Our STN: BL 125449/44

SUPPLEMENT APPROVAL
August 12, 2019

Diagnostic Grifols, S.A.
Attention: Mr. Joaquín Alberto Tamparillas
Medion Grifols Diagnostics AG
Avda. de la Gerneralitat, 152
Sant Cugat del Valles
Barcelona 08174
Spain

Dear Mr. Alberto Tamparillas:

We have approved your request submitted December 15, 2017, and received December 26, 2017, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Blood Grouping Reagent, Anti-A (Murine Monoclonal). This request is to change the For Further Manufacturing Use (FFMU) antibody solution used to manufacture your Anti-A Blood Grouping Reagent from FFMU antibody solution, clone DAM-1, supplied by (b) (4) , to FFMU antibody solutions, clones 16243G2 and 16247E6, supplied by Diagast and manufactured at its LOOS, France facility.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 10, dated July 15, 2019. 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 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

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research