DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-621/S-023
NDA 50-622/S-017

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

Dear Ms. Staub:

Please refer to your supplemental new drug applications dated January 18, 2001, received January 22, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Suprax® (cefixime) Tablets (NDA 50-621/S-023) and Suprax® (cefixime) Oral Suspension (NDA 50-622/S-017). We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated December 10, 2001 and April 9, 2003. Your submission of April 9, 2003, constituted a complete response to our April 17, 2002 action letter.

These "Changes Being Effected" supplemental new drug applications propose a new statement in the **WARNINGS** section regarding anaphylactoid reactions; statements in the **PRECAUTIONS** section regarding drug interactions with warfarin and anticoagulants; and revisions to the **ADVERSE REACTIONS** section of the package insert.

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 9, 2003.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to the 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LT Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: labeling

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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