DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	5/13/2025-5/21/2025* FEI NUMBER 3017596057

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marie C. Stroughter, Lead Processor

FIRM NAME	STREET ADDRESS
AVEM Labs LLC	5670 Wynn Rd Ste E
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Vegas, NV 89118-2355	HCT/P Manufacturer

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 WE OBSERVED:

OBSERVATION 1

Processes with results which could not be fully verified by inspection and tests, were not validated and approved according to established procedures.

Specifically, your firm has not validated the manufacturing process for amniotic membrane (b) (4) derived from human amniotic membrane. Since January 2025, you have manufactured and distributed (b) (4) amniotic membrane (b) (4)

OBSERVATION 2

Labeling procedures did not include verification of label accuracy.

Specifically, your quality assurance personnel are not reviewing and approving all appropriate finished product labels as they relate to the amniotic membrane (b) (4) of BioVair DL that are distributed as (b) (4), and (b) (4) (b) (4).

OBSERVATION 3

Equipment used for measuring was not calibrated according to established schedules.

Specifically, you have not calibrated your temperature monitoring devices, (b) (4), S/N (b) (4) and S/N (b) (4). These temperature monitoring devices are used to monitor temperatures of finished and quarantined lots of amniotic membrane (b) (4) BioVair DL.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Garrad R Poole, Investigator Laurissa S Flowers, Investigator	X Garrad R Poole Investigator Signed By: GARRAD R. POOLE - S Date Signed: 05-21-2025 08:05:12	5/21/2025

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OBSERVATION 4

Documentation of the receipt of supplies was not maintained.

Specifically, you did not maintain records of receipt that includes the date of receipt, quantity obtained, and quality release for use of your (b) (4) part ID: (b) (4) and (b) (4) part ID: (b) (4) that were manufactured by your supplier on 03/19/2019 and are currently being used as primary packaging for your BioVair DL (b) (4) and (b) (4) amniotic membrane (b) (4).

OBSERVATION 5

Records pertaining to HCT/Ps were not retained at least 10 years after the date of distribution, disposition, or expiration, whichever was latest when the date of administration of the HCT/P was unknown.

Specifically, records related to manufacturing and donor eligibility were not available for review for products manufactured prior to January 2025. For example, we requested to review lot (b) (4) (b) (4) of commercially distributed (b) (4); however, the requested documentation was not made available during our inspection.

***DATES OF INSPECTION**

5/13/2025(Tue), 5/14/2025(Wed), 5/15/2025(Thu), 5/20/2025(Tue), 5/21/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Garrad R Poole, Investigator Laurissa S Flowers, Investigator	X Garrad R Poole Investigator Signed By: GARRAD R. POOLE - S Date Signed: 05-21-2025 08:05:12	5/21/2025

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Las Vegas, NV 89118-2355	HCT/P Manufacturer

X Laurissa S Flowers
Investigator
Signed By: LAURISSA S. FLOWERS -S
Date Signed: 05-21-2025 08:05:40

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Garrad R Poole, Investigator
Laurissa S Flowers, Investigator

X Garrad R Poole
Investigator
Signed By: GARRAD R. POOLE -S
Date Signed: 05-21-2025 08:05:12

DATE ISSUED
5/21/2025

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."