DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-741/S-016

Schering Corporation
Attention: Yvette Henderson
Manager, Global Labeling
Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Dear Ms. Henderson:

Please refer to your supplemental new drug application dated June 26, 1992, received July 2, 1992, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diprolene (augumented betamethasone dipropionate) Ointment, 0.05%.

We acknowledge receipt of your submissions dated March 25 and November 12, 2004, February 11, and April 6, 2005. Your submission of April 6, 2005, constituted a complete response to our March 11, 2004, action letter.

This supplemental new drug application provides for revisions in the DESCRIPTION, CLINICAL PHARMACOLOGY, Pharmacokinetics, INDICATIONS and USAGE, CONTRAINDICATIONS PRECAUTIONS, Information for Patients, Laboratory Tests, Carcinogenesis, Mutagenesis, and Impairment of Fertility, Pregnancy: Teratogenic Effects: Pregnancy Category C, Pediatric Use, ADVERSE REACTIONS, DOSAGE and ADMINISTRATION and HOW SUPPLIED sections.

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 (text for the package insert).

Please submit an electronic version of *the FP*L according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Fo*rmat - 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 18-741/S-016." Approval of this submission by FDA is not required before the labeling is used.

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) 796-2110.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic 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

10/7/2005 11:54:20 AM