DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	9/2/2025-9/16/2025* FEI NUMBER 3038258929

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lan Luo, M.D, Clinical Investigator

FIRM NAME	STREET ADDRESS
Lan Luo, M.D.	Ocala Cardiovascular Research, 2801 Se 1st Ave Ste 301
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34471-0478	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:
The following observations related to your conduct of protocols (b) (4) and (b) (4).

OBSERVATION 1
An investigation was not conducted in accordance with the signed statement of investigator and investigational plan.

Specifically,

You did not provide adequate oversight to ensure study procedures were conducted in accordance with the protocols, as follows:

Protocol (b) (4)

A. For two (2) of the nine (9) subject records reviewed, randomization and investigational Product (IP) administration was not performed in accordance with the protocol.

1. Subject (b) (6), (b) (7)(C) was randomized outside the Sponsor's Interactive Web Response system (IWRS), was dispensed the wrong IP (b) (4) # (b) (6), (b) (7)(C) at the screening visit on (b) (6), (b) (7)(C). Subject was dosed with the wrong IP (b) (4) on (b) (6), (b) (7)(C)

2. Subject (b) (6), (b) (7)(C) was randomized and received IP before all eligibility criteria for enrollment was confirmed. This subject lacks the laboratory assessment for (b) (4) levels to evaluate exclusion criteria (b) (4) prior to randomization.

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	Chinyere A Asanya, Investigator X Chinyere A Asanya Investigator Signed By: Chinyere A. Asanya -S Date Signed: 09-16-2025 15:02 09	9/16/2025

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B. For six (6) of the nine (9) subject records reviewed, specimens for safety laboratory tests were not collected, or prepared to ensure that valid samples were received and analyzed by the laboratory. Safety laboratory tests were not repeated when the specimens were deemed not suitable for analysis by the laboratory.

Subject	Date of Randomization	Visit/Date	Test/Lab Findings
(b) (6), (b) (7)(C)		Visit 20 (b) (6), (b) (7)(C)	Missing (b) (4) and total (b) (4)
		Visit 24 (b) (6), (b) (7)(C)	Missing (b) (4) and (b) (4) and (b) (4)
		Visit 1 (b) (6), (b) (7)(C)	(b) (4) beyond stability, needed verification before randomization and was not done.
		Visit 16 (b) (6), (b) (7)(C)	Missing (b) (4) and total (b) (4) and (b) (4)
		Visit 20 (b) (6), (b) (7)(C)	Missing (b) (4) Efficacy and safety Labs

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(b) (6), (b) (7)(C)	Visit 16 (b) (6), (b) (7)(C)	Missing (b) (4) and total (b) (4) and (b) (4)
	Visit 20 (b) (6), (b) (7)(C)	Missing (b) (4) Efficacy and safety Labs

Protocol (b) (4)

One (1) out of one (1) subject enrolled and randomized for the study was incorrectly stratified based on triglyceride levels at randomization and treated with (b) (4) doses of IP prior to obtaining baseline safety laboratory assessments, as required per the protocol.

Subject	IP administered	IP administered	IP administered	IP administered	Labs collected
(b) (6), (b) (7)(	Randomization	week (b) (4	week (b) (4	Week (b) (4)	(b) (6), (b) (7)(C)
(b) (6), (b) (7)(C)					
	(b) (4)	(b) (4)	(b) (4)	(b) (4) (b) (4) (b) (4)	

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OBSERVATION 2

Investigational drug disposition records are not adequate with respect to quantity and use by subjects.

Specifically,

You did not provide adequate oversight to ensure proper IP accountability at your site.

Protocol (b) (4)

For six (6) of nine (9) enrolled subjects' records reviewed, the subject visit source was incomplete, and the amount of IP used and/ or returned by the subjects was not documented as in the following examples:

Subject	Visit number	Visit Date	Unused IP Returned
(b) (6), (b) (7)(C)	6	(b) (6), (b) (7)(C)	Not entered
	20		Not entered
	23		Not entered
	18		Not entered
	6		Not entered
	12		Not entered

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Ocala, FL 34471-0478	Clinical Investigator

	18	(b) (6), (b) (7)(C)	Not entered

Protocol (b) (4)

The IP Master Accountability Log for Protocol (b) (4) documented that of (b) (4)(b) (4) received at the site, (b) (4) IP (b) (4) were missing and could not be accounted for.

