



NDA 50-521/S-026
NDA 50-522/S-024

Eli Lilly and Company
Attention: Elizabeth C. 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 August 21, 2001, received August 22, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ceclor[®] (cefaclor pulvules) Pulvules[®] (NDA 50-521) and Ceclor[®] (cefaclor for oral suspension) Suspension (NDA 50-522).

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 June 3, 2002 and October 2, 2002.

Your submission of October 2, 2002 constituted a complete response to our May 24, 2002 action letter.

These supplemental new drug applications provide for the addition of a *Geriatric Use* subsection of the **PRECAUTIONS** section.

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 October 2, 2002.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely yours,

{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

**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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