DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020563/S-172
NDA 205747/S-008

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Leah Helvering
Consultant – Global Regulatory Affairs- U.S. Diabetes
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Dear Ms. Helvering:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received June 1, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Humalog (insulin lispro [rDNA origin] injection) 100 units/mL and 200 units/mL.

These Prior Approval supplemental new drug applications propose an update to the instructions for use (IFU).

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (package insert, patient package insert, instructions for use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Callie Cappel-Lynch, Regulatory Project Manager, at (301) 796-8436.

Sincerely,

{See appended electronic signature page}

Jean-Marc Guettier, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Humalog Package Insert (previously approved May 26, 2015, for NDA 205747 and June 12, 2015 for NDA 20563)
Humalog U-100 Patient Package Insert (previously approved March 13, 2015)
Humalog U-200 Patient Package Insert (previously approved May 26, 2015)
Humalog U-100 KwikPen Instructions for Use
Humalog U-200 KwikPen Instructions for Use
Humalog U-100 Vial Instructions for Use (previously approved March 13, 2015)

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/s/

JEAN-MARC P GUETTIER
01/06/2017