BLA 761219/S-001

SUPPLEMENT APPROVAL

Celltrion, Inc.
c/o Parexel International
2520 Meridian Parkway, Suite 200
Durham, NC 27713

Attention: Laya Keyvan, MS, MBA
Senior Consultant

Dear Laya Keyvan:

Please refer to your supplemental biologics license application (sBLA) dated and received May 30, 2023, and your amendments, submitted under section 351(k) of the Public Health Service Act for Yuflyma (adalimumab-aaty) injection.

This Prior Approval sBLA provides changes to Yuflyma (adalimumab-aaty) for:

1. Introduction of Yuflyma (adalimumab-aaty) injection for subcutaneous use 80 mg/0.8 mL as biosimilar to its reference product, US-licensed Humira (adalimumab) injection for subcutaneous use 80 mg/0.8 mL, and Yuflyma (adalimumab-aaty) injection for subcutaneous use 20 mg/0.2 mL as biosimilar to its reference product, US-licensed Humira (adalimumab) injection for subcutaneous use 20 mg/0.2 mL. Yuflyma (adalimumab-aaty) injection for subcutaneous use 80 mg/0.8 mL is available in prefilled auto-injector, prefilled syringe with safety guard, and prefilled syringe presentations; and Yuflyma (adalimumab-aaty) injection for subcutaneous use 20 mg/0.2 mL is available in a prefilled syringe presentation
2. Introduction of Starter Packages
3. Introduction of Celltrion Pharm, Inc., Cheongju-si, Republic of Korea (FEI: 3012279978) as an alternative commercial manufacturing, secondary packaging/final assembly, and QC testing site for CT-P17 40 mg/0.4 mL Drug Product
4. Change of the in-use shelf-life of the finished product of CT-P17 40 mg/0.4 mL from 30 days to 31 days
5. Change in the corporate name of (b) (4)

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, Instructions for Use, 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*.[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, 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 LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted September 14 and 27 (starter packages), 2023, 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 "**Product Correspondence – Final Printed Carton and Container Labeling for approved BLA 761219/ S-001**." Approval of this submission by FDA is not required before the labeling is used.

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

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.

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

If you have any questions, call Sadaf Nabavian, Sr. Regulatory Project Manager, at 301-796-2777.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, MD, MPH
Deputy Director
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
- Prescribing Information
- Medication Guide
- Instructions for Use

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/

OZLEM A BELEN
09/29/2023 04:20:26 PM