008 provides for revised labeling to conform to labeling for ELOCON Cream and Ointment, and revised geriatric labeling pursuant to 21 CFR 201.57(f)(10).

Supplement 015 provides for a completed pediatric study report in response to the issued written request dated March 17, 1999, and revised on December 15, 2000 and September 5, 2001.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL), including carton and container labeling, 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 19-796/S-008 and S-015." Approval of the submission by FDA is not required before the labeling is used.

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).

Since safety and efficacy of ELOCON Lotion have not been established in pediatric patients below 12 years of age, its use in this age group is not recommended and we are waiving the pediatric study requirement for pediatric patients below 12 years of age for ELOCON Lotion.

We note that you have fulfilled the pediatric study requirement at this time for ELOCON Lotion in pediatric patients 12 years of age or older.

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

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
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