DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration
Rockville, MD 20857

NDA 50-261/S-100

Stiefel Laboratories, Inc.
Attention: Stephen Richardson
Senior Director, Regulatory Affairs
20 TW Alexander Drive
PO Box 14910
Research Triangle Park, NC 27709

Dear Mr. Richardson:

Please refer to your supplemental new drug application dated July 19, 2007 received July 23, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Declomycin® (demeclocycline) Tablets, 150 mg and 300 mg.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application has been submitted in response to an Agency letter requesting an update to the **WARNINGS** and **PRECAUTIONS** section of the labeling concerning *Clostridium difficile* associated diarrhea.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on July 19, 2007.

We note that your July 19, 2007 submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, M.D.
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for 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/

Kathrine Laessig
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