America's Blood Centers®
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September 26, 2025

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

Submitted via https://www.regulations.gov

Re: Docket No. FDA-2024-D-5942, "Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry."

Dear Dockets Manager:

America's Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers. Our member organizations operate more than 700 blood collection sites in more than 1,100 communities, providing close to 60 percent 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. All ABC U.S. members are regulated by the U.S. Food and Drug Administration (FDA).

I. ABC applauds FDA's proposal to remove the hepatitis B surface antigen (HBsAg) testing requirement for whole blood and blood components.

ABC appreciates the opportunity to provide feedback on FDA's draft guidance on Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry (draft guidance) and applauds FDA's recognition that nucleic acid tests (NAT) and hepatitis B core antigen (anti-HBc) testing adequately reduce the risk of transmission of hepatitis B virus (HBV) for whole blood and blood components intended for transfusion. As stated in the draft guidance, "when donations, other than for Source Plasma, are tested for HBV DNA by nucleic acid tests…and for antibody to hepatitis B core antigen…using screening tests that FDA has licensed, approved, or cleared for such use, in accordance with the manufacturer's instructions, testing for HBsAg is not necessary to reduce adequately and appropriately the risk of transmission of HBV."

ABC has long advocated for the removal of the HBsAg testing requirement. FDA was poised to eliminate this testing requirement in 2020, and the Blood Products Advisory Committee (BPAC) was scheduled to meet April 2-3, 2020 to discuss the discontinuation of the HBsAg requirement. However, the meeting was postponed, and when it ultimately occurred, it did not address the elimination of HBsAg testing. ABC continued to advocate for this change. We thank FDA for making this change and commend FDA's efforts to maintain a safe and available blood supply by ensuring that testing requirements and donor deferrals are evidence-based, and that testing burdens are justified by commensurate increases in safety.

Additionally, ABC is pleased that FDA's draft guidance reduces potential reporting burdens by only requiring blood centers who discontinue HBsAg testing to revise their Circular of Information and report the change in their annual report.

While we greatly appreciate the proposed removal of the HBsAg testing requirement for whole blood and blood components, ABC urges the FDA to consider removing this testing requirement for Recovered Plasma as well. Not treating all plasma-derived medicinal products source materials equally creates a regulatory inconsistency for blood collectors and fractionators and contributes to fractionators' unwillingness to accept recovered plasma that has not been tested for HBsAg.

II. ABC urges the FDA to update current testing requirements to one-time donor testing for antibodies to human T-lymphotropic virus types I and II (HTLV-I/II) coupled with effective leukoreduction for donors of whole blood and blood components intended for transfusion.

ABC recognizes that FDA intends to develop draft guidance on the topic of HTLV-1/II testing and encourages FDA to continue the removal of unnecessary testing requirements by publishing this draft guidance as expeditiously as possible.

The HTLV-I/II antibody testing requirement at each donation of whole blood and blood components intended for transfusion should be revised based on: (1) the declining prevalence of HTLV-I/II infection in US blood donors; (2) the low incidence observed among US repeat blood donors; (3) the low likelihood of infection and disease in individuals receiving HTLV-I/II antibody-reactive Whole Blood and blood components, (4) the efficacy of leukoreduction in reducing the infectivity of HTLV-I/II antibody-reactive donations, and (5) the use of effective pathogen reduction technology (PRT) for some platelets.

On March 26, 2025, ABC submitted a joint comment letter to FDA requesting the change to a one-time testing requirement. The letter contains additional information on relevant studies and supportive experience outside of the United States.

By updating the testing requirement to one-time donor testing for antibodies to HTLV-I/II, coupled with effective leukoreduction in donations of whole blood and blood components intended for transfusion, FDA will continue to ensure that testing requirements are evidence-based and testing burdens are justified by commensurate increases in safety, all while ensuring a safe and available blood supply.

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ABC appreciates the opportunity to comment on the draft guidance. If you have any questions or require additional information, please contact Justine Coffey, Director of Regulatory Affairs and Public Policy (jcoffey@americasblood.org).

Thank you for your collaborative work to ensure a safe, adequate, and available blood supply.

Sincerely yours,

Kate Fry, MBA, CAE
Chief Executive Officer