

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-738

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-738

Stiefel Laboratories, Inc.
Attention: Marcia Gaido, Ph.D., R.A.C., Director, Regulatory Affairs
20 TW Alexander Drive
Research Triangle Park, NC 27709

Dear Dr. Gaido:

Please refer to your new drug application (NDA) dated December 11, 2006, received December 12, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Extina (ketoconazole) Foam, 2%.

We acknowledge receipt of your submissions dated December 21, 2006, January 9 (3), 17, April 10, 27 (2), 30, May 18, and 23, and June 1, 8 (facsimile), and 11 (facsimile), 2007.

The November 1, 2006, and December 11, 2006, submissions constitute a complete response to our November 23, 2004, action letter.

This new drug application provides for the use of Extina (ketoconazole) Foam, 2% for the topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older.

We 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 revision listed below.

On the carton labeling, relocate the route of administration statement, "For Topical Use Only", on the primary display panel.

Within 21 days of the date of this letter, submit 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> <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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. We note that you have fulfilled the pediatric study requirement for this application. In addition, we are waiving the pediatric study requirement for ages 0 to 12 years.

We remind you of your postmarketing study commitment in your submission dated June 8, 2007. This commitment is listed below.

1. The applicant should conduct a study in which the long-term safety of their product is assessed, as per the ICH E1A guidelines.

Protocol Submission:	by December 28, 2007
Study Start:	by June 2, 2008
Final Report Submission:	by June 30, 2011

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.”**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly 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

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

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 Melinda Bauerlien, M.S., Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, M.D.
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
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