OBSERVATION 3

Failure to report non-serious adverse events to the sponsor in accordance with the study protocol timetable for reporting.

Specifically,

For Protocol (b) (4) three (3) of the nine (9) subject records reviewed documented adverse events that were unreported/not promptly reported to the Sponsor. Additionally, the adverse events records had incomplete data.

Subject	Adverse Events	Date of Awareness	Event Date	EDC Entry Date
(b) (6), (b) (7)(C)	Weight Loss	13 Aug 2021	Not in source	Unreported
	Loss of Appetite	14 Dec 2021	Not in source	Unreported
	Nausea	Not in source	03 Mar 2022	30 July 2023
	Syncope	Not in source	03 Mar 2022	30 July 2023

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	Abdominal Pain	Not in source	03 Mar 2022	30 July 2023
	Vomiting	Not in source	03 Mar 2022	30 July 2023
	Nausea	Not in source	25 Mar 2022	30 July 2023
	Syncope	Not in source	25 Mar 2022	30 July 2023
	Abdominal Pain	Not in source	25 Mar 2022	30 July 2023
	Vomiting	Not in source	25 Mar 2022	30 July 2023
(b) (6), (b) (7)(C)	Fatigue	Not in source	15 Nov 2021	08 Aug 2024
	Nausea	Not in source	16 Nov 2021	08 Aug 2024
	Breast Cancer	Not in source	08 Jul 2024	08 Aug 2024

OBSERVATION 4

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

Specifically,

Protocol (b) (4)

A. For at least six (6) of the nine (9) subjects' records reviewed, data entry was incomplete, non-contemporaneous, and often were not attributable to the person who performed the task. Some examples are:

Subject	Visit	Visit Date	Incomplete or missing information

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(b) (6), (b) (7)(C)		(b) (6), (b) (7)(C)	
	Visit 16		Missing information for concomitant medication
	Visit 18		Missing information for dispensed study drug
	Visit 3		Subject visit note is not attributable to the person who performed the task (no name or signature).
	Visit 14		Missing information for dispensed study drug
	Visit 9		Visit note is not attributable to the person who performed the task.
	Visit 15		duplicate source records for this visit
	Visit 5 – visit 18		No visit records

B. For of seven (7) of the nine (9) Individual Subject Investigational Drug Accountability Logs reviewed as source had incomplete or missing data in respect to IP use and return.

Subject records (b) (6), (b) (7)(C)

C. For at least three (3) of the nine (9) subjects reviewed that were enrolled, randomized and dosed, the documented study visit day does not correspond to source visit dates, IWRS reports and EDC entries. Some examples are:

Subject #	Visit number	IWRS Report Date	Paper Source date	EDC Visit Date

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(b) (6), (b) (7)(C)		(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)
	Visit 18		Changed to visit 19 on (b) (6), (b) (7)(C) (b) (6), (b) (7)	
	Visit 19		(b) (6), (b) (7)(C) Changed to unscheduled visit	
	Visit 20		(b) (6), (b) (7)(C) Changed to visit 22, no date	
	Visit 26		(b) (6), (b) (7)(C) Changed twice: on 04 Mar 2025 and on 04 Oct 2025	
	Visit 20		(b) (6), (b) (7)(C) changed to (b) (6), (b) (7)(C) on 14 Nov 2024	
	Visit 18		(b) (6), (b) (7)(C) Changed to (b) (4) on 11 Jun 2024. Source records signed on 19 July 2023	
	Visit 19		Changed from visit 18 to visit 19 on 06 Dec 2024.	

***DATES OF INSPECTION**
9/02/2025(Tue), 9/03/2025(Wed), 9/04/2025(Thu), 9/05/2025(Fri), 9/08/2025(Mon), 9/09/2025(Tue), 9/10/2025(Wed), 9/11/2025(Thu), 9/12/2025(Fri), 9/16/2025(Tue)

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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."