DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-095/S-062

Eli Lilly and Company
Attention: Gregory T. Brophy, Ph.D.
Director
Lilly Corporation Center
Indianapolis, IN 46285

Dear Dr. Brophy:

Please refer to your supplemental new drug application dated and received January 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Capastat® Sulfate (capreomycin for injection).

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the **PRECAUTIONS/Laboratory Tests** subsection and the **ADVERSE REACTIONS/Nephrotoxicity** subsection of the package insert (~~strikethrough~~ = deleted text and underlined = added text) .

1. In the **PRECAUTIONS/ Laboratory Tests** subsection, the third paragraph is revised as follows:

   Since hypokalemia, hypomagnesemia and hypocalcemia may occur during therapy, these serum ~~potassium~~ electrolyte levels should be determined frequently.

2. In the **ADVERSE REACTIONS/Nephrotoxicity** subsection, the third paragraph is revised as follows:

   Electrolyte disturbances ~~resembling Batter's syndrome have been reported in 1 patient~~ including hypokalemia, hypomagnesemia and hypocalcemia, sometimes serious in nature, have been reported.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted January 28, 2008.

The final printed labeling (FPL) must be identical to the enclosed labeling for the text for the package insert.

Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMED website.

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
Food and Drug Administration
Suite 12B05
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 June Germain, Regulatory Project Manager, at (301) 796-4024.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, MD
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Renata Albrecht

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