DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-405/S-092

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

Dear Dr. Bearby:

Please refer to your supplemental new drug application dated November 12, 2001, received November 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Keflex® (cephalexin, USP) Pulvules, 250 mg and 500 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.

We also acknowledge receipt of your submission dated February 11, 2004, received February 12, 2004, which constitutes a complete response to our approvable letter dated January 15, 2004, and provides for a revised statement in the Pediatric Use subsection of the Keflex® US package insert, along with data from the literature to support the revision.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, and with the following change listed below:

1. References to the fact that "Keflex for oral suspension is no longer commercially available from Eli Lilly and Company" should be deleted to the statements added to the labeling, since the oral suspension is currently being marketed by several pharmaceutical companies as a generic drug product. These statements occur in the **PRECAUTIONS, PEDIATRIC USE,** and **DOSAGE AND ADMINISTRATION** sections.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the package insert submitted February 11, 2004. These revisions are terms of the approval of this application.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-405/S-092." 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, HFD-410
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 J. Christopher Davi, Regulatory Project Manager, at (301) 827-2125.

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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