DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-781/S-057
NDA 19-717/S-032
NDA 20-563/S-027

Eli Lilly and Company
Attention: Gregory G. Enas, Ph.D.
Director
U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Enas:

Please refer to your supplemental new drug applications dated May 15, 2000, received May 17, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following drug products:

NDA 18-781/S-057	Humulin N (human insulin isophane suspension, [rDNA origin])
NDA 19-717/S-032	Humulin 70/30 (70% human insulin isophane suspension and 30% human insulin injection, [rDNA origin])
NDA 20-563/S-027	Humalog (insulin lispro injection, [rDNA origin])

These "Changes Being Effected" supplemental new drug applications provide for labeling changes to the Disposable Insulin Delivery Device User Manual (PA 9112 FSAMP).

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) submitted on May 15, 2000.

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:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 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, M.D.
Director
Division of Metabolic
and Endocrine Drug Products
Office of Drug Evaluaiton II
Center for Drug Evaluation and Research

Enclosure: Disposable Insulin Delivery Device User Manual (PA 9112 FSAMP)

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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