DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022013/S-005

SUPPLEMENT APPROVAL

Stiefel Laboratories, Inc.
Attention: Alicia V. Tatro, Ph.D. RAC
Associate Director, Regulatory Affairs Labeling
20 TW Alexander Drive
Research Triangle Park, NC 27709

Dear Dr. Tatro:

Please refer to your Supplemental New Drug Application (sNDA) dated January 21, 2010, received January 22, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Olux-E (clobetasol propionate) Foam, 0.05%.

We acknowledge receipt of your amendments dated April 12, October 29, and November 4, 2010.

This "Prior Approval" supplemental new drug application provides for the revision of the full prescribing information to meet the new labeling content and format requirements for human prescription drug and biological products according to 21 CFR 201.56(d) and 201.57. The supplement also provides for updates to the "ADVERSE REACTIONS" and "CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY" sections of the labeling.

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 revision listed below in the enclosed labeling.

In the FULL PRESCRIBING INFORMATION, CLINICAL PHARMACOLOGY, Pharmacodynamics section, the reference statement "see Warnings and Precautions (5.1) and Use In Specific Populations (8.4)" has been italicized.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using 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) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (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 approved in this supplemental application.

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 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 Margo Owens, Team Leader, Project Management Staff, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, M.D., M.P.H.
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

TATIANA OUSSOVA
11/10/2010