



March 13, 2017
SUPPLEMENT APPROVAL

Our STN: BL 125342/15

Alba Bioscience Limited
Attention: Mr. Robert Dorris
21 Ellen's Glen road
Edinburgh EH17 7QT
United Kingdom

Dear Mr. Dorris:

We have approved your request dated Sept 1, 2014, to supplement your biologics license application, submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262), for Blood Grouping Reagent Anti-Fy^b to be used with the Ortho ID-Micro Typing System.™ The Anti-Fy^b product will be distributed by Ortho-Clinical Diagnostics (Raritan, NJ) under the trade name ORTHO™ Sera.

We hereby approve the draft package insert labeling submitted under amendment 20, dated March 7, 2017, and the draft carton and container labeling submitted under amendment 18, dated Feb 8, 2017.

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

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

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

Sincerely yours,

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