U.S. FOOD & DRUG ADMINISTRATION

May 5, 2020

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

Re: Docket No. FDA-2019-P-6100

Dear Ms. Buck:

I am writing to inform you that the Food and Drug Administration (FDA, the Agency, or we) has not yet reached resolution of the issues raised in your citizen petition (Petition) on behalf of petitioner, the American Association of Tissue Banks (AATB), and received by the Dockets Management Staff on December 31, 2019. In your Petition, you request that the Commissioner of Food and Drugs (the Commissioner) take certain actions with respect to human-derived acellular dermal matrix (human ADM) allografts intended for use in post-mastectomy breast reconstruction surgery. Specifically, you request the Commissioner to "[c]onfirm in response to this Petition that human ADM allografts that otherwise meet the requirement for regulation solely under Section 361 of the [Public Health Service Act] shall not be considered non-homologous or otherwise ineligible for classification as '361 HCT/Ps' solely because they are labeled and/or advertised for use in post-mastectomy breast reconstruction." Additionally, you request a revision of FDA's Final Guidance, entitled "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use," December 2017, to present human ADM allografts for post-mastectomy breast reconstruction as an example of a homologous use.

FDA takes these issues seriously but has not yet reached a resolution on your Petition because it raises issues requiring review and analysis by multiple Agency components. To date, FDA has solicited information regarding the use of human ADM for breast reconstruction. For example, we solicited feedback to develop guidances for the regulation of human cell, tissue, and cellular and tissue-based products, including during a two-day public hearing in 2016. Additionally, the March 25 and 26, 2019 Advisory Committee Meeting supported public discussion about risks and benefits of breast implants, including dedicating a significant amount of time to the use of mesh including ADM in breast reconstruction surgery. We also had a discussion on October 23, 2019 with you regarding the use of human ADM in post-mastectomy breast reconstruction. As these examples of FDA efforts reflect, the Agency appreciates the importance of these issues and it continues to consider them at this time. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). 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

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