DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-261/S-095

Lederle Laboratories
Attention: Patricia Kuker Staub RPh, JD
Associate Director II, Worldwide Regulatory Affairs
P. O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Kuker Staub:

Please refer to your supplemental new drug application dated August 14, 2001, received August 15, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Declomycin ® Tablets (demeclocycline hydrochloride tablets, U.S.P.). 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 provides for changes to the **DESCRIPTION, CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, PRECAUTIONS/General, PRECAUTIONS/Carcinogenesis, Mutagenesis, Impairment of Fertility, PRECAUTIONS/Labor and Delivery, DOSAGE AND ADMINISTRATION, ANIMAL PHARMACOLOGY and ANIMAL TOXICOLOGY,** and **REFERENCES** sections of the package insert.

We have completed our review of this application and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling submitted on August 14, 2003, and include the minor editorial revisions indicated below. These revisions are terms of the approval of this application.

In the **REFERENCES** section, update the NCCLS references to reflect the most recent edition (2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case 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 submissions should be designated "FPL for approved supplement NDA 50-261/S-095." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M.Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Janice Soreth

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