



February 5, 2025

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-0464, Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry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, [Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\); Draft Guidance for Industry.](#)

COMMENT 1 – Support for draft guidance recommendations

Our organizations would like to take this opportunity to express our support for the FDA's commitment to evolving policies which result in new, evidence-based recommendations. These updated recommendations are critical to ensuring these lifesaving products are safe and available to meet the critical needs of patients.

COMMENT 2 – Support for updated guidance format

We support FDA's updated guidance format which incorporates separate guidance documents with recommendations for reducing the risk of transmission of specific communicable disease agents or diseases.

COMMENT 3 - Request for an extended implementation period

Our organizations request an extended implementation period of at least one year. This period should allow facilities to focus on successful implementation of changes to highly complex systems which must be updated, tested, and validated for performance. These include changes to the establishment computer system, HCT/P Donor History Questionnaires, Flowcharts, Circular of Information, policies and procedures, and extensive staff training and education.

AABB (Association for the Advancement of Blood & Biotherapies) is an international, not-for-profit organization representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. The Association works 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.

Sincerely,

[signatures on file]

Sharon Carayiannis
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AABB

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America's Blood Centers

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