Our STN: BL 125176/38

SUPPLEMENT APPROVAL
May 7, 2020

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

Dear Ms. Lecce:

We have approved your request submitted January 24, 2019, received February 21, 2019, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Blood Grouping reagent, Anti-e (Monoclonal) (Formulated for Automated Testing) intended for the Beckman Coulter Automated System PK7400, product code QHR. The change includes a new Anti-e Blood Grouping Reagent prepared from cell line P3GD512 manufactured by DIAGAST, and cell lines MS63, MS16, and MS21, supplied and manufactured by Millipore UK Ltd, located in Livingston, United Kingdom. The final Anti-e Blood Grouping Reagent formulated from the four cell lines will be manufactured by DIAGAST located at Loos, France.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 13, dated March 24, 2020. 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

During the COVID-19 pandemic, through June 1, 2020, but may be extended, we are unable to receive mail. Please submit via email to CBERDCC_eMailSub@fda.hhs.gov.

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