



June 8, 2020

Diana Buck, M.Ed., MBA, CTBS and David M. Smith, MD
American Association of Tissue Banks
8200 Greensboro Drive, Suite 320
McLean, VA 22102

Re: Citizen Petition [Docket No. FDA-2019-P-6100]

Dear Ms. Buck and Mr. Smith:

Thank you for your letter dated June 4, 2020 requesting a timeframe for a substantive response from the Food and Drug Administration (FDA, the Agency, or we) to your citizen petition and providing a point of clarification. We appreciate your letter and welcome the opportunity to respond.

We understand and appreciate the critical importance of these issues to your membership, hospitals, surgeons, and patients. FDA recognizes the importance of these issues and takes them seriously. Given the COVID-19 pandemic and multiple public health priorities, we are unable to give you a timeframe for our substantive response at this time. However, please be assured that we are actively considering all the issues you have raised.

We appreciate you contacting us concerning this matter and we will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff