Our STN: BL 125680/0

BLA APPROVAL
August 12, 2019

Diagast
Attention: Ms. Sonia Lecce
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Dear Ms. Lecce:

Please refer to your Biologics License Application (BLA) submitted June 4, 2018, and received June 5, 2018, under section 351(a) of the Public Health Service Act (PHS Act) for Blood Grouping Reagent, Anti-A (Murine Monoclonal) (For Further Manufacturing Use).

LICENSING

We have approved your BLA for Blood Grouping Reagent, Anti-A (Murine Monoclonal) (For Further Manufacturing Use) manufactured from the cell line 16427E6, effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Blood Grouping Reagent, Anti-A (Murine Monoclonal) (For Further Manufacturing Use)under your existing Department of Health and Human Services U.S. License No. 1744. The Blood Grouping Reagent, Anti-A (Murine Monoclonal) (For Further Manufacturing Use) is to be utilized by Diagnostic Grifols, S.A. in the manufacture of the final product, Blood Grouping Reagent, Anti-A (Murine Monoclonal), under a shared manufacturing agreement.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Blood Grouping Reagent, Anti-A (Murine Monoclonal) (For Further Manufacturing Use) at your facility located at LOOS, France for shipment to Diagnostic Grifols S.A., Spain.

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 Blood Grouping Reagent, Anti-A (Murine Monoclonal) (For Further Manufacturing Use) shall be (b) (4) from the date of manufacture of the corresponding lot of (b) (4) when stored at (b) (4). The date of manufacture shall be defined as the date of (b) (4) .

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

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(k)(2). Since your product is characterized as a device as well as a biologic, submit these reports 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
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Sincerely,

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