



May 20, 2026  
Division of Dockets Management (HFA-305)  
Director  
Center for Biologics Evaluation and Research (CBER)  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Madams and Sirs,

The Association for Advancing Tissue and Biologics (AATB) appreciates the opportunity to comment on the Food and Drug Administration (FDA) January 2025 draft guidance for industry titled “Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).”

AATB is a non-profit organization dedicated to advancing the safety, quality, availability, and benefits of donated human tissue for transplantation worldwide. AATB achieves this through standards development, accreditation, education, and collaboration with regulatory partners to ensure donated tissue has the greatest impact on patient care.

We appreciate the opportunity to provide the following comments:

- 1) Section IV(A)(1), Screening a Donor for Risk Factors and Conditions of HBV Infection, requires that “[p]ersons who have ever had a positive or reactive **screening test** for HBV (Refs. 20-25, 42)” be found ineligible to donate.

AATB requests that FDA provide clarification and examples of what constitutes a “screening” test. Was it the agency’s intention to exclude diagnostic tests from this definition?

- 2) Section IV(B), Testing a Donor for Evidence of HBV Infection, indicates that HBV testing should include tests for hepatitis B surface antigen testing (HBsAg), antigens to hepatitis B core antibodies (anti-HBc), and nucleic acid testing (NAT) for hepatitis B virus.

AATB believes that HCT/P donor testing requirements for HBV should be aligned with the blood donor HBV guidance, which only requires testing for anti-HBc and HBV NAT.

The data and rationales provided in the July 2025 guidance document titled “Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen,” indicate that HBsAg testing in addition to HBV NAT and anti-HB core is not necessary to “adequately and appropriately reduce the risk of transmission of HBV.”

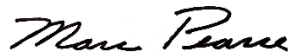
As noted by FDA in the Discussion (section III) of this guidance, under A, Risk of Transmission, “[w]hile the studies used to support blood donor deferral recommendations (e.g., ADVANCE study, risk assessments) are not specific to HCT/Ps, **they are nonetheless relevant beyond blood donation**. These studies considered certain risk factors associated with blood donors acquiring HIV, which are also risk factors for acquiring HBV.”

Given the lack of licensed supplemental tests for cadaveric specimens, obtaining comparable data for deceased tissue donors is challenging. Deceased donors cannot be followed and retested over time, and the number of donors tested per year is far lower than that performed for blood donations.

HCT/P donors are only tested using Individual Donation NAT, so the NAT assay sensitivity will not be decreased due to the pooling of donations / donor specimens.

AATB believes that HCT/P donor testing requirements for HBV should be aligned with the blood donor testing requirements.

Thank you for considering this request. AATB stands ready to work with you to achieve our shared goals.  
Regards,

A handwritten signature in cursive script that reads "Marc Pearce".

Marc Pearce, MBA  
President and CEO  
Association for Advancing Tissue and Biologics