DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-563/S-082

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

Dear Dr. Enas:

Please refer to your supplemental new drug application dated March 5, 2007, received March 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humalog (insulin lispro injection [rDNA origin]) 100 U/mL.

This supplemental new drug application provides final printed labeling for revised a package insert, patient package insert for cartridges, and Humalog cartridge carton that adds a reference to the use of the cartridges with Eli Lilly and Company's reusable insulin delivery device, HumaPen LUXURA HD.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

We note your March 5, 2007, submission includes the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format for the package insert (PI) and patient package inserts (PPI's). This SPL labeling submission has not been reviewed. We will review this labeling postapproval to confirm it is identical to the agreed upon labeling text. Prior approval of this labeling in SPL format by FDA is not required before the labeling is used.

We also note that your March 5, 2007, submission includes final printed labeling in electronic format for the 5 X 3 mL Cartridge carton. This labeling has been reviewed and is acceptable.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Enid Galliers, Chief, Project Management Staff, at 301.796.1211.

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:
Package Insert (PA 9351 FSAMP)
Patient Package Insert for the 3 mL Cartridge (PA 9089 FSAMP)
Carton label – 5 X 3 mL Cartridges (SH 8662 FSAMS)

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

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