DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-477/S-024
NDA 50-519/S-024

Eli Lilly and Company
Attention: Gregory G. Enas, PhD
Director, US Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Enas:

Please refer to your supplemental new drug applications dated May 21, 2001, received May 22, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nebcin (tobramycin sulfate injection, USP)-Vials and Hyporets (NDA 50-519), and Nebcin (tobramycin sulfate for injection, USP)-Vials (NDA 50-519).

These applications are 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 April 2, 2002.

These supplemental new drug applications provide for revised geriatric labeling.

We have completed our review of these applications as amended, and they are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to package insert submitted on May 21, 2001, with the addition of the following information in the PRECAUTIONS section, end of the *Geriatric Use* subsection:

For NDA 50-477/S-024

> "Nebcin 80 mg/2mL vial contains 1.59 mg (0.069 mEq) of sodium"

For NDA 50-519/S-024

> " Nebcin 1.2 g/30 mL vial contains 22.3 mg (.970 mEq) of Sodium. Nebcin 1.2 g/40 mL vial does not contain sodium"

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 heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-477/S-024 and NDA 50-519/S-024" Approval of these submissions 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 Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

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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