



NDA 20-563/S-054

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 application dated November 18, 2004, received November 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humalog (insulin lispro [rDNA origin] injection).

This "Changes Being Effected" supplemental new drug application provides for a revised package insert and patient package insert for cartridge to reflect the deletion of the 1.5 mL cartridge presentation and minor editorial changes.

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 November 18, 2004.

However, we request that you make the following changes at the time of the next final printed label:

1. Under the DESCRIPTION section of the package insert, replace "Metacresol" with "metacresol".
2. Under GENERAL INSTRUCTIONS in the patient package insert, replace the word "a" with "the" in the first sentence under item #6 between "injecting" and "dose". So it would read "After injecting the dose, pull the needle out and apply gentle pressure over the injection site for several seconds."

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

Attachments: 1. Package insert (PA 9129 FSAMP)  
2. INFORMATION FOR THE PATIENT 3 ML CARTRIDGE (PA 9087 FSAMP)

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

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David Orloff

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