



NDA 19-452/S-018

Hill Dermaceuticals, Inc.
Attention: Jerry S. Roth, President
2650 South Mellonville Avenue
Sanford, Florida 32773

Dear Mr. Roth:

Please refer to your supplemental new drug application dated November 8, 2002, received November 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Derma-Smothe/FS (fluocinolone acetonide) Topical Oil, 0.01%.

We acknowledge receipt of your submissions dated, February 13, March 14 and 19, and April 15, 2003.

This supplemental new drug application provides for a 4-ml glass vial with a rubber lined phenolic cap to dispense physician's samples of the drug product sample.

We have completed our review of this application, as amended. This application is approved, effective the date of this letter, for use with the revised container labels. (Attached)

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, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products
(HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Wilson H. DeCamp
4/21/03 11:00:18 AM
approved