NDA 019452/S-027

SUPPLEMENT APPROVAL

Hill Dermaceuticals, Inc
Attention: Gerardo P. Mendez
Executive Vice President, Director of Business Development
2650 South Mellonville Avenue
Sanford, FL 32773

Dear Gerardo Mendez:

Please refer to your supplemental new drug application (sNDA) dated and received May 11, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Derma-Smoothe/FS Scalp Oil (fluocinolone acetonide) topical oil, Derma-Smoothe/FS Body Oil (fluocinolone acetonide) topical oil, and DermOtic Oil (fluocinolone acetonide oil) ear drops.

We acknowledge receipt of your amendment dated May 11, 2022, which constituted a complete response to our September 25, 2009, action letter.

This Prior Approval sNDA provides for:

- a Pregnancy and Lactation Labeling Rule (PLLR) conversion of the Prescribing Information (PI) for Derma-Smoothe/FS Scalp Oil (fluocinolone acetonide) topical oil, Derma-Smoothe/FS Body Oil (fluocinolone acetonide) topical oil, and DermOtic Oil (fluocinolone acetonide oil) ear drops.

- a correction to the statement regarding the amino acid test for peanut protein.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

- **DERMA-SMOOTHE/FS Body Oil (fluocinolone acetonide) topical oil PI**:
  - **Section 8.4 Pediatric Use**
    - Evaluation in Pediatric Patients 2 to 6 years old – in the first sentence the word “on” was changed to the word “in”.

- **DERMOTIC OIL (fluocinolone acetonide) ear drops PI:**
  - **Section 8.4 Pediatric Use**

- Evaluation in Pediatric Patients 2 to 6 years old – in the first sentence the word “on” was changed to the word “in”.

- **Table 2: Efficacy Results at Day 7 in Subjects with Chronic Eczematous External Otitis in Trial 1 and 2**
  - The word Erythema was capitalized.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling Prescribing Information, with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

REPORTING REQUIREMENTS

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, email H. F. Van Horn III, PharmD, MBA, Senior Regulatory Project Manager, at Howard.VanHornIII@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TATIANA OUSSOVA
08/30/2024 02:29:22 PM