



NDA 17-931/S-025
NDA 17-933/S-026
NDA 17-936/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 April 20, 1998, received April 24, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Regular Iletin I Insulin, Lente Iletin I Insulin, and NPH Iletin I Insulin, respectively.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the following statement to the side and upper panels of the cartons, "THIS INSULIN IS BEING DISCONTINUED CONTACT YOUR PHYSICIAN TO CHANGE TO ANOTHER LILLY INSULIN".

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (carton labels submitted April 20, 1998). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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.

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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 Evaluation II
Center for Drug Evaluation and Research

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

/s/

Mary Parks
2/11/02 02:37:30 PM
for Dr. Orloff