



October 21, 2016
BLA APPROVAL

Our STN: BL 125529/0

Bio-Rad Medical Diagnostics GmbH
Attention: Dr. Rolf Vornhagen
Industriestrasse 1
D-63303 Dreieich
Germany

Dear Dr. Vornhagen:

Please refer to your Biologics License Application (BLA) for Anti-Human Globulin (Rabbit/Murine Monoclonal) (Formulated for Automated Testing) dated February 27, 2014, received March 7, 2014, submitted under section 351(a) of the Public Health Service Act (PHS Act).

We have approved your BLA for Anti-Human Globulin (Rabbit/Murine Monoclonal) (Formulated for Automated Testing) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Anti-Human Globulin (Rabbit/Murine Monoclonal) (Formulated for Automated Testing) under your existing Department of Health and Human Services U.S. License No. 1845. The Anti-Human Globulin (Rabbit/Murine Monoclonal) (Formulated for Automated Testing) is indicated for use in IH-Cards AHG Anti-IgG,-C3d product. The intended use of the IH-Cards AHG Anti-IgG,-C3d product is detection of antibodies and complement on human red blood cells using Direct and Indirect Antiglobulin Tests on the IH Analyzer System.

Under this license, you are approved to manufacture Anti-Human Globulin (Rabbit/Murine Monoclonal) (Formulated for Automated Testing) at your facility located at Dreieich, Germany. You may label your product with the proprietary name IH-Card AHG Anti-IgG,-C3d and market it as approved in your license application.

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) (Formulated for Automated Testing) contained in the IH-Cards AHG Anti-IgG,-C3d shall be 16 months from the date of manufacture when stored at 18 to 25°C.

The date of manufacture shall be defined as the date when the gel bulk is filled into the cards. Following the final sterile filtration, no reprocessing/reworking is allowed without prior approval from the Agency.

FDA LOT RELEASE

Please submit the lot release protocols for the product showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

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 including but not limited to, the manufacturing, testing, packaging or labeling of Anti-Human Globulin (Rabbit/Murine Monoclonal) (Formulated for Automated Testing) or in the manufacturing facilities.

LABELING

We hereby approve the draft package insert labeling submitted under amendment #27, dated June 27, 2016, and the draft carton and container labeling submitted under amendment #29, dated August 26, 2016. 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, <http://www.fda.gov/udi>.

Please submit all final printed labeling at the time of use and include implementation information on Form FDA 356h as appropriate. Please provide a PDF electronic copy (eCopy) as well as two original paper copies for circulars and other labels.

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

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). Because 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 February 2014 document *Questions and Answers about eMDR – Electronic Medical Device Reporting – Guidance for Industry, User Facilities and FDA Staff* at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/UCM2019327.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 yours,

Jay S. Epstein, MD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research