CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-930

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-930

Hill Dermaceuticals, Inc.
Attention: Rosario G. Ramirez, M.D.
Director, Medical and Regulatory Affairs
2650 South Mellonville Avenue
Sanford, Florida 32773

Dear Dr. Ramirez:

Please refer to your new drug application (NDA) dated May 4, 2005, received May 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for fluocinolone acetonide oil, 0.01% ear drops.

We acknowledge receipt of your submissions dated May 31, June 13, 20, and 27, July 6, and 11, August 18, and 29, September 8, October 27, and November 8, and 9, 2005.

This new drug application provides for the use of fluocinolone acetonide oil, 0.01% ear drops for treatment of chronic eczematous external otitis.

We completed our review of this application, as amended. It 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 consistent with the enclosed draft labeling submitted on November 8, 2005. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 19-452 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling and promotional materials requested above.

If you have any questions, call Michael Puglisi, Project Manager, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and
Ophthalmology Products, HFD-520
Office of Antimicrobials
Center for Drug Evaluation and Research

Enclosure