DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021978/S-007 **SUPPLEMENT APPROVAL**

Stiefel Laboratories, Inc.
Attention: Alicia V. Tatro, Ph.D RAC
Associate Director
20 T.W. Alexander Drive
Research Triangle Park, NC 27709

Dear Dr. Tatro:

Please refer to your June 29, 2009 Supplemental New Drug Application (sNDA), received June 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Verdeso® (desonide) Foam, 0.05%.

We acknowledge receipt of your submissions dated February 16 and April 2, 2010.

This "Prior Approval" supplemental new drug application provides for the revision of the Verdeso® (desonide) Foam, 0.05% 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.

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. In the Highlights of Prescribing Information, under Dosage and Administration, the word "be" was deleted from the fourth bulleted statement.

2. In the Highlights of Prescribing Information, under Warnings and Precautions, italics and underlining were removed from the first bulleted statement.

3. In the Highlights of Prescribing Information, the Revision date was changed to "04/2010".

4. In the Full Prescribing Information: Contents section, the subheading 6.1 was changed to "Clinical Trial Experience".

5. In the Full Prescribing Information, under Warnings and Precautions, italics was removed from the first sentence in that section.

6. In the Full Prescribing Information, under Dosage and Administration section, italics and underlining were removed from the first sentence of the fourth paragraph.

7. In the Full Prescribing Information, the subheading 6.1 was changed to "Clinical Trial Experience".

8. In the Full Prescribing Information, Adverse Reactions section, a duplicate entry of Table 1 titled "Adverse Reactions in the Clinical Trial" was deleted.

9. In the Full Prescribing Information, Patient Counseling Information, FDA-Approved Patient Labeling section, italics and underlining were removed from all sections.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 021978/S-007.

POSTMARKETING COMMITMENTS

We remind you of your postmarketing commitments provided in the September 19, 2006, approval letter. These commitments are listed below.

1. Conduct a dermal carcinogenicity study with Verdeso (desonide) Foam.

   90-day dose range-finding study: 04/08
   Protocol Submission: 10/08
   Study Start Date: 06/09
   Final Report Submission: 12/12

2. Conduct a study to determine the photo-carcinogenic potential of Verdeso (desonide) Foam.

   90-day dose range-finding study: 04/08
   Protocol Submission: 10/08
   Study Start: 06/09
   Final Report Submission: 12/11

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All

submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Nichelle Rashid, Regulatory Project Manager, at (301) 796-3904

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21978	SUPPL-7	STIEFEL LABORATORIES INC	DESONIDE FOAM 0.05%

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
04/22/2010