

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702		DATE(S) OF INSPECTION 11/18/2024-11/22/2024 FEI NUMBER 3014298539	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dr. Mesfin W. Mengesha, Chief Executive Officer			
FIRM NAME Berkeley Advanced Biomaterials, LLC		STREET ADDRESS 2800 7th St	
CITY, STATE, ZIP CODE, COUNTRY Berkeley, CA 94710-2703		TYPE ESTABLISHMENT INSPECTED Tissue Processor	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 HCT/Ps were not processed in a way that does not cause contamination or cross contamination during processing. Specifically, On 11/21/2024, I observed your Processing Supervisor processing Lot (Donor ID) and Lot (Donor ID) of H-Genin DPM Putty in one (b)(4). The processing of the lots was (b)(4) in the by a (b)(4). The processing of donors (b)(4) was not validated in the 09/2018 <i>HENIN Putty Validation</i> to ensure cross contamination does not occur. Your work instruction, <i>H-Genin DPM Putty, Crush-Mix, and Cortical-Mix Compounding</i> (Rev. 00, effective 08/01/2017), does not state that (b)(4) donors may be processed (b)(4). Processing Record <i>H-GENIN DBM Putty, Crush-Mix and Cortical-Mix Compounding Record</i> (Rev. 00, effective 08/01/2017) does not state that the donor were processed within the (b)(4). Per your firm's Senior Quality Assurance Administrator, the frequency your firm has processed (b)(4) (b)(4) is unknown.			
OBSERVATION 2 Environmental conditions are not monitored when such conditions could cause contamination or cross contamination of HCT/Ps or equipment.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Emily S McGann, Investigator Emily S McGann Investigator Signed By: Emily S. McGann S Date Signed: 11-22-2024 12:10:18 X _____	
DATE ISSUED 11/22/2024			

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Specifically, Your firm does not conduct environmental monitoring of the bone (b)(4) (b)(4) (b)(4) utilized in the processing of bone. You process and distribute approximately (b)(4) bone product units (b)(4).			
OBSERVATION 3 Records were not detailed as necessary to provide a complete history of work performed. Specifically, 1. <i>Production Room/Equipment</i> (b)(4) <i>Cleaning Record</i> (Rev. 05, effective 03/14/2022) does not include documentation of 'Production Areas/Equipment Cleaning' steps 12.2-12.17 in your work instruction, <i>Production Rooms and General Area Cleaning Instructions</i> (Rev. 06). These steps include cleaning work surfaces, floors, equipment, chairs, and door handles in production areas (i.e. (b)(4) room). 2. (b)(4) <i>Use Log</i> (Rev. 00, effective 12/01/2018) does not itemize equipment (b)(4), and does not document that sterilization was successful. The equipment you (b)(4) includes but is not limited to (b)(4) used in tissue (b)(4) 3. The processing record <i>H-GENIN DBM Putty, Crush-Mix, and Cortical-Mix Compound Record</i> (Rev. 00, effective 08/01/2017) does not include cleaning documentation of equipment utilized, nor does the processing record include the time the product is stirred. The product work instruction, <i>H-GENIN DBM Putty, Crush-Mix, and Cortical-Mix Compounding</i> (Rev. 00), requires the compound be (b)(4) as described in steps 6.3.11, 6.3.15, and 6.3.16 under 'Compounding Putty.' Additionally, the form does not provide indication if the donor tissue was processed within the (b)(4) donor's tissue.			
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Berkeley, CA 94710-2703	Tissue Processor

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."