DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-781/S-060 and S-070

Eli Lilly and Company
Attention: Jeffrey L. Winn, D.D.S., R.Ph.
Senior Regulatory Research Scientist
U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Winn:

Please refer to your supplemental new drug applications dated February 26, 2001, received February 27, 2001, for S-060, and dated September 17, 2002, received September 18, 2002, for S-070, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humulin® N (human insulin [rDNA origin] isophane suspension).

We acknowledge receipt of your submissions dated July 16 and 25, 2003.

Your submission of July 16, 2003, constituted a complete response to our April 9, 2003, (for S-060) and March 14, 2003, (for S-070) action letter.

These supplemental new drug applications provide for the following labeling changes:

Supplement 060: Additional language for the "good control message" in the DIABETES section, and deletion of the pictorial graphic of cartridge in the **Identification** section to the INFORMATION FOR THE PATIENT (for Humulin N Pen).

Supplement 070: Revisions to the INFORMATION FOR THE PATIENT (for Humulin N Pen) and insulin Pen User Manual to emphasize the need to priming before injection.

We completed our review of these applications, as amended. These applications are 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 (text for the patient package insert, insulin Pen user manual, and carton label).

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-781/S-060 and S-070." 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, HFD-410
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 Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

{See appended electronic signature page}

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

Enclosures:
1. INFORMATION FOR THE PATIENT (5.0 PA 9133-A FSAMP)
2. Disposable Insulin Delivery Device (Humulin N Pen) User Manual (5.0 PA 9113-A FSAMP)
3. Carton label for Humulin N Pen (SH MAQ 001 AM)