



NDA 020563/S-124

**SUPPLEMENT APPROVAL**

Eli Lilly and Company  
Attention: Sumitra Ghate  
Consultant, Global Regulatory Affairs  
Lilly Corporate Center  
Indianapolis, Indiana 46285

Dear Ms. Ghate:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 15, 2011, received submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Humalog (insulin lispro [rDNA origin] injection), 100 units/mL

We acknowledge receipt of your amendments dated March 25, 2013, May 27, 2014, and March 11, 2015.

This “Prior Approval” supplemental new drug application provides for addition of a vial instructions for use (IFU) and minor changes to the patient package insert (PPI). Included in this supplement approval are minor corrections to the KwikPen IFU.

**APPROVAL & LABELING**

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.

**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 (text for the package insert (PI), patient package insert, instructions for use (IFU)), 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 includes 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:

Content of Labeling  
PI (previously approved February 25, 2015)  
PPI  
KwikPen IFU  
Vial IFU

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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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JEAN-MARC P GUETTIER  
03/13/2015