DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22563/S-001

SUPPLEMENT APPROVAL

Stiefel Laboratories, Inc.
Attention: Jeffrey S. Troughton, M.S., R.A.C.
Associate Director, Regulatory Affairs
20 T.W. Alexander Drive
Research Triangle Park, NC 27709

Dear Mr. Troughton:

Please refer to your Supplemental New Drug Application (sNDA) dated November 12, 2010, received November 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sorilux (calcipotriene) Foam, 0.005%.

We acknowledge receipt of your amendments dated November 15, 2010, and March 10, March 23, and March 28, 2011.

This "Changes Being Effected" supplemental new drug application provides for the addition of two package sizes (120 g commercial package and a 6 g professional sample) of the drug product.

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

- In Full Prescribing Information under Special Populations, Pregnancy, the italics was removed from the phrase "Teratogenic Effects, Pregnancy Category C:"
- In Full Prescribing Information under PATIENT COUNSELING INFORMATION, the wording "*(Patient Information)*" was added after "*See FDA-Approved Patient Labeling*"
- In Full Prescribing Information under Patient Counseling Information, Patient Information, under "What are the ingredients of SORILUX Foam?", the statement "The Patient Information Leaflet was last revised: October 2010" was replaced with "This Patient Information has been approved by the U.S. Food and Drug Administration."

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions listed, the enclosed labeling (text for

the package insert, text for the patient package insert) 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 titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 MS Word format, that includes the changes with the revisions listed approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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).

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.

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 Matthew White, Regulatory Project Manager, at (301) 796-4997.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

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
04/21/2011