DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-796/S-020

Schering Corporation
Attention: Yvette Henderson, Manager
Global Labeling
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Henderson:

Please refer to your supplemental new drug application dated March 8, 2005, received March 11, 2005, 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 September 7, 8, and 9 (3 facsimiles), 2005.

This supplemental new drug application provides revised carton and container labeling in an effort to prevent patients from accidentally instilling ELOCON® Lotion, 0.1%, into their eyes.

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 (immediate carton and container carton labels)

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-796/S-020.**" Approval of this submission by FDA is not required before the labeling is used.

As per your September 7 and 9, 2005, facsimile transmissions, we concur with your commitment to:

1. Not distribute professional samples of ELOCON® Lotion, 0.1%, in the future.

2. Continue monitoring the adverse events of patients instilling the ELOCON® Lotion, 0.1%, in their eyes after implementation of the labeling with re-evaluation of such adverse events at one year.

3. Report any adverse events of patients instilling ELOCON® Lotion, 0.1%, in their eyes promptly to the Agency and to report these findings in the Annual Periodic Safety Report.

4. Notify healthcare professionals and pharmacists of the potential misuse of ELOCON® Lotion, 0.1%, in patients.

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, HFD-410
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., MT (ASCP), CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Division Director
Division of Dermatologic and
Dental Drug Products
Office of Drug Evaluation III
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/

Stanka Kukich
9/9/2005 04:29:07 PM
sign off for Dr. Jonathan Wilkin, Division Director