DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-781/S-085 + 3 others

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 May 9, 2005, received May 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA 18-781/S-085	Humulin N (human insulin [rDNA origin] isophane suspension)
NDA 19-717/S-065	Humulin 70/30 (70% human insulin isophane suspension and 30% human insulin injection, [rDNA origin])
NDA 20-563/S-060	Humalog (insulin lispro [rDNA origin] injection)
NDA 21-017/S-025	Humalog Mix 75/25 (75% insulin lispro protamine suspension and 25% insulin lispro injection, [rDNA origin])

These "Changes Being Effected" supplemental new drug applications provide for labeling revisions to the Disposable Insulin Delivery Device User Manual.

We completed our review of these supplemental new drug applications. These applications are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 9, 2005.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 207051266

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:

Food and Drug Administration
MEDWATCH
Building 22, Mail Stop 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 796-1280.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolism
and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Disposable Insulin Delivery Device User Manual (PV 3734 AMP)

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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