BLA 125521/S-031

APPROVAL LETTER

Eli Lilly and Co
Attention: Jennifer Camp
Senior Director-Global Regulatory Affairs-North America
Lilly Corporate Center, Drop Code 2543
Indianapolis, IN 46285

Dear Jennifer Camp:

Please refer to your supplemental biologics license application (sBLA) dated and received November 20, 2023, submitted under section 351(a) of the Public Health Service Act for Taltz (ixekizumab) injection.

This "Changes Being Effected" supplemental biologics license application proposes changes to the container labels and carton labels to indicate which end of the device is the needle end on the container labels for the commercial and sample prefilled autoinjector presentations and an updated image of the autoinjector on the corresponding carton labels.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to enclosed carton and container labeling and carton and container labeling submitted on November 20, 2023, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labeling for approved BLA 125521/S-031.**" Approval of this submission by FDA is not required before the labeling is used.

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

If you have any questions, please contact Shazma Aftab, PharmD, Regulatory Business Process Manager, at shazma.aftab@fds.hhs.gov or (301) 796 - 3138.

Sincerely,

{See appended electronic signature page}

Susan Kirshner, PhD
Division Director
Division of Product Quality Assessment XV
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

- Carton and Container Labeling
  - Commercial autoinjector carton label 1-pack
  - Commercial autoinjector carton label 2-pack
  - Commercial autoinjector carton label 3-pack
  - Commercial autoinjector container label
  - Sample autoinjector carton 1-pack
  - Sample autoinjector container label

Susan Kirshner

Digitally signed by Susan Kirshner
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