DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-821/S-014
NDA 19-821/S-015

Stiefel Laboratories, Inc.
Attention: Devon L. Allen, RAC
Associate Director, Regulatory Affairs
20 TW Alexander Drive
Research Triangle Park, NC 27709

Dear Ms. Allen:

Please refer to your pending supplemental new drug applications submitted February 17, 2005 (S-014) and December 21, 2006 (S-015), received February 18, 2005 and December 22, 2006, respectively, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SORIATANE®, (acitretin) Capsules, 10 mg & 25 mg.

We acknowledge your submissions dated April 11 and 29, December 21, 2005, November 21, 2006, May 21, and September 24, 2007 for supplement S014.

We acknowledge your submissions dated March 21, May 21 and 31, September 24, and October 3, 2007 for supplement S015.

These supplements provide for revisions to the risk management program for the indication of severe psoriasis.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to approve these supplements. Accordingly, these submissions are approved effective on the date of this letter.

The final printed labeling must be identical to the agreed upon text of the label submitted October 3, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 19-821/S-014, and NDA 19-821/S-015**".

Please submit one copy to the Division of Dermatology & Dental Products and two copies of the Package Insert and Medication guide 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(s), 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 www.fda.gov/cder/ddmac.

We remind you that you are required under 21 CFR 314.550, to submit copies of all promotional materials intended for dissemination or publication within 120 days after NDA approval.

If you have any questions, please call Kalyani Bhatt, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, MD, FAAD
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Susan Walker
10/18/2007 11:59:52 AM