DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

BLA 125521/S-002

SUPPLEMENT APPROVAL

Eli Lilly and Co
Attention: Sally Anliker, PhD
Advisor, Global Regulatory Affairs - U.S.
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Dear Dr. Anliker:

Please refer to your Supplemental Biologics License Application (sBLA) dated December 7, 2017, received December 7, 2017, and your amendments, submitted under section 351(a)of the Public Health Service Act for Taltz (ixekizumab) injection, solution.

We also refer to our approval letter dated April 5, 2018, which contained the following error: the prescribing information, instructions for use, and Medication Guide were omitted from the approval letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain April 5, 2018, the date of the original approval letter.

We acknowledge receipt of your amendment dated December 7, 2017, which constituted a complete response to our January 25, 2017 action letter.

This Prior Approval supplemental biologics license application proposes to update the labeling and label to allow for the storage of the prefilled syringe and auto injector drug products at temperatures $\leq 30°C$ for up to 5 days.

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.

We note that you have not submitted final printed labeling (FPL) for your prescribing information, instructions for use and Medication Guide. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the prescribing information, instructions for use, and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 7, 2017, submission containing final printed carton and container labels.

This information will be included in your biologics license application file.

If you have any questions, call Anita Brown, Regulatory Business Process Manager, at (301) 796 - 2066.

Sincerely,

{See appended electronic signature page}

Amy Rosenberg, M.D.
Director
Division of Biotechnology Review and Research III
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling

Amy Rosenberg

Digitally signed by Amy Rosenberg
Date: 4/19/2018 11:03:47AM
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