



BLA 761024/S-004

SUPPLEMENT APPROVAL

Amgen Inc.
One Amgen Center Drive
Mail Stop 28-2-D
Thousand Oaks, CA 91320-1799

Attention: Augustus Kamassah, MS, RAC
Senior Manager, Global Biosimilars Regulatory Affairs

Dear Mr. Kamassah:

Please refer to your supplemental biologics license application (sBLA), dated December 14, 2018, received December 14, 2018, and your amendments, submitted under section 351(k) of the Public Health Service Act for Amjevita (adalimumab-atto) Injection.

This Prior Approval supplemental biologics application proposes revisions to Sections 8.1 and 8.2, Pregnancy and Lactation, of the Package Insert (PI) and updates on the pregnancy and lactation information in the Medication Guide (MG) to incorporate relevant information from the labeling for US-licensed Humira approved on December 6, 2018.

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.

WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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,

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Patient Package Insert, and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effectuated” (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*.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 Effectuated” (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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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).

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 Sadaf Nabavian, Senior Regulatory Project Manager, at (301) 796-2777.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD

Acting Director

Division of Pulmonary, Allergy, and

Rheumatology Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Medication Guide

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/

NIKOLAY P NIKOLOV

06/13/2019 04:42:47 PM

Signed under the authority delegated by Dr. Sally Seymour, Acting Division Director,
DPARP.