SUPPLEMENT APPROVAL
August 7, 2025

Immucor, Inc.
Attention: Howard Yorek
3130 Gateway Drive
Norcross, GA 30071

Dear Howard Yorek:

We have approved your requests received June 27, 2025, to supplement your Biologics License Applications (BLAs) submitted under section 351(a) of the Public Health Service Act to add the following limitations to the Instructions for Use for the following products:

- User is responsible for validating the use of the products in methods other than the manual tube method described in the insert.

- Weak or variant expression of the D antigen may result in weak or negative reactivity with Anti-D reagents.

STN	Name of Biological Product
BL 102707/5112*	Reagent Red Blood Cells
BL 103523/5066	Blood Grouping Reagent, Anti-D (Monoclonal Blend)

*Primary STN

LABELING

We hereby approve the draft package insert labeling submitted June 27, 2025. 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

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

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

Sincerely,

Wendy Paul, MD
Acting Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research