Our STN: BL 125684/0

BLA APPROVAL
April 18, 2019

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

Dear Mr. Kimball:

Please refer to your Biologics License Application (BLA) submitted June 4, 2018, received June 27, 2018, under section 351(a) of the Public Health Service Act (PHS Act) for Blood Grouping Reagent, Anti-k (Monoclonal) (IgG) (For Further Manufacturing Use) manufactured from cell line (b) (4) .

LICENSING

We have approved your BLA for Blood Grouping Reagent, Anti-k (Monoclonal) (IgG) (For Further Manufacturing Use) effective this date. Millipore (UK) Ltd. is hereby authorized to introduce or deliver for introduction into interstate commerce, Blood Grouping Reagent, Anti-k (Monoclonal) (IgG) (FFMU) under their existing Department of Health and Human Services U.S. License No. 1761. The Blood Grouping Reagent, Anti-k (Monoclonal) (IgG) (FFMU) is to be used by (b) (4) for the manufacture of (b) (4) , under a shared manufacturing arrangement.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Blood Grouping Reagent, Anti-k (Monoclonal) (IgG) (For Further Manufacturing Use) at your facility located at (b) (4) for shipment to (b) (4)

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-k (Monoclonal) (IgG) (For Further Manufacturing Use) shall be (b) (4) from the date of manufacture when stored at (b) (4) The date of manufacture shall be defined as the date the (b) (4) the 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, 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

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 the Blood Grouping Reagent, Anti-k (Monoclonal) (IgG) (For Further Manufacturing Use), or in the manufacturing facilities.

Required reports are to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR Policy Branch
10903 New Hampshire Avenue
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Sincerely,

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