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To: Users of Circular of Information

From: Margaret Hannan mh
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Date: March 30, 2022

Subject: Revised Circular of Information

On March 22, 2022 FDA issued guidance formally recognizing the December 2021 Circular of Information for the Use of Human Blood and Blood Components (Circular) as an "extension of labeling," which provides specific instructions for the administration and use of blood and blood components intended for transfusion as required in 21 CFR 606.122; this Circular replaces the October 2017 version.

Below is a change to the December 2021 FDA-Approved Circular of Information:

**ZIKV Testing – Effective August 11, 2021**

Guidance for Industry: Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components was withdrawn by FDA on May 12, 2021. Accordingly, references to Zika testing are not included in the December 2021 Circular.

BBD discontinued Zika testing on August 11, 2021, however components that were tested for Zika remain in inventory. To meet FDA requirements, the following change to the December 2021 Circular applies:

**CIRCULAR CHANGES – Section:** Required Testing of Blood Donations

***"Blood components collected between November 13, 2017 and August 11, 2021 were tested with a licensed nucleic acid test (NAT) for Zika Virus RNA and found to be nonreactive."***

**BLOOD UNIT LABELING –** No changes. Units tested for Zika are labeled with the following statement:

***A licensed nucleic acid test (NAT) for Zika virus RNA has been performed and found to be nonreactive.***