BLA 761219/S-006, S-007, S-008

SUPPLEMENTS APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Celltrion, Inc.
c/o Parexel International
Attention: Laya Keyvan, MS, MBA
Senior Regulatory Affairs Consultant
2520 Meridian Parkway Suite 200
Durham NC 27713

Dear Laya Keyvan:

Please refer to your supplemental biologics license applications (sBLA), dated and received June 30, 2023 (S-006), November 21, 2023, (S-007), December 6, 2023, (S-008), and your amendments, submitted under section 351(k) of the Public Health Service Act for YUFLYMA (adalimumab-aaty) injection.

Supplement 006 - This Category D Prior Approval supplemental biologics license application provides for the inclusion of treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

Supplement 007 - This Changes Being Effected supplemental biologics application provides for change of National Drug Code (NDC) for YUFLYMA 80 mg/0.8 mL and 40 mg/0.4 mL PFS-S Starter Package.

Supplement 008 - This Changes Being Effected supplemental biologics application provides for change of National Drug Code (NDC) for YUFLYMA 80 mg/0.8 mL and 40 mg/0.4 mL AI Starter Package.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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, 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*

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

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)

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on November 21, 2023 (S-007), and December 06, 2023 (S-008), 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 761219/S-007 and BLA 761219/S-008**." 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 (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, we have determined that, with respect to uveitis (UV) in pediatric patients 0 to <2 years of age, no pediatric studies will be required under PREA for your BLA. You have provided a pediatric assessment for UV in pediatric patients 2 to 17 years of age, and nothing further is required at this time.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated August 18, 2023, containing the final reports for the following post marketing requirements listed in the May 23, 2023, approval letter for BLA 761219.

4433-2 Assessment of YUFLYMA (adalimumab-aaty) for the treatment of pediatric hidradenitis suppurativa (HS) in patients 12 years to 17 years of age.

4433-3 Assessment of YUFLYMA (adalimumab-aaty) for the treatment of pediatric ulcerative colitis (UC) in patients 5 years to 17 years of age.

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that there is a post marketing requirement 4433-1 listed in the May 23, 2023, approval letter that is still open.

[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.

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.*[3]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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 post marketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product post marketing safety reporting is available at FDA.gov.

If you have any questions, please contact Ahmed Ayodeji, PharmD, 301-837-7390.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Director
Division of Ophthalmology
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

[3] For the most recent version of a guidance, check the FDA guidance web page athttps://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] 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/

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