July 21, 2022

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

Submitted via http://www.regulations.gov

Re: **Docket No. FDA-2022-D-0588,** "Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Draft Guidance for Industry"

Dear Dockets Manager:

The Association for the Advancement of Blood and Biotherapies (AABB), America's Blood Centers (ABC) and the American Red Cross (ARC) are pleased to submit joint comments to the U.S. Food and Drug Administration (FDA) in response to the recently released guidance entitled, "Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements" (Draft Guidance).

We appreciate FDA's response to our continued requests for regulatory relief. As described in our 2017 Joint Letter on Regulatory Reform our organizations have consistently encouraged the agency to reevaluate the new requirements of the May 2015 Final Rule which resulted in the destruction of blood products, based on inadvertent collection errors which do not adversely impact product safety, purity, or potency, do not increase safety, and unnecessarily restricts access to products for further manufacture.

We support FDA's draft compliance policy for the release of blood components collected following an inadvertent failure to follow procedures to ensure that the donation would not adversely affect the health of the donor, namely for blood pressure, pulse, weight, donation frequency, pregnancy history and red blood cell loss. Our organizations continue to support requirements that blood establishments must continue to determine donor eligibility consistent with 21 CFR 630.10 and 21 CFR 630.15 and must not collect blood from a donor found to be ineligible prior to collection.

In addition, our organizations support FDA's intention not to take regulatory action if a blood establishment clarifies a donor's response or obtains omitted information required to determine donor eligibility and component suitability within 72 hours of the time of collection, instead of within 24 hours of the time of collection, provided all other donor eligibility requirements are met.

We do, however, have a comment regarding the requirements for Record Maintenance, Investigation and Annual Reporting, in section III A., Compliance Policy – Donation Suitability Requirements (21 CFR 630.30(a)(2) and 630.30(b)(1)), of the draft guidance. We believe the requirement to report annually the number and type of donations released under the conditions of the draft guidance is overly burdensome and may actually be an inadvertent deterrent to releasing units – which is counter to the intent to increase available units for the blood supply. As a part of their existing quality systems, blood centers maintain processes to record, track and trend deviations, as well as thresholds for process improvement. As an alternative to the annual reporting requirement, we recommend that FDA allow the review and monitoring of error rates and corrective actions to be conducted by FDA investigators during the inspection process.

The Association for the Advancement of Blood & Biotherapies (AABB) is an international, not-for-profit organization representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. Since 1947, AABB has worked collaboratively to advance the field through the development and delivery of standards, accreditation and education programs. AABB is dedicated to its mission of improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

Thank you for the opportunity to offer these comments. Questions concerning these comments may be directed to scarayiannis@aabb.org.

Sincerely,

[*signatures on file*]

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