SUPPLEMENT APPROVAL
April 24, 2019

American National Red Cross
Attention: Mr. J. Scott Webber
431 18th Street, Northwest
Washington, DC 20006

Dear Mr. Webber:

We have approved your requests submitted March 12, 2019, received March 13, 2019, to supplement your Biologics License Applications (BLA) submitted under section 351(a) of the Public Health Service Act to revise the limitation statements, in the package inserts for the following products:

STN	Name of Biological Products
BL 101728/5020*	Blood Grouping Reagent, Anti-Fy[a]
BL 101729/5021	Blood Grouping Reagent, Anti-k
BL 101730/5021	Blood Grouping Reagent, Anti-Kp[a]
BL 101731/5021	Blood Grouping Reagent, Anti-Kp[b]
BL 101732/5020	Blood Grouping Reagent, Anti-M
BL 101733/5022	Blood Grouping Reagent, Anti-s
BL 101734/5021	Blood Grouping Reagent, Anti-S
BL 103292/5021	Blood Grouping Reagent, Anti-K

LABELING

We hereby approve the draft package inserts labeling submitted March 13, 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 devices, and the device identifiers that have been discontinued for the subject devices 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

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

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