DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-741/S-028

Schering Plough Research Institute
Attention: Craig Ostroff, Pharm.D.
Associate Director and Liaison,
Global Regulatory Affairs
2000 Galloping Hill Road
K-6-1, Mailstop: 1610
Kenilworth, NJ 07033-0530

Dear Dr. Ostroff:

We acknowledge your supplemental new drug application dated October 28, 2005, received October 31, 2005, 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 December 9, 2005, and July 20, 2006, August 18, 2006 (fax).

This supplemental new drug application provides for a Geriatric Use section.

We have 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 approved labeling.

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. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved supplement NDA 18741/S028" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional material that you propose to use for this product. Submit all proposed materials should be submitted in draft or mock-up form, not final print. Send one copy to this Division/Division of Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising and Communications,
5901-B Ammendale Road
10903 New Hampshire Avenue
Beltsville, MD 20705-1266

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Shalini Jain, Project Manager, at (301) 796-0692.

Sincerely yours,

Susan Walker, M.D.
Division Director
Division of Dermatologic and Dental 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/

Stanka Kukich
8/28/2006 12:14:10 PM
sign off for Dr. Susan Walker, Division Director