Our STN: BL 103898/5097

SUPPLEMENT APPROVAL
June 30, 2021

Medion Grifols Diagnostics AG
Attention: Mr. Joaquín Alberto Tamparillas
Bonnstrasse 9
3186 Düedingen, Fribourg
Switzerland

Dear Mr. Alberto Tamparillas:

We have approved your request submitted May 19, 2021, received May 24, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Reagent Red Blood Cells, Product Code QHT, to increase the number of 10 mL vials included in the final product packaging from 1 to 3 and the labeling changes to the Specimen Collection and Preparation section of the Instructions for Use.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 5000, dated June 17, 2021, and the draft carton and container labeling submitted May 20, 2021. 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.

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), 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. 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.

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