DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	5/4/2026-5/7/2026 FEI NUMBER 3043638019

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tamar F. Brionez, M.D., Clinical Investigator

FIRM NAME	STREET ADDRESS
Tamar F. Brionez, M.D.	10857 Kuykendahl Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
The Woodlands, TX 77382-2937	Clinical Investigator

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:
For study protocol (b) (4)

OBSERVATION 1

An investigation was not conducted in accordance with the investigational plan.

Specifically, 3 out of 5 subjects scheduled study visits were not performed within the protocol-specified visit windows and were not identified and reported as protocol deviations to the sponsor as listed below:

Subject	Visit	Actual Date	Allowable Window per protocol	Days Outside Window
(b) (6), (b) (7)(C)	Week 16	(b) (6), (b) (7)(C)		1 day late
	Week 20			3 days late
	Week 24			3 days late
	Week 36			2 days late
	Week 48			1 day late
(b) (6), (b) (7)(C)	Week 48			2 days late
(b) (6), (b) (7)(C)	Week 24			6 days late

OBSERVATION 2

Failure to prepare or maintain adequate case histories with respect to observations and data pertinent to the investigation.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Vidhi J Jani, Investigator

X Vidhi J Jani
Investigator
Signed By: 2004378950
Date Signed: 05-07-2026
12:52:11

DATE ISSUED
5/7/2026

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Specifically, 3 out of 5 subjects reviewed did not have original source documentation for (b) (4) (b) (4) assessment, (b) (4) to verify the accuracy and reliability of the data reported. Missing documentation of values included, collection start time, collection end time, individual sample volumes, and total collected volume necessary to calculate (b) (4). These values constitute key data supporting secondary endpoint(s) as defined in the study protocol. Subject visit examples are as below,

- Subject (b) (6), (b) (7)(C), Visit 48, Date of Visit: (b) (6), (b) (7)(C)
- Subject (b) (6), (b) (7)(C), Visit 48, Date of Visit: (b) (6), (b) (7)(C)
- Subject (b) (6), (b) (7)(C), Visit 36, Date of Visit: (b) (6), (b) (7)(C)
- Subject (b) (6), (b) (7)(C), Visit 36, Date of Visit: (b) (6), (b) (7)(C)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Vidhi J Jani, Investigator X Vidhi J Jani Investigator Signed By: 2004378950 Date Signed: 05-07-2026 12:52:11	5/7/2026

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."