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	4/7/2026-4/10/2026
	FEI NUMBER 3004538500

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Fariba (NMI) Chalajour, Managing Director

FIRM NAME	STREET ADDRESS
Comparative Biosciences, Inc	786 Lucerne Dr
CITY, STATE, ZIP CODE, COUNTRY Sunnyvale, CA 94085-3844	TYPE ESTABLISHMENT INSPECTED Good Laboratory Practice (Nonclinical Laboratories)

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:

The following Observation(s) relates to:

- Study (b) (4)
- Study

OBSERVATION 1

The study director failed to assure that unforeseen circumstances that might affect the quality and integrity of the nonclinical laboratory study were noted when they occurred and corrective action was taken and documented.

Specifically,

A. For study (b) (4), test article ((b) (4) contamination was detected in pre-dose baseline samples from 5 animals (201, 254, 454, 305, and 405). No corrective actions were documented.

B. For study (b) (4), conducted by the same Study Director, test article ((b) (4)) contamination was detected in vehicle control samples from all 16 Group 1 animals (23 of 72 samples). No corrective actions were documented.

C. For study (b) (4), the same freeze-thaw error occurred on three occasions within 47 days (June 1, July 15, and July 18, 2023), affecting animals in Groups 2, 3, and 4. No corrective actions were documented.

Furthermore, the Quality Assurance Manager signed Quality Assurance Statements certifying study compliance for the above studies, despite corrective actions not having been documented for the circumstances identified above.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Scott N Lim, Consumer Safety Officer

X Scott N Lim
Consumer Safety Officer
Signed By: 2002619245
Date Signed: 04-10-2026
12:06:02

DATE ISSUED
4/10/2026

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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."