



NDA 21-018/S-035

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

SUPPLEMENT APPROVAL

Dear Dr. Enas:

Please refer to your supplemental new drug application dated October 19, 2006, received October 20, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humalog Mix 50/50 (50% insulin lispro protamine suspension/50% insulin lispro injection [rDNA origin]).

This "Changes Being Effected" supplemental new drug application provides for minor changes to the immediate container label and carton label for the 10 mL vial presentation of Humalog Mix 50/50; e.g., providing a different telephone number for contacting Lilly and replacing the phrase "trace amounts of phenol" with "phenol, 0.89 mg" on the carton label.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the final printed carton and container labels (FPL) submitted October 19, 2006.

We acknowledge that this supplement also included a revised package insert (PI) and patient package insert (PPI). However, the PI and PPI have been superseded by Supplement-034, which was approved September 6, 2007. Therefore, the PI and PPI will not be reviewed but they will be retained in our files.

LETTERS TO HEALTH CARE PROFESSIONALS

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
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Rachel Hartford, Regulatory Project Manager, at 301.796.0331.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology
Products (DMEP)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

Carton label for 10 mL Vial

Container label for 10 mL Vial

**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

5/1/2008 06:07:37 AM