BLA 125521/S-028

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Jennifer Riddle Camp
Senior Director-Global Regulatory Affairs-North America
Lilly Corporate Center
Indianapolis, IN 46285

Dear Jennifer Riddle Camp:

Please refer to your supplemental biologics license application (sBLA), dated February 6, 2023, received February 7,2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for Taltz (ixekizumab) injection.

This Prior Approval supplemental biologics application provides for the addition of a Near Field Communication (NFC) chip on the Taltz (ixekizumab) sample container and carton labels for the autoinjector 1-pack.

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.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the container labeling submitted on August 14, 2023, and to the carton labeling submitted on September 1, 2023, for the sample autoinjector 1-pack, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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 "**Final Printed Carton and Container Labeling for approved BLA 125521/S-028**." Approval of this submission by FDA is not required before the labeling is used.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-*

Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.[1]

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[2] Information and Instructions for completing the form can be found at FDA.gov.[3]

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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, call H. F. Van Horn III, PharmD, MBA, 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: Sample Autoinjector 1-pack Carton and
Sample Autoinjector 1-pack Container Labeling

[1] For the most recent version of a guidance, check the FDA guidance web page athttps://www.fda.gov/media/128163/download.
[2] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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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