BLA 761118/S-012

**SUPPLEMENT APPROVAL**

Pfizer Inc.
Attention: Bindhu Bhargavi
Manager Global Regulatory Sciences
1 Burrt Road
Andover, MA 01810

Dear Bindhu Bhargavi:

Please refer to your supplemental biologics license application (sBLA) dated and received October 31, 2023, and your amendment, submitted under section 351(k) of the Public Health Service Act for Abrilada (adalimumab-afzb).

This Prior Approval supplemental biologics license application provides to update the label with the latex statement for the prefilled syringe (PFS) and prefilled pen (PFP).

## APPROVAL & LABELING

We have completed our review of this sBLA, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling and with minor editorial revisions reflected in the enclosed 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to, except with the revisions indicated, the enclosed labeling (text for the perscribing information, text for the patient package insert, 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 *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 Microsoft Word format that includes the changes approved in this

supplemental application, as well as annual reportable changes. 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).

## CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and container labels and submitted carton and container labels, except with the revisions listed above, 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 "**Final Printed Carton and Container Labels for approved BLA 761118/S-012.**" Approval of this submission by FDA is not required before the labeling is used.

## REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## 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).

If you have any questions, contact Kristine Leahy, RPh., Senior Regulatory Business Process Manager, at (240) 402 – 5834, or Kristine.Leahy@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Rapti Madurawe, Ph.D.
Director
Division of Product Quality Assessment
XVI Office of Product Quality Assessment
III Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

**U.S. Food & Drug Administration**
**Silver Spring, MD 20993**
**www.fda.gov**

Content of Labeling
Carton and Container Labeling

Appears This Way on Original

Rapti Madurawe

Digitally signed by Rapti Madurawe
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