CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 50-741

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-741

Stiefel Laboratories, Inc.
Attention: William A. Carr, Jr.
Vice President
Route 145
Oak Hill, New York 12460

Dear Mr. Carr:

Please refer to your new drug application (NDA) dated February 22, 2002, received February 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DUAC (clindamycin, 1% - benzoyl peroxide, 5%) Topical Gel.

We acknowledge receipt of your submissions dated March 15 (two), June 14, July 9, and August 20, 2002; and facsimile transmission August 5, 2002. Your submission of February 22, 2002, constituted a complete response to our September 6, 2000, action letter.

This new drug application provides for the use of DUAC Topical (clindamycin, 1% - benzoyl peroxide, 5%) Gel for the topical treatment of inflammatory acne vulgaris.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert, immediate container, and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 50-741." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submission dated August 20, 2002. These commitments are listed below.

1. The Applicant commits to performing dermal carcinogenicity testing of the

combination drug product.

Commitment Category: NON-CLINICAL TOXICOLOGY

Protocol Submission:	Within 4 months of the date of this letter
Study Start:	Within 6 months of the date of the approval of the protocol
Final Report Submission:	Within 12 months after the study completion

2. The Applicant commits to a study to evaluate the effects of the drug products on UV-induced skin cancers.

Commitment Category: NON-CLINICAL TOXICOLOGY

Protocol Submission:	Within 4 months of the date of this letter
Study Start:	Within 6 months of the date of the approval of the protocol
Final Report Submission:	Within 12 months after the study completion

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 Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application for pediatric patients below the age of 12.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available

We remind you that you must comply with the requirements for an approved NDA set forth under

21 CFR 314.80 and 314.81.

If you have any questions, call Victoria Lutwak, Project Manager, at 301/827-2073.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure