

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 11/20/2024-12/3/2024* FBI NUMBER 3003942615					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Sima NMI Taghizadeh, Executive Director							
FIRM NAME California Fertility Partners, A Medical Group, Professional Corporations		STREET ADDRESS 11818 Wilshire Blvd Ste 300					
CITY, STATE, ZIP CODE, COUNTRY Los Angeles, CA 90025-6648		TYPE ESTABLISHMENT INSPECTED Reproductive Fertility Center					
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 screened by a review of relevant medical records for risk factors and clinical evidence of communicable disease agents and diseases. Specifically, From July 2021 - October 2024, your firm has failed to adequately screen (b)(4) donors ((b)(4) oocyte donors, (b)(4) oocyte donors, and (b)(4) semen donors) based on (b)(4) different donor history questionnaires titled "Screening of Potential Donors of Oocyte or Semen, RCDADs Questionnaire" with revision dates 07/29/2021; 01/28/2022; 05/06/2022; 07/22/2022; 08/26/2022; 05/22/2023; 05/23/2024; 07/24/2024. Your (b)(4) donor history questionnaires failed to screen for critical risk factors and relevant communicable disease agents and diseases (RCDADs) pertaining to Human Immunodeficiency Virus (HIV), Hepatitis B (Hep B), Hepatitis C (Hep C), and Creutzfeldt-Jakob Disease (CJD). Donors were determined eligible based on these inadequate screening questionnaires, reproductive tissues were recovered, and fertilized oocytes were transferred into recipients. There are (b)(4) oocytes and (b)(4) semen (b)(4) remaining that are currently stored at your facility from the affected (b)(4) donors. (b)(4) oocytes have been transferred into recipients from the affected (b)(4) donors since 2021.							
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> EMPLOYEE(S) SIGNATURE Celeta S Covas, Investigator </td> <td style="width: 40%; border: none; text-align: center;"> DATE ISSUED 12/3/2024 </td> </tr> <tr> <td style="border: none;"> Celeta S Covas Investigator Signed By: Celeta S. Covas -S Date Signed: 12-03-2024 13:05:59 </td> <td style="border: none;"></td> </tr> </table>		EMPLOYEE(S) SIGNATURE Celeta S Covas, Investigator	DATE ISSUED 12/3/2024	Celeta S Covas Investigator Signed By: Celeta S. Covas -S Date Signed: 12-03-2024 13:05:59	
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*DATES OF INSPECTION 11/20/2024(Wed), 11/21/2024(Thu), 11/25/2024(Mon), 12/02/2024(Mon), 12/03/2024(Tue)			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Celeta S Coves, Investigator		DATE ISSUED 12/3/2024
	Celeta S Coves Investigator Signed By: Celeta S. Coves -S Date Signed: 12-03-2024 13:05:59 X		
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 of 2 PAGES			

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."