BLA 761088/S-035

SUPPLEMENT APPROVAL

Celltrion Inc.
c/o Parexel International
Attention: Laya Keyvan
Senior Consultant
541 Church at North Hills Street, Suite 1000
Raleigh, NC 27609

Dear Ms. Keyvan:

Please refer to your supplemental biologics license application (sBLA) received August 29, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Truxima (rituximab-abbs).

This Category F Prior Approval sBLA provides for:

- Truxima 100 mg/10 mL (10 mg/mL), injection, in a single-dose vial for intravenous use as interchangeable with US-licensed Rituxan 100 mg/10 mL, injection, in a single-dose vial for intravenous use

- Truxima 500 mg/50 mL (10 mg/mL) injection, in a single-dose vial for intravenous use as interchangeable with US-licensed Rituxan 500 mg/50 mL, injection, in a single dose vial for intravenous use

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.

FIRST INTERCHANGEABLE EXCLUSIVITY

Section 351(k)(6) of the PHS Act provides:

> The Secretary shall not make approval as an interchangeable biological product effective with respect to an application submitted under this subsection that relies on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)

(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term “final court decision” means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken and the term “first interchangeable biosimilar biological product” means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product.

FDA has determined that the following products qualify as first interchangeable biosimilar biological products for purposes of section 351(k)(6) of the PHS Act:

- Truxima (rituximab-abbs) injection, 100 mg/10 mL (10 mg/mL) for intravenous use in a single-dose vial
- Truxima (rituximab-abbs) injection, 500 mg/50 mL (10 mg/mL) for intravenous use in a single-dose vial

The expiration date of any first interchangeable exclusivity for these products has yet to be determined.

Please submit a general correspondence to this 351(k) BLA within 30 days of this approval informing the Agency of **any action implicating this BLA instituted under section 351(l)(6) of the PHS Act**. If no action implicating this BLA has been instituted under section 351(l)(6), please inform the Agency accordingly within 30 days of this

approval. If an action implicating this BLA has been instituted under section 351(l)(6), then inform the Agency of the date of any final court decision (as defined in section 351(k)(6) of the PHS Act) on all patents in suit in any action implicating this BLA instituted under section 351(l)(6) of the PHS Act, or the date of dismissal with or without prejudice of any action implicating this BLA instituted under section 351(l)(6), within 30 days of such date or within 30 days of this approval if such date occurred prior to approval. If any action implicating this BLA instituted under section 351(l)(6) is still ongoing at the time of this approval, submit a general correspondence informing the Agency accordingly within 30 days of this approval. Submit a duplicate copy of the correspondence(s) via email to PurpleBook@fda.hhs.gov.

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 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 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

[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.

the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

At this time, we have determined that no pediatric studies will be required under PREA for this supplemental BLA. We remind you that postmarketing requirement 3772-1 listed in the December 18, 2019, approval letter for Truxima (rituximab-abbs) under BLA 761088/S-006 is still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

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).

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, contact Megan Sybeldon, Regulatory Project Manager, at 240-402-4730 or Megan.Sybeldon@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Bindu Kanapuru, MD
Director (Acting)
Division of Hematologic Malignancies II
Office of Oncologic Diseases
Office of New Drugs
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/

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