DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax: (913)495-5115	5/5/2025-5/9/2025
	FEI NUMBER 3003571688

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul E. Pfeiffer, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Cardinal Biologicals, Inc.	821 Progress St
CITY, STATE, ZIP CODE, COUNTRY Cape Girardeau, MO 63703-7551	TYPE ESTABLISHMENT INSPECTED HCT/P Establishment

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

Records of the use of each piece of equipment, and the HCT/Ps manufactured with the equipment, were not maintained.

Specifically,

Although your firm has a written procedure, titled, (b)(4), that instructed cleaning and documenting during the following cleaning and sanitizing operation (pre-use cleaning, cleaning between inter-specimen and cleaning at (b)(4)).

From (b)(4), your firm distributed approximately [redacted] human birth tissues without documentation of (b)(4).

From (b)(4), your firm did not document inter-specimen cleaning. For example, your firm failed to document the cleaning and sanitizing between each new tissue processed on (b)(4).

On (b)(4) at (b)(4), your firm processed Lot Number (b)(4) (Donor [redacted]) in (b)(4) - the following birth tissues also processed, Lot number (b)(4) (Donor ID [redacted]) processed at (b)(4) and Lot number (b)(4) (Donor ID [redacted]) processed at (b)(4). Later on (b)(4), Donor [redacted] resulted (b)(6) (b)(7)(C).

OBSERVATION 2

Environmental conditions were not monitored for microorganisms.

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Specifically,

Since (b)(4), you firm failed to perform environmental monitoring for microorganisms within your (b)(4) when such conditions could cause contamination or cross contamination of human birth tissues or equipment and accidental exposure of human birth tissues to communicable disease agents. Your firm processes human birth tissues for further manufacture within this (b)(4). Your firm distributed approximately [redacted] human birth tissues that were processed within this (b)(4).

OBSERVATION 3

Supplies and reagents were used before they were verified to meet specifications designed to prevent the introduction, transmission, or spread of communicable disease.

Specifically,

Since [redacted], your firm utilizes "Saline Solution (b)(4) your human birth tissues (b)(4) for further manufacture and transplant. However, the saline solution (lot number currently in your inventory: (b)(4)) is labeled, "For Research Use Only".

OBSERVATION 4

Procedures for the maintenance of equipment were not established, documented and implemented.

Specifically,

Your firm failed to establish and document procedures for routine maintenance of checking the [redacted] (b)(4)

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Investigator
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required by the (b)(4) *Operating and Maintenance Manual* to prevent the introduction, transmission, or spread of communicable disease from contamination and cross-contamination between each new birth tissues ((b)(4)).

OBSERVATION 5

HCT/Ps shipped [ ] the completion of the donor-eligibility determination were not kept in [ ] during shipment.

Specifically,

Your firm distributes human birth tissues to your customers for further manufacture and final donor eligibility determination. However, your human birth tissues are not sent under (b)(4).

OBSERVATION 6

HCT/Ps in (b)(4) pending completion of the donor eligibility determination were not clearly identified as (b)(4).

Specifically,

A. Your firm does not identify human birth tissues ((b)(4) (b)(4)) with a statement that the donor eligibility has not been completed, and a statement that the product must not be used until completion of the donor eligibility determination.

B. From 4/2022 to 3/2025, your firm does not identify instructions for use when related to the prevention of the introduction, transmission, or spread of communicable diseases for your human birth tissues that are sent to your customers for further manufacture.

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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."