DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-946/S-003 **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 Ms. Tatro:

Please refer to your supplemental new drug application dated June 29, 2009, received July 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xolegel® (ketoconazole) Topical Gel, 2% indicated for the topical treatment of seborrheic dermatitis in immunocompetent adults and children 12 years of age and older.

We acknowledge receipt of your submissions dated November 16, 2009 and December 14, 2009.

This supplement provides for the revision of the Xolegel Topical Gel, 2% 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 enclosed, agreed-upon labeling text.

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, text for the patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 21946/S-003".

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
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-21946	SUPPL-3	STIEFEL LABORATORIES INC	KETOCONAZOLE 2% TOPICAL GEL 20MG/G

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
12/30/2009