Carter BloodCare

To:Carter BloodCare CustomersFrom:Hospital Relations DepartmentDate:October 29, 2024

Re: Updated Circular of Information

On September 25, 2024, the FDA issued guidance formally recognizing the June 2024 Circular of information as an extension of labeling which provided specific instructions for the administration and use of blood and blood components intended for transfusion as required in 21 CFR 606.122. This guidance replaces the previous December 2021 edition.

Please find attached the updated electronic version of the Circular of Information. Hard copies are also available through the distribution department.

New in this version:

 RED BLOOD CELLS, ADENINE SALINE ADDED, LEUKOCYTES REDUCED, O₂/CO₂ REDUCED

Revised in this version:

- The Cryoprecipitated Antihemophilic Factor and Plasma Cryoprecipitate Reduced sections were revised to reflect that:
 - Cryoprecipitated Antihemophilic Factor (AHF) is prepared by thawing frozen whole-blood-derived or apheresis plasma between 1 and 6 C and recovering the precipitate.
 - "plasma cryoprecipitate reduced is prepared from whole-blood-derived or apheresis-collected plasma after thawing and centrifugation and removal of the cryoprecipitate"

Additionally, the electronic version can be accessed and viewed at the following link:

Direct link: <u>Circular of Information Carter BloodCare</u> or by visiting https://www.cbcspecialtyservices.org and then click on Licenses & Accreditations.