BLA 761219/S-016

SUPPLEMENT APPROVAL

Celltrion, Inc.
c/o Paraxel International
Attention: Laya Keyvan, MS, MBA
Senior Consultant
2520 Meridian Parkway, Suite 100
Durham, NC 27713

Dear Laya Keyvan:

Please refer to your supplemental biologics license application (sBLA) received November 21, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Yuflyma (adalimumab-aaty) injection.

This Prior Approval supplemental biologics application provides for:

- Yuflyma (adalimumab-aaty) 40 mg/0.4 mL injection for subcutaneous use in a prefilled autoinjector as interchangeable with US-Humira (adalimumab) 40 mg/0.4 mL injection for subcutaneous use in a prefilled pen, and
- Yuflyma (adalimumab-aaty) 80 mg/0.8 mL injection for subcutaneous use in a prefilled autoinjector as interchangeable with US-Humira (adalimumab) 80 mg/0.8 mL injection for subcutaneous use in a prefilled pen.

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, and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements.

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

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(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.

At this time, no pediatric assessments will be required under PREA for this sBLA. We remind you that postmarketing requirement 4433-1 listed in the May 23, 2023, approval letter is still open.

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, contact Jacquelyn Rosenberger, Regulatory Project Manager, at 301-796-9179 or jacquelyn.rosenberger@fda.hhs.gov.

[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.

Sincerely,

{See appended electronic signature page}

Raj Nair, MD
Director
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Branded Product Labeling
    - Prescribing Information
    - Medication Guide
    - Instructions for Use
  - Unbranded Biological Product 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/

RAJ NAIR
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