



NDA 20-563/S-032

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

Dear Dr. Winn:

Please refer to your supplemental new drug application dated March 30, 2001, received April 2, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humalog® (insulin lispro [rDNA origin] injection).

This "Changes Being Effectuated" supplemental new drug application provides for the following changes to the INFORMATION FOR THE PATIENT VIAL (PA 6603 AMP)) labeling:

1. Removal of the pictorial graphic of the Humalog carton and vial in the *Identification* section, and
2. Revision in the "Good Control" messages in the "DIABETES" section.

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 enclosed marked-up labeling.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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 insert 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 Evaluation II
Center for Drug Evaluation and Research

Enclosure: Marked-up INFORMATION FOR THE PATIENT VIAL (PA 6603 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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