Our STN: BL 125705

BLA APPROVAL
May 20, 2022

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

Dear Joaquín Alberto Tamparillas:

Please refer to your Biologics License Application (BLA) received May 6, 2019, submitted under section 351(a) of the Public Health Service Act (PHS Act) for Anti-Human Globulin (Rabbit/Murine Monoclonal).

LICENSING

We have approved your BLA for Anti-Human Globulin (Rabbit/Murine Monoclonal) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Anti-Human Globulin (Rabbit/Murine Monoclonal) under your existing Department of Health and Human Services U.S. License No. 1887. Anti-Human Globulin (Rabbit/Murine Monoclonal) is indicated for use with the DG Gel System to detect in vivo coating of human red blood cells with IgG and C3d (direct antiglobulin test).

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Anti-Human Globulin (Rabbit/Murine Monoclonal) at your facility located at Parets del Valles, Barcelona, Spain. You may label your product with the proprietary name DG Gel 8 Direct Coombs (Anti-IgG, -C3d) and will market it as approved in your license application.

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 Anti-Human Globulin (Rabbit/Murine Monoclonal) shall be 25 months from the date of manufacture when stored at 2 - 8 °C. The date of manufacture shall be defined as the date when gel is manufacturered.

FDA LOT RELEASE

You are not currently required to submit samples but are required to submit the protocols showing results of applicable tests of future lots of Anti-Human Globulin (Rabbit/Murine Monoclonal) to the Center for Biologics Evaluation and Research (CBER) for release by the Director, CBER, under 21 CFR 610.2(a). We will continue to monitor compliance with 21 CFR 610.1 requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

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, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations :

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 note:
In response to the COVID-19 public health emergency, CBER's Document Control Center (DCC) does not have staff on site to accept packages. Device submissions for CBER regulated devices may still be submitted electronically using the Electronic Submissions Gateway (ESG) (under 10GB) 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 may also be submitted electronically via email (under 150MB) 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.

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 Anti-Human Globulin (Rabbit/Murine Monoclonal), or in the manufacturing facilities.

Please note: The change in the (b) (4) used to manufacture DG Gel 8 cards which was submitted as an unsolicited amendment dated May 3, 2022 , is **not** a part of this approval. You must submit a supplement to this BLA in order to implement the change in the (b) (4) used to manufacture DG Gel 8 cards.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 13, dated November 15, 2021, and the draft carton and container labeling originally submitted, dated May 6, 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 a 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 via DCC as described above.

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the Medical Device Reporting (MDR) requirements for medical devices (21 CFR 803). Submit these reports, listing device product code QHS, 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
WO66-3217
Silver Spring, MD 20993-0002

Sincerely,

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