



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 (augmented 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 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 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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Stanka Kukich  
10/7/2005 11:53:20 AM  
sign off for Dr. Jonathan Wilkin, Division Director