Our STN: BL 125753/0

BLA APPROVAL
January 8, 2025

Immucor, Inc.
Attention: Howard Yorek
3130 Gateway Drive
Norcross, GA 30071

Dear Howard Yorek:

Please refer to your Biologics License Application (BLA) received June 14, 2021, submitted under section 351(a) of the Public Health Service Act (PHS Act) for Anti-Human Globulin (Murine Monoclonal).

LICENSING

We have approved your BLA for Anti-Human Globulin (Murine Monoclonal) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Anti-Human Globulin (Murine Monoclonal) under your existing Department of Health and Human Services U.S. License No. 0886. Anti-Human Globulin (Murine Monoclonal) is indicated for use on Echo Lumena and Galileo Echo in automated direct antiglobulin tests (DAT) where detection of C3d is required.

MANUFACTURING LOCATION

Under this license, you are approved to manufacture Anti-Human Globulin (Murine Monoclonal) at your facility located at 3130 Gateway Drive, Norcross, GA. You may label your product with the proprietary name Automated C3d Plate and market it as approved in your license application.

ADVISORY COMMITTEE

We did not refer your application to the Blood Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for Anti-Human Globulin (Murine Monoclonal) shall be 12 months from the date of manufacture when stored at 1-30 °C. The date of manufacture shall be defined as the first day of the Automated C3d Plate production on the (b) (4) instrument.

FDA LOT RELEASE

You are not currently required to submit samples but are required to submit protocols of future lots of Anti-Human Globulin (Murine Monoclonal) to the Center for Biologics Evaluation and Research (CBER) for release by the Director, CBER, under 21 CFR 610.2(a). 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.

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, 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 the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations :

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging, or labeling of Anti-Human Globulin (Murine Monoclonal), or in the manufacturing facilities.

LABELING

We hereby approve the draft package insert labeling submitted under amendment # 31, dated December 16, 2024, and the draft container labeling originally submitted on June 10, 2021. This is a reminder that as of September 24, 2014, medical devices that are licensed under the PHS Act are subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18 and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device, and the device identifiers that have been discontinued for the subject device as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website at http://www.fda.gov/udi.

Please submit all final printed labeling as a PDF electronic copy (eCopy) at the time of use and include implementation information on Form FDA 356h as appropriate.

Two draft copies of the proposed introductory advertising or promotional labeling may be voluntarily submitted for advisory comment with a completed Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the Medical Device Reporting (MDR) requirements for medical devices (21 CFR 803) as required by 21 CFR 600.80(m)(2). Since your product is characterized as a device as well as a biologic, submit these reports, listing device product code KSF, to the MedWatch System using MedWatch Reporting Form 3500A or an electronic equivalent. Please refer to the *Questions and Answers about eMDR – Electronic Medical Device Reporting – Guidance for Industry, User Facilities and FDA Staff* at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm.

Required reports are to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR Policy Branch
10903 New Hampshire Avenue
WO66-3217
Silver Spring, MD 20993-0002

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Anne Eder, MD, PhD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research