DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-504/S-062

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 application dated August 7, 2001, received August 9, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mandol® (cefamandole nafate for injection, USP).

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 acknowledge receipt of your submissions dated October 16, 2001, October 29, 2001, and January 13, 2003.

This supplemental new drug application provides for the following changes to the package insert:

DESCRIPTION

- The addition of "Cefamandole Nafate is a white to off-white crystalline powder." to the second paragraph.
- The revision of the molecular weight as 512.50.
- The revision of the upper endpoint of pH range as 8.0.

STABILITY

- The addition of "*Note*: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit."

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 January 13, 2003.

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.

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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