DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-741/S-011

Stiefel Laboratories, Inc.
Attention: Colleen A. McGraw, MBA
Associate Director, Labeling, Regulatory Affairs
20 T.W. Alexander Drive
P.O. Box 14910
Research Triangle Park, North Carolina 27709

Dear Ms. McGraw:

Please refer to your supplemental new drug application dated July 10, 2007, received July 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duac Topical Gel (clindamycin, 1% - benzoyl peroxide, 5%).

We acknowledge receipt of your submission(s) dated February 7 and June 18, 2008.

Thise "Changes Being Effected" supplemental new drug application provide(s) for the addition of information regarding hypersensitivity reactions to PRECAUTIONS and ADVERSE REACTIONS sections of the package insert.

We 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 text for the package insert. 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 NDA 50-741."

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 Bronwyn Collier, Acting Chief Project Management Staff, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, M.D., F.A.A.D.
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/

Susan Walker
7/22/2008 03:26:08 PM