DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-377/S-036

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 Winn:

Please refer to your supplemental new drug application dated December 18, 2002, received December 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humulin L Lente (human insulin [rDNA origin] zinc suspension).

We acknowledge receipt of your submissions dated February 5 and March 6, 2003.

This supplemental new drug application provides for an additional manufacturing site for Humulin L Lente Vials HI-410 in Building 200 at the Fegersheim, France, location.

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 and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the patient package insert, immediate container and carton labels) These revisions are terms of the approval of this application.

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, this submission should be designated "FPL for approved supplement NDA 19-377/S-036." 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, 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 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 (NL 4480 AMP)
2. Immediate container label (NL 4020 AMX)
3. Carton label (NL 3720 AMS)

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

/s/

Robert Misbin
4/18/03 03:41:41 PM
authorized to sign for David Orloff MD