



Our STN: BL 125716/0

**BLA APPROVAL**  
**June 18, 2020**

Millipore (UK) Ltd.  
Attention: Benjamin Kimball, JD  
EMD Millipore Corporation  
6600 Sierra College Blvd  
Rocklin, CA 95677

Dear Mr. Kimball:

Please refer to your Biologics License Application (BLA) submitted and received August 29, 2019, under section 351(a) of the Public Health Service Act (PHS Act) for Blood Grouping Reagent, Anti-Le<sup>b</sup> (Murine Monoclonal)(For Further Manufacturing Use) (FFMU) manufactured from cell line (b) (4).

## **LICENSING**

We have approved your BLA for Blood Grouping Reagent, Anti-Le<sup>b</sup> (Murine Monoclonal)(FFMU) effective this date. Millipore (UK) Ltd. is hereby authorized to introduce or deliver for introduction into interstate commerce, Blood Grouping Reagent, Anti-Le<sup>b</sup> (Murine Monoclonal)(FFMU) under their existing Department of Health and Human Services U.S. License No. 1761. The Blood Grouping Reagent, Anti-Le<sup>b</sup> (Murine Monoclonal)(FFMU) is used by (b) (4) for the manufacture of the final product, Blood Grouping Reagent, Anti-Le<sup>b</sup> (Murine Monoclonal), (b) (4) under a shared manufacturing arrangement.

## **MANUFACTURING LOCATIONS**

Under this license, you are approved to manufacture Blood Grouping Reagent, Anti-Le<sup>b</sup> (Murine Monoclonal)(FFMU), at your facility located at (b) (4) and ship to (b) (4) under a shared manufacturing arrangement.

## **ADVISORY COMMITTEE**

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

## DATING PERIOD

The dating period for Blood Grouping Reagent, Anti-Le<sup>b</sup> (Murine Monoclonal)(FFMU) shall be (b) (4) from the date of manufacture when stored at (b) (4). The date of manufacture shall be defined as the date when the (b) (4) final containers.

## 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.

In response to the COVID-19 public health emergency, CBER's Document Control Center (DCC) will not process any submission received by mail or courier including submissions provided on paper and electronic media (e.g., CDs, USB) after Wednesday, April 29, 2020 until further notice. Device submissions, for CBER regulated devices, can still be submitted electronically using the Electronic Submissions Gateway (ESG) (under 10GB) or in some cases via email (under 150MB) in accordance with final industry guidance, eCOPY Program for Medical Devices Submissions found at <https://www.fda.gov/media/83522/download>. CBER strongly encourages sending submissions through the ESG, FDA's preferred secure method of transmission. Instructions for setting up an ESG account can be found at <https://www.fda.gov/industry/electronic-submissions-gateway>.

Submissions regarding this file may also be submitted electronically via email at [CBERDCC\\_eMailSub@fda.hhs.gov](mailto:CBERDCC_eMailSub@fda.hhs.gov). We will accept submissions through this email option only during the COVID-19 public health emergency. For additional information regarding CBER operations during this public health emergency, please see the CBER COVID -19 CBER Regulated Biologics page found at <https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics>.

**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 Blood Grouping Reagent, Anti-Le<sup>b</sup> (Murine Monoclonal) (FFMU), or in the manufacturing facilities.

Sincerely,

Nicole Verdun, MD  
Director  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research