DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-504/S-059

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 application dated October 13, 1994, received October 17, 1994, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mandol® (cefamandole nafate) Vials. We note that 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 August 7, 2001, October 16, 2001, and January 9, 2002. Your submission of January 9, 2002 constituted a complete response to our December 14, 1995 action letter.

This supplemental new drug application provides for an updated *Microbiology* subsection of the **CLINICAL PHARMACOLOGY** subsection in response to the Agency's January 26, 1993 letter to all NDA holders and revisions to the **WARNINGS**, **PRECAUTIONS**, and **ADVERSE REACTIONS** sections of the label in response to the Agency's June 25, 1993 letter.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

1. In the **DOSAGE AND ADMINISTRATIONS** section, the *Infants and Children* subheader should be revised to read "*Pediatric Patients*".

2. In the **DOSAGE AND ADMINISTRATIONS** section, the *"Intermittent intravenous infusion with a Y-type administration or volume control set ...*", statement should be revised to read "*Intermittent intravenous infusion with volume control set ...*" since the piggyback presentation of Mandol is no longer marketed.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted January 9, 2002). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-504/S-059." Approval of this submission by FDA is not required before the labeling is used.

In addition, a new and separate supplement should be submitted

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 LTJG 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

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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