DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/23/2026-2/27/2026
	FEI NUMBER 3015983165

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Wilber W. Su MD, Clinical Investigator

FIRM NAME	STREET ADDRESS
Wilber W. Su, MD	755 E Mcdowell Rd
CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85006-2506	TYPE ESTABLISHMENT INSPECTED 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 according to the signed agreement and investigational plan.

Specifically,

For protocol (b) (4) "(b) (4) ,"

A. Enrollment of Ineligible Subjects

Protocol (b) (4) (Rev C, Rev D and Rev E), Section 7.5, Exclusion criteria 6.b states, "subjects are not eligible if the subject has (b) (4) or (b) (4) as described below…6.b. (b) (4) or (b) (4) based on most recent (b) (4) or (b) (4) performed (b) (4) prior to enrollment.

The following subjects were enrolled into the (b) (4) study despite meeting exclusion criteria 6b

- Subject (b) (6), (b) (7)(C) Enrolled (b) (6), (b) (7)(C): (b) (4) Exam dated (b) (6), (b) (7)(C) states the (b) (4) as (b) (4). Subject (b) (6), (b) was included in the study and underwent (b) (4) procedure on (b) (6), (b) (7)(C)
- Subject (b) (6), (b) (7)(C) Enrolled (b) (6), (b) (7)(C). (b) (4), Exam dated (b) (6), (b) (7)(C), states the (b) (4) as (b) (4) Subject (b) (6), (b) was included in the study and underwent

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jose A Leyva, Investigator	X Jose A Leyva Investigator Signed By: 2004493455 Date Signed: 02-27-2026 10:56:36	2/27/2026

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(b) (4) procedure on (b) (6), (b) (7)(C)

B. Incomplete Baseline Assessment and Enrollment

Protocol (b) (4) (Rev C, Rev D, and Rev E), Section 8.4 requires (b) (4) (b) (4) or (b) (4) with measurements including (b) (4) and (b) (4) (b) (4) to be performed within (b) (4) prior to the (b) (4) procedure. Exclusion Criterion 6.b addresses assessment of (b) (4) and (b) (4) to determine eligibility.

The following subjects are missing (b) (4) or (b) (4) measurements in the study source documents:

- Subject (b) (6), (b) (7)(C) Missing (b) (4)
- Subject (b) (6), (b) (7)(C) Missing (b) (4) (b) (4)
- Subject (b) (6), (b) (7)(C) Missing
- Subject (b) (6), (b) (7)(C) Missing
- Subject (b) (6), (b) (7)(C) Missing
- Subject (b) (6), (b) (7)(C) Missing
- Subject (b) (6), (b) (7)(C) Missing
- Subject (b) (6), (b) (7)(C) Missing
- Subject (b) (6), (b) (7)(C) Missing

(b) (4)

Without both (b) (4) measurements, complete verification of Exclusