



BLA 761376

BLA APPROVAL

Dr. Reddy's Laboratories SA
c/o PAREXEL International
Attention: Ally Danta
U.S. Agent, Regulatory Affairs Consultant
541 Church at North Hills St., Suite 1000
Raleigh, NC 27609

Dear Ms. Danta:

Please refer to your biologics license application (BLA) received April 20, 2023, and your amendments, submitted under section 351(k) of the Public Health Service Act for Zimrixby (rituximab-cdxx) injection.

We acknowledge receipt of your resubmission dated February 2, 2026, which constituted a complete response to our October 16, 2025, action letter.

This BLA seeks licensure of:

- Zimrixby (rituximab-cdxx) 100 mg/10 mL (10 mg/mL) injection for intravenous use in a single-dose vial as biosimilar to US-Rituxan (rituximab) 100 mg/10 mL (10 mg/mL) injection for intravenous use in a single-dose vial, and
- Zimrixby (rituximab-cdxx) 500 mg/50 mL (10 mg/mL) injection for intravenous use in a single-dose vial as biosimilar to US-Ritxuan (rituximab) 500 mg/50 mL (10 mg/mL) injection for intravenous use in a single-dose vial.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2320 to Dr. Reddy's Laboratories SA, Basel, Switzerland, under the provisions of section 351(k) of the Public Health Service Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product Zimrixby (rituximab-cdxx). Zimrixby is indicated for the treatment of:

- Adult patients with Non-Hodgkin's Lymphoma (NHL)
 - Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent.

- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy.
- Non-progressing (including stable disease), low-grade, CD20positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens.
- Adult patients with Chronic Lymphocytic Leukemia (CLL).
 - Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide.
- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies.
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture rituximab-cdxx at Dr. Reddy's Laboratories, Ltd, Biologics (FEI 3014250111) in Hyderabad, Telangana, India. You may label your product with the proprietary name, Zimrixby, and market it in 100mg/10 mL and 500 mg/50mL solution in single-dose vials.

DATING PERIOD

The dating period for Zimrixby shall be 36 months from the date of manufacture when stored at 2°C to 8°C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be (b) (4) months from the date of manufacture when stored at (b) (4)

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Zimrixby to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Zimrixby, or in the manufacturing facilities, will require the submission of information to your BLA for our review and written approval, consistent with 21 CFR 601.12.

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.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide). 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.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling submitted on July 24, 2026, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to 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 761376**” 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.

¹ See <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 at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

- **Treatment of adult patients with Non-Hodgkin's Lymphoma (NHL),**
At this time, we have determined that no pediatric studies will be required under PREA for your BLA.
- **Treatment of adult patients with Chronic Lymphocytic Leukemia (CLL),**
At this time, we have determined that no pediatric studies will be required under PREA for your BLA.
- **Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies.**
At this time, we have determined that no pediatric studies will be required under PREA for your BLA.
- **Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)**
At this time, we have determined that, with respect with GPA/MPA 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 GPA/MPA in pediatric patients 2 years and older, and nothing is further required at this time.

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

You must submit adverse experience reports under the adverse experience reporting requirements at 21 CFR 600.80.

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements at 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>

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

If you have any questions, contact Denise Felluca, Regulatory Project Manager, at denise.felluca@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

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Medication Guide
- Carton and Container Labeling

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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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