DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-780/S-086
NDA 18-781/S-080

Eli Lilly and Company
Attention: William L. Current, Ph.D.
Associate Director, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Current:

Please refer to your supplemental new drug applications dated October 27, 2004, received October 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA 18-780/S-086	Humulin R (human insulin [rDNA origin] injection)
NDA 18-781/S-080	Humulin N (human insulin [rDNA origin] isophane suspension)

These supplemental new drug applications provide for revised labeling for Sterile Diluent ND-800, Vial No. 7250 to add Humulin R be used with this diluent.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for immediate container and carton label submitted on October 27, 2004. As agreed previously, the FPL was submitted to the NDA 18-781 (Humulin N), which is the lead NDA, and not to the Humulin R application.

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, HFD-410
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 Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

{See appended electronic signature page}

David G. Orloff
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Vial container label (A1.0 NL 7533 AMX)
Carton label (A1.0 NL 2950 AMS)

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

/s/

Eric Colman
2/25/05 02:57:03 PM
Eric Colman for David Orloff