DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-821/S-017

APPROVAL LETTER

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

Dear Ms. Allen:

Please refer to your supplemental new drug application dated March 31, 2009, received April 1, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Soriatane® (acitretin) Capsules, 10mg and 25mg.

We acknowledge receipt of your submissions dated April 23, June 5, June 9, June 17, July 2, July 15, July 21, July 22, July 29, and August 5, 2009 (via email).

This supplemental new drug application provides for the addition of two intermediate strengths (17.5 mg and 22.5 mg) of Soriatane® (acitretin) Capsules.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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)] 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, text for the Medication Guide, immediate container and carton labels).Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved supplement NDA 19-821/S-017."**

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 (October 2005).* 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 supplement NDA 19-821/S-017."** 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.

POST-MARKETING COMMITMENTS

We remind you of your postmarketing study commitment provided in the October 28, 1996, approval letter. This commitment is listed below.

2. A study to determine whether etretinate is detectable in a representative group of patients who received acitretin. Relevant results from this study must be available prior to making any labeling modifications regarding pregnancy. This study should contain the following elements:
   A. A study of 100 women of child bearing potential to monitor compliance of the effect of the label warning against alcohol use and pregnancy.

   B. Determinations of plasma concentrations of acitretin and etretinate will be made during treatment and for two years after cessation of treatment.

Protocol Submission:	September 30, 2009
Study Start:	December 10, 2009
Final Report Submission:	Part A – February 16, 2011
	Part B – February 16, 2013

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, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Commitment Protocol"**, **"Postmarketing Study Commitment Final Report"**, or **"Postmarketing Study Commitment Correspondence."**

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.

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
Suite 12B-05
5600 Fishers Lane
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 Kelisha Turner, Regulatory Project Manager, at (301) 796-0766.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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
08/06/2009