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	2/23/2026-3/2/2026* FEI NUMBER 3037451774

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William D. Turner, Chief Reguatory Officer

FIRM NAME	STREET ADDRESS
Vera Therapeutics, Inc.	2000 Sierra Point Pkwy STE 1200
CITY, STATE, ZIP CODE, COUNTRY Brisbane, CA 94005-1806	TYPE ESTABLISHMENT INSPECTED Sponsor

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

Failure to obtain a complete investigator statement, form FDA-1572, before permitting an investigator to participate in an investigation.

Specifically, at least three (3) domestic clinical sites were found to have consented and enrolled subjects under the (b) (4) portion of the Study Protocol (b) (4) without completing an updated form FDA 1572. These sites were initially activated under the (b) (4) portion of the study (b) (4) and had completed a form FDA 1572 for (b) (4) . However, the sponsor failed to request an updated form FDA 1572 after the sites continued study participation under (b) (4) .

Although (b) (4) was executed as a protocol amendment, (b) (4) is described as a dose-ranging study in the protocol title whereas (b) (4) is not a dose-ranging study. In addition, the forms FDA 1572 that were completed for (b) (4) specified participation of the (b) (4) portion only. Therefore, the protocol titles and study objectives of (b) (4) and (b) (4) are different, and not all requirements of 21 CFR 312.53(c)(1) could be fulfilled without updating the form FDA 1572.

OBSERVATION 2

Failure to provide investigators with the information needed to conduct the study properly and ensure the study is conducted in accordance with the protocol and/or investigational plan.

Specifically, three (3) out of the fifteen (15) reported serious adverse events (SAEs) were found to have been reported by the clinical sites without providing the date of site awareness of the event. As stated within the clinical investigational plan ((b) (4)), the clinical sites are to report SAEs directly into

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Cynthia J Tsui, Investigator X Cynthia J Tsui Investigator Signed By: Cynthia J. Tsui -S Date Signed: 03-02-2026 09:10:23	3/2/2026

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the electronic data capture (EDC) system within (b) (4) of site awareness. However, the EDC was found to have not been configured to require sites to provide the site awareness date. Subsequently, several SAE case report forms (eCRFs) were found to lack this information. In addition, the study monitors did not always confirm whether the SAEs were reported on time in the available monitoring reports. Therefore, it is unclear how the sponsor can confirm that an investigator is in compliance with the (b) (4) reporting requirement for SAEs.

Subject	Serious Adverse Event	Event Start Date	Date of Initial Report
(b) (6), (b) (7)(C)	Worsening kidney function	23 Oct 2024	14 Nov 2024
	High-grade epithelial malignant neoplasia in the left ovary	11 Mar 2025	19 Mar 2025
	Hip necrosis	03 Sep 2024	01 Oct 2024

***DATES OF INSPECTION**
2/23/2026(Mon), 2/24/2026(Tue), 2/25/2026(Wed), 2/26/2026(Thu), 2/27/2026(Fri), 3/02/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Cynthia J Tsui, Investigator X Cynthia J Tsui Investigator Signed By: Cynthia J. Tsui -S Date Signed: 03-02-2026 09:10:23	3/2/2026

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."