BLA 125521/S-014

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Eli Lilly and Company
Attention: Brian E. Wagner, PharmD
Director, Global Regulatory Affairs – North America
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Wagner:

Please refer to your supplemental biologics license application (sBLA), dated and received May 31, 2018, and your amendments, submitted under section 351(a) of the Public Health Service Act for Taltz (ixekizumab) injection, for subcutaneous use.

This Prior Approval supplemental biologics application provides for labeling changes to reflect the outcome of the clinical study to assess whether ixekizumab alters the metabolism or pharmacokinetics of CYP substrates in psoriasis patients treated with ixekizumab.

APPROVAL & LABELING

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

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 FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

FULFILLMENT OF POSTMARKETING COMMITMENT

We have reviewed your submission and conclude that the postmarketing commitment listed below was fulfilled.

3049-5 Conduct a clinical study to assess whether ixekizumab alters the metabolism or pharmacokinetics of CYP substrates in psoriasis patients treated with ixekizumab.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the March 22, 2016 approval letter that are still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, call H. F. Van Horn III, Regulatory Project Manager, at (301) 837-7389.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TATIANA OUSSOVA
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