**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 31, 2019

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following two actions described below:

(1) Confirm in response to this Petition that human ADM allografts that otherwise meet the requirement for regulation solely under Section 361of the PHSA 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.

(2) Revise the Final Guidance, Regulatory Considerations for Human Cells,Tissues, and Cellular and Tissue-Based Products: Minimal Manipulationand Homologous Use (2017) to present human ADM allografts for post-mastectomy breast reconstruction as an example of a homologoususe.

This petition was received by this office on 12/31/2019 and it was assigned docket number FDA-2019-P-6100. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.12.31 14:55:36 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)