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	5/13/2025-5/16/2025
	FEI NUMBER 3003969216

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Edward J. Ramirez, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Central Coast Multispecialty Medical Group, Inc.	9833 Blue Larkspur Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Monterey, CA 93940-6535	Human Reproductive Tissue

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

Donors were not determined to be ineligible that had risk factors or clinical evidence of communicable disease agents.

Specifically, your firm failed to determine ineligible all donors with risk factors for relevant communicable diseases agents and diseases (RCDAD). On (b) (6), (b) (7)(C), during your firm's interview with known sperm donor (b) (6), (b) (7) he was found to have risk factors or conditions that increase his risk for transmitting the RCDADs: (b) (6), (b) (7)(C), including a history of (b) (6), (b) (7)(C) and a diagnosis for (b) (6), (b) (7)(C). You determined this known donor eligible on (b) (6), (b) (7)(C). Sperm was collected from this donor on (b) (6), (b) (7)(C). Embryos derived from this donor's sperm are in your inventory and your firm intends to transfer these to a gestational carrier that is (b) (6), (b) (7)(C) to the sperm donor.

OBSERVATION 2

Donors were not screened by a review of relevant medical records for risk factors and clinical evidence of communicable disease agents and diseases.

Your firm did not adequately screen all sperm and egg donors for all the relevant communicable disease agents and diseases (RCDADs). During my inspection of your establishment, I reviewed your screening and testing records for (b) (4), (b) (6), (b) (7)(C) of the (b) (4), (b) (6), (b) (7)(C) known sperm and egg donors that you screened and made an eligibility determination. The initials for the (b) (4), (b) (6), (b) (7)(C) donors reviewed are (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C). I made the following observations; however, this is not an all-inclusive list.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shelley H Beausoleil, Investigator	X Shelley H Beausoleil Investigator Signed By: Shelley H. Beausoleil - S Date Signed: 05-16-2025 11:25:23	5/16/2025

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A. Donor testing was not complete prior to making an eligibility determination. Donor (b) (6), (b) (7) was determined eligible on (b) (6), (b) (7)(C); however, testing for evidence of the relevant communicable diseases: (b) (6), (b) (7)(C) were not completed until the following day, on (b) (6), (b) (7)(C)

B. **This is a repeat FDA-483 Observation.** Donor (b) (6), (b) (7) was not screened by review of medical records or through an interview between your firm and the donor for:

1. A medical diagnosis of (b) (6), (b) (7)(C) within the past (b) (4), or
2. A suspicion of a (b) (6), (b) (7)(C) infection in the past (b) (4), or
3. A positive test for (b) (6), (b) (7)(C), or
4. A history of any blood transfusion in France.

Donor (b) (6), (b) (7) was determined to be eligible by the responsible person on (b) (6), (b) (7)(C). Sperm was collected from this donor on (b) (6), (b) (7)(C). (b) (6), (b) (7)(C) embryos were created using this donor's sperm and frozen. All (b) (6), (b) (7)(C) remain in your firm's inventory.

C. Donor (b) (6), (b) (7)(C) was not screened by review of relevant medical records and by asking questions about her history of:

1. A suspicion of a (b) (6), (b) (7)(C) infection in the past (b) (4), or
2. A positive test for (b) (6), (b) (7)(C).

Donor (b) (6), (b) (7)(was determined to be eligible by the responsible person on 5/3/2022. Eggs were retrieved from this donor on (b) (6), (b) (7)(C). (b) (6), (b) (7)(C) embryo was transferred to the recipient that is (b) (6), (b) (7)(C) to the donor on (b) (6), (b) (7)(C). There is one embryo remaining in your firm's inventory.

OBSERVATION 3

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Procedures were not designed to ensure compliance with the donor eligibility requirements.

Specifically, your firm has not established written procedures covering all steps your firm should take to review the relevant medical records and ask the donors questions about their social and medical history as those relate to the risk factors for relevant communicable disease agents and diseases (RCDADs). This is not an all-inclusive list.

A. **This is a repeat FDA-483 Observation.** The procedures that your firm provided to me, which were being used by the clinic to screen and test tissue donors, does not include all of the steps necessary to ensure donors are adequately screened for Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD), vaccinia, Syphilis, Chlamydia, Gonorrhea, and West Nile Virus including the management of donors where an infection was suspected or there was a positive test for WNV using a nucleic acid test or other investigational test.

   For example, Donor (b) (6), (b) (7), a known sperm donor, indicated to your firm that he had a history of treatment, or a (b) (6), (b) (7)(C) test, for (b) (6), (b) (7)(C). You have not established as part of your written donor screening procedures any steps your firm must take to establish the donor's eligibility to be a human tissue (HCT/P) donor such as date donor tested (b) (6), (b) (7)(C) or the date the donor completed treatment. Your firm told me Donor (b) (6), (b) (7) was treated for (b) (6), (b) (7)(C), but a record could not be provided.

B. Written procedures covering the physical examination of sperm donors has not been established. Specifically, your firm does not conduct (b) (4). Records are not gathered from (b) (4) about the donor(s). Currently, your firm relies on the physical examination results (b) (4) for the purposes of screening for eligibility.

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X Shelley H Beausoleil
Investigator
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5/16/2025

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."