DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-095/S-044

Lilly Research Laboratories
A Division of Eli Lilly and Company
Attn: Bryan A. Bright, Pharm.D.
Senior Regulatory Associate
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Bright:

Please refer to your supplemental new drug application, dated August 13, 2002, received August 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Capastat® Sulfate (capreomycin for injection, USP)

We acknowledge the receipt of your submissions dated September 8, and 16, 2002.

This supplemental new drug application provides for the addition of a new **Geriatric Use** subsection at the end of the **PRECAUTIONS** section of the package insert in accordance with the August 27, 1997 final rule and 21 CFR 201.57(f)(10).

The changes were as follows. Added text is double underlined.

Geriatric Use*:* Clinical studies of Capastat Sulfate did not analyze the safety and efficacy of patients aged 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
Capastat Sulfate is known to be substantially excreted by the kidney (see CLINICAL PHARMACOLOGY), and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (see PRECAUTIONS, Laboratory Tests). Patients with reduced renal function should have dosage reduction based on creatinine clearance using the guidelines included in Table 1 (see DOSAGE AND ADMINISTRATION).
The geriatric population is also more likely to have impaired hearing at baseline. Audiometric measurements and assessment of vestibular function should be performed prior to initiation of therapy with Capastat Sulfate and at regular intervals during treatment (see PRECAUTIONS, General).

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted September 16, 2002).

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 ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-095/S-044." 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, HF-2
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 Christine Lincoln, RN, MS, MBA, Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic 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/

Renata Albrecht

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