DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Building 51 Silver Spring, MD 20993 301-796-3150 Fax:(301)594-1204	9/1/2025-9/4/2025 FEI NUMBER 3009568404

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Frederick J. Raal, Clinical Investigator, PhD, MD

FIRM NAME	STREET ADDRESS
Frederick J. Raal, FCP(SA), PhD, MD	7 York Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Johannesburg, Gauteng, 2193 South Africa	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:
Discrepancies for protocol LIB003-003.

OBSERVATION 1

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

Specifically,

A. (b) (6) out of (b) (6) enrolled, dosed, and completed subjects were missing data in the source document pertinent to the measurement(s) of their injection site reactions (ISRs) reported to the sponsor in the Electronic Data Capture (eDC) system. The following are the affected subjects:

Subject number	Data reported in the Electronic Data Capture (eDC)/electronic case report form (eCRF)	
(b) (6)	Treatment A, Day 1 on 6/22/2020	Erythema - 20mm
		Swelling - 20mm
	Treatment A, Day 1 on 6/22/2020	Erythema - 20mm
		Swelling - 1mm
	Treatment B, Day 1 on	Erythema - 5mm

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Angelica M Chica, Investigator

X Angelica M Chica Investigator Signed By: ANGELICA M. CHICA -S Date Signed: 09-04-2025 06:05:41

DATE ISSUED
9/4/2025

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FIRM NAME Frederick J. Raal, FCP(SA), PhD, MD	STREET ADDRESS 7 York Road
CITY, STATE, ZIP CODE, COUNTRY Johannesburg, Gauteng, 2193 South Africa	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

	2/9/2021	
		Swelling - 1mm
(b) (6)	Treatment B, Week 4 on 2/9/2021	Erythema - 5mm
		Swelling - 1mm

B. Subject (b) (6) who was enrolled, dosed, and completed the study has source data reported to the sponsor in the eDC/eCRF that is not accurately captured in the study visit source record as follows:

- Adverse Event (AE) of UTI (urinary tract infection) is captured on study visit 11/25/2020 with no start or end date. In the AE log/eDC/eCRF this AE has a start date of 11/16/2020 with end date 11/20/2020.

- ISR one out of three is captured in the AE log/eDC/eCRF with a start date of 2/12/2020 and end date of 3/10/2020. These dates are not captured in the study visit source record and there is no corresponding ISR assessment source.

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."