SUPPLEMENT APPROVAL
June 16, 2017

Alba Bioscience Limited
Attention: Mr. Robert Dorris
21 Ellens Glen road
Edinburgh, Medlothian EH17 7QT
United Kingdom

Dear Mr. Dorris:

We have approved your request dated July 31, 2014, to supplement your Biologics License Applications for the Blood Grouping Reagents (BGRs) listed below to be used with the Ortho ID-Micro Typing System™ (MTS)™ Gel Card for the qualitative detection of the RhD, Le^a, Le^b, and N antigens on human red blood cells by direct agglutination or indirect antiglobulin test. These BGRs will be distributed by Ortho-Clinical Diagnostics (Raritan, NJ) under the trade name ORTHO™ Sera.

STN	Name of Biological Products
BL 125304/35	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM)
BL 125309/30	Blood Grouping Reagent, Anti-N (Murine Monoclonal)(IgG)
BL 125310/30	Blood Grouping Reagent, Anti-Le^a (Murine Monoclonal)
BL 125311/29	Blood Grouping Reagent, Anti-Le^b (Murine Monoclonal)
BL 125314/34	Blood Grouping Reagent, Anti-D (Monoclonal Blend)

We hereby approve the draft package insert labeling submitted under amendment 16, dated June 2, 2016, and the draft carton and container labeling submitted under amendment 11, 13, dated July 30, 2015 and Dec 16, 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.

We will include information contained in the above-referenced supplement in your biologics license application files.

Sincerely,

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