DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-521/S-027
NDA 50-522/S-027

Eli-Lilly and Company
Attention: Elizabeth Sloan, Pharm.D.
Director, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Sloan:

Please refer to your supplemental new drug applications dated July 28, 2003, received July 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ceclor® (cefaclor pulvules)(NDA 50-521/S-027) and Ceclor® (cefaclor for oral suspension) (NDA 50-522/S-027). This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected" supplemental new drug applications propose the following changes to the **INDICATIONS AND USAGE** section, **General and Information for Patients** subsections of the **PRECAUTIONS** section, **ADVERSE REACTIONS** section and **Microbiology** subsection of the **CLINCIAL PHARMACOLOGY** section of the label:

1. The addition of statements to four sections of the labeling concerning the development of drug-resistant bacteria.

2. The addition of moniliasis to the **ADVERSE REACTIONS** subsection.

3. A change in nomenclature for two microorganisms in the **Microbiology** subsection under **CLINICAL PHARMACOLGY**.

We have completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 28, 2003.

If a letter communicating important information about this drug product (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 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 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 text (updates highlighted)

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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