

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**22-563**

***Trade Name:*** Sorilux Foam, 0.005%

***Generic Name:*** calcipotriene

***Sponsor:*** Stiefel Laboratories

***Approval Date:*** October 6, 2010

***Indications:*** Topical treatment of plaque psoriasis in patients aged 18 years and older

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*APPLICATION NUMBER:*

**22-563**

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**APPROVAL LETTER**



NDA 022563

**NDA APPROVAL**

Stiefel Laboratories, Inc.  
Attention: Salisa Hauptmann, MPH, RAC  
Vice President, Global Regulatory Affairs  
20 T. W. Alexander Drive  
Research Triangle Park, NC 27709

Dear Ms. Hauptmann:

Please refer to your New Drug Application (NDA) dated December 18, 2009, received December 21, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sorilux™ (calcipotriene) Foam, 0.005%.

We acknowledge receipt of your submissions dated January 19, February 10, March 11, March 12, April 21, April 22, April 23, May 7, May 17, June 4, June 28, June 30, August 6, August 23, September 10, September 14, September 24, October 4 (2), and October 5, 2010.

This new drug application provides for the use of Sorilux™ (calcipotriene) Foam, 0.005% for the topical treatment of plaque psoriasis in patients aged 18 years and older.

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 agreed-upon labeling text and with the minor editorial revisions listed below.

1. The cross-referencing format in the FULL PRESCRIBING INFORMATION, WARNINGS AND PRECAUTIONS, Ultraviolet Light Exposure section has been changed from [*See NONCLINICAL TOXICOLOGY (13.1).*] to [*See Nonclinical Toxicology (13.1).*].
2. The cross-referencing format in the FULL PRESCRIBING INFORMATION, OVERDOSAGE section, has been changed from [*See WARNINGS AND PRECAUTIONS (5.2).*] to [*See Warnings and Precautions (5.2).*].
3. The cross-referencing format in the FULL PRESCRIBING INFORMATION, NONCLINICAL TOXICOLOGY, Carcinogenesis, Mutagenesis, Impairment of Fertility section has been changed from [*See WARNINGS AND PRECAUTIONS (5.3).*] to [*See Warnings and Precautions (5.3).*].

4. In the FULL PRESCRIBING INFORMATION, PATIENT COUNSELING INFORMATION section, brackets have been added around the statement “See FDA-Approved Patient Labeling”.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 022563.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirements for ages 0 months to 2 years because necessary studies are impossible or impracticable. This is because there are too few children with the condition to study.

We are deferring submission of your pediatric studies for ages 2 to 16 years for this application, because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

- 1684-1     Deferred pediatric study under PREA for the topical treatment of plaque psoriasis in pediatric patients ages 12 through 16.  
A Pharmacokinetic/Pharmacodynamic trial of calcipotriene foam under maximal use conditions in 20 evaluable pediatric subjects with plaque psoriasis age 12 through 16 years. Evaluate the effect of the product on calcium metabolism in all subjects.

Final Protocol Submission: April, 2011  
Trial Completion: June, 2013  
Final Report Submission: January, 2014

- 1684-2     Deferred pediatric study under PREA for the topical treatment of plaque psoriasis in pediatric patients ages 2 through 11.  
A Pharmacokinetic/Pharmacodynamic trial of calcipotriene foam under maximal use conditions in 25 evaluable pediatric subjects with plaque psoriasis age 2 through 11 years. Evaluate the effect of the product on calcium metabolism in all subjects.

Final Protocol Submission: April, 2011  
Trial Completion: September, 2013  
Final Report Submission: March, 2014

- 1684-3     Deferred pediatric study under PREA for the topical treatment of plaque psoriasis in pediatric patients ages 2 through 11.  
A vehicle-controlled trial of the safety and efficacy of calcipotriene foam in 100 evaluable pediatric subjects with plaque psoriasis age 2 through 11 years. Evaluate the effect of the product on calcium metabolism in all subjects.

Final Protocol Submission: September, 2011  
Trial Completion: June, 2013  
Final Report Submission: January, 2014

Submit final study reports to this NDA. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated “**Required Pediatric Assessment(s)**”.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to [CDERMedWatchSafetyAlerts@fda.hhs.gov](mailto:CDERMedWatchSafetyAlerts@fda.hhs.gov), and to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

## **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, call Jeannine M. Helm, Regulatory Project Manager, at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

Susan J. Walker, M.D., F.A.A.D.  
Director  
Division of Dermatology and Dental Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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SUSAN J WALKER  
10/06/2010