DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-606/S-020

Eli Lilly and Company
Attention: Elizabeth C. Bearby, Pharm. D.
Director, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Bearby:

Please refer to your supplemental new drug application dated October 15, 2003, received October 16, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vancocin® (vancomycin hydrochloride) Pulvules. 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 submission dated February 24, 2004.

This supplemental application, submitted as "Supplement - Changes Being Effected in 0 days," proposes the following changes:

1. The additions of wording to be in compliance with the "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" Final Rule, as published in the Federal Register, Vol. 68, No. 25, February 6, 2003.

2. A minor editorial change in the **CLINICAL PHARMACOLOGY** section.

3. An update to the **HOW SUPPLIED** section to remove information on Vancocin Oral Solution, which is no longer manufactured or sold by Lilly.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 16, 2004.

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 LT 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

Enclosure: Labeling

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

5/27/04 05:30:18 PM