



NDA 18-781/S-072

Eli Lilly and Company  
Attention: Jeffrey L. Winn, D.D.S., R.Ph.  
Senior Regulatory Research Scientist  
US Regulatory Affairs  
Lilly Corporate Center  
Indianapolis, IN 46285

Dear Dr. Winn:

Please refer to your supplemental new drug application dated February 10, 2003, received February 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humulin® N (human insulin [rDNA origin] isophane suspension).

We acknowledge receipt of your submission dated April 11, 2003.

This “Changes Being Effected” supplemental new drug application provides for an addition of tamper evident tape with the text “**If the seal is broken before first use, contact pharmacist**” added to the 3 mL disposable insulin delivery devices (HP 8730, Humulin N Pen) carton label.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 11, 2003.

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 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, HFD-510  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: Carton label (circular SH 8722 FSAMS) submitted on April 11, 2003

-----  
**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

6/22/03 04:09:42 PM