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and Biologics (AATB) appreciates the opportunity to comment on the Food and Drug Administration (FDA) January 2025 draft guidance for industry titled "Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based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following comment, which is substantively similar to a question raised in our comments to the agency's January 2025 HBV draft guidance for HCT/P donors:

> 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 HCV (Refs. 55-57, 59-62, 79)" 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?

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

Marc Pearce

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