



NDA 018780/S-133

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Beth C. Weinberg, R.Ph.
Director, Global Regulatory Affairs – U.S.
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Weinberg:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 28, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Humulin R (insulin human injection, USP [rDNA origin]), 100 IU/mL.

We acknowledge receipt of your amendment dated June 24, 2011.

This “Changes Being Effected” supplemental new drug application removes [REDACTED] (b) (4) [REDACTED] from the Humulin R, 100 IU/mL, 10 mL vial cartons.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton labels as soon as they are available, but no more than 30 days after they are printed.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:

Humulin R, 100 IU/mL, 10mL Vial - Carton

Humulin R, 100 IU/mL, 10mL Vial (b) (4) – Carton

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

/s/

MARY H PARKS
10/30/2011