Blood Systems, Inc.

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2003N-0211: **Proposed Rule**: "Revision to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma"

Dear Docket Officer:

Blood Systems appreciates the opportunity to comment on this proposed rule. Blood Systems, based in Scottsdale AZ, is one of the nation's oldest and largest non-profit community blood service providers. Its community blood center operations (United Blood Services, Tri-Counties Blood Bank and Blood Centers of the Pacific) have facilities in 14 states and serve patients and volunteer blood donors in 18 states. Blood Systems Laboratories comprises two national testing laboratories that serve more than 70 blood and tissue collections sites across the nation and test more than 2.5 million samples annually. Blood Systems also operates Blood Systems Research Institute (based at Blood Centers of the Pacific), Blood Systems Foundation and BioCARE, a distribution network for reagents, derivatives and other biological products.

Our comments are focused on FDA proposed revisions to 21 CFR 610.53, 640.34(b), and 640.54 to change the storage and shipping temperature for frozen noncellular blood components, e.g., Cryoprecipitated Antihemophilic Factor (AHF) and for Fresh Frozen Plasma (FFP) to –25 °C or colder if stored for 24 months after the date of collection, and –18 to –25 °C if stored for 3 months after the date of collection.

BSI Comments:
Blood Systems opposes this revision and finds it unnecessary, burdensome and costly.

- **Unnecessary:**
  - Years of clinical experience indicate effective therapeutic effects using FFP and cryoprecipitated AHF (produced, stored and shipped under current requirements) for their accepted clinical indications.
  - Blood centers perform monthly quality control tests on cryoprecipitated AHF. Using current production methodology, results frequently exceed the requirement of 80 IU of factor VIII and 150 mg of fibrinogen.
  - The only reference cited in the proposed rule did not address cryoprecipitated AHF. The article concluded that FFP prepared from whole blood collection or by apheresis shows normal values for the proteins and activities of clotting factors and inhibitors tested at time zero and after storage at 24 or 36 months. In addition, it was shown that FFP may be stored at –20 °C for 2 years or at –25 °C, -30 and –40 °C for 3 years without any detectable changes in the sensitive plasma proteins.

- **Burdensome:**
  - We disagree with FDA beliefs that these requirements reflect current industry practice and do not impose an additional burden.
  - Current industry practice to store FFP and Cryoprecipitated AHF at -18 °C is consistent with the American Association of Blood Banks Standards (AABB) and the Code of Federal Regulations (CFR). We are not aware of any blood center or hospital that complies with the proposal of the FDA.
  - To meet the proposed changes:
    - Blood Collection Agencies (BCA) and Transfusion Services (TS) that choose to maintain the frozen non-cellular blood components at –25 °C or colder for 24 months must:
      - Update or, if necessary, replace their freezers
      - Update/replace cold rooms
      - Update/validate computer systems to apply 24 months expiration date to these products.
      - Validate all shipping containers.
      - Validate temperature monitoring and alarm systems, including their software.
    - BCA and/or TS that choose to use their current freezers (at –18°C) must:
      - Change the expiration date and re-label the products to 3 months from receipt when they receive frozen non-cellular blood components from a facility that stores at <-25 °C. Re-labeling frozen products is difficult and error prone.
  - The proposed rule will ultimately create two inventories for both FFP and Cryoprecipitated AHF. Management of two inventories at either the BCA or at the TS is complex and burdensome

- **Costly:**
  - We disagree with FDA certification that the proposed rule will have no compliance cost and no significant economic impact on a substantial number of small entities.
    - As discussed above, the added burden of the proposed rule is bound to financially impact all Blood Collection Agencies, large and small, and all Transfusion Services, large and small,

We would welcome any added burden and/or cost if they add to the safety, purity, potency and quality of blood components. Unfortunately, the proposed changes to the shipping and storage temperature of frozen non-cellular blood components can not be justified.

Thank you for the opportunity to comment. If you have any questions, please contact me at (480) 675-5659 or at hkamel@bloodsystems.org.

Sincerely,

Hany Kamel

Hany Kamel, MD
Associate Director, Medical Affairs