DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-717/S-060

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

Dear Dr. Winn:

Please refer to your supplemental new drug application dated January 9, 2004, received January 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humulin 70/30 (70% human insulin isophane suspension and 30% human insulin injection, [rDNA origin]).

We acknowledge receipt of your submission dated August 4, 2004.

Your submission of August 4, 2004, constituted a complete response to our July 12, 2004, action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to the (1) INFORMATION FOR THE PATIENT for Humulin 70/30 Pen, (2) Disposable Insulin Delivery Device (Humulin 70/30 Pen) User Manual, and (3) Humulin 70/30 Pen carton, to increase the safe use of Humulin 70/30 Pen.

We completed our review of this application, as amended. 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 (text for the patient package insert for Humulin 70/30 Pen, Humulin 70/30 Pen User Manual, and Humulin 70/30 Pen carton labels).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. 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 19-717/S-060." Approval of this submission by FDA is not required before the labeling is used.

In addition, you must submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5). Current guidance for industry specifies that the content of labeling should be provided in PDF or SPL file format. This new submission requirement was published on December 11, 2003 (68 FR 69009) and was effective June 8, 2004. For additional information, consult the following guidance for industry: *Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004)."

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 for Humulin 70/30 Pen (2.0 PV 3672 AMP)
2. Disposable Insulin Delivery Device (Humulin 70/30 Pen) User Manual (3.0 PV 3734 AMP)
3. Carton label for Humulin 70/30 Pen (A1.0 NL 2483 AMS)

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

/s/

David Orloff

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