



February 3, 2025

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

**In Re: FDA-2024-N-4821, Food and Drug Administration’s Best Practices for Food and Drug Administration Communication with Interested Parties: Draft Report for Public Comment; Availability**

To Whom It May Concern:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Banks’ Tissue Policy Group (TPG) submit these comments related to the Food and Drug Administration (FDA) document titled “Best Practices for FDA Communication with Interested Parties: Draft Report for Public Comment.”

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated tissue. The TPG’s membership is responsible for the vast majority of tissue available for transplantation within the U.S.

**FDA Methods for Communications:** The AATB and TPG appreciate FDA’s efforts to communicate with external stakeholders in a timely, transparent manner. The agency’s increased use of innovative communications methods, starting with the COVID-19 public health emergency (PHE), has helped foster a more collaborative relationship between the FDA and the tissue industry. In particular, the use of town halls and webinars, blog posts, and workshops/meetings has helped tissue banks better understand the agency’s position on a variety of topics. These communications strategies are generally helpful when the FDA communicates with a broad range of interested parties, but other improvements could be made to enhance FDA-to-tissue bank communications.

For example, during the COVID-19 PHE, the FDA provided advanced notice of an audit or inspection, which was helpful so that tissue banks could ensure personnel were available during the agency’s visit. This advanced notice could be modeled after CDRH’s policy for inspections and be as short as a day or

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two, which would ensure the appropriate staff are on-site as needed (especially during certain times of the year, like the summertime, when people may be traveling, working remotely, or on vacation). We are also aware that the FDA was considering a potential change to the 21 CFR 1271 regulations to allow the agency to request records in advance of or in lieu of an inspection. We encourage the agency to continue work on that proposal, which has the potential to reduce the burden on tissue banks and the agency without compromising the safety or availability of tissue products for transplant.

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Thank you for taking these comments into consideration. The AATB and TPG stand ready and willing to assist in any way that you deem appropriate.

Respectfully,



Marc Pearce  
President & CEO  
American Association of Tissue Banks



Dean Elliott  
Chair  
Tissue Policy Group