DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	2/17/2026-2/24/2026* FEI NUMBER 3041668878

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephane Leung Wai Sang, MD, Clinical Investigator

FIRM NAME	STREET ADDRESS
Stephane Leung Wai Sang, MD	100 Michigan St. NE
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Grand Rapids, MI 49503-2560	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:

OBSERVATION 1

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

Specifically,

A. Adverse events were not reported as required by Protocol Number (b) (4) (b) (4). According to Section 7.3. CRF Completion Schedule, any adverse event-related Case Report Forms (CRFs) should be completed as soon as possible; and all CRFs should be completed within 30 days from the date the subject visit occurred. Additionally, Section 9.1.3. Adverse Event Reporting and Coding states that adverse events will be reported on the appropriate CRF and documented in the subject's permanent medical record from the time of enrollment. For example:

Subject Number	*Adverse Event*	*Discovery Date*
(b) (6), (b) (7)(C)	Ankle Injury	(b) (4)
	Community Acquired Pneumonia	
	Anemia	
	Hyponatremia	
	Hypophosphatemia	

B. For Subject (b) (6), (b) (7)(C) was discovered on (b) (6), (b) (7)(C) prior to discharge. However, a serious adverse event assessment was not documented until 12/3/2025. According to Protocol Number (b) (4). Study-Specific Appendix, (b) (4) a Serious Adverse Events Assessment is required to be made at the discharge evaluation.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Chelsea W Lamm, Investigator

X Chelsea W Lamm Investigator Signed By: CHELSEA W. LAMM - S Date Signed: 02-24-2026 15:26:05

DATE ISSUED
2/24/2026

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***DATES OF INSPECTION**
2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 2/24/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Chelsea W Lamm, Investigator	X Chelsea W Lamm Investigator Signed By: CHELSEA W. LAMM - S Date Signed: 02-24-2026 15:26:05	DATE ISSUED 2/24/2026

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."