DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-716/S-021

Schering Corporation
Attention: Suzan Aygen
Associate Manager
Global Labeling, Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Aygen:

Please refer to your supplemental new drug application dated October 21, 2005, received October 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diprolene (betamethasone dipropionate, augmented) Lotion.

This supplemental new drug application provides revised carton and container labeling for the 30 mL and 60 mL container sizes in an effort to prevent patients from accidentally instilling Diprolene Lotion into their eyes.

We completed our review of this application. 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 immediate container and carton labels submitted October 21, 2005.

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 19-716/S-021." Approval of this submission by FDA is not required before the labeling is used.

As per your October 21, 2005, submission, we concur with your commitment to:

1. Not distribute professional samples of Diprolene Lotion in the future.

2. Continue monitoring the adverse events of patients instilling the Diprolene Lotion 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 Diprolene Lotion 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 Diprolene Lotion in patients.

At the next printing of the carton/container labeling for the 30 mL and 60 mL container sizes of Diprolene Lotion, please implement the following revisions:

1. Increase the prominence of the statements, “For Topical Use Only”, and “Not for Ophthalmic Use”.

2. Increase the prominence of the text within the eye graphic “Do Not Use in Eyes” and use a contrasting color to make the warning against use in the eye more prominent. In addition, relocate the eye graphic towards the center of the principal display panel to further increase prominence.

Also, the Agency recommends that you conduct a Consumer and Healthcare testing survey to determine the effectiveness of the eye graphic and applicable warnings.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 796-2110.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Acting Division Director
Division of Dermatology and Dental 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

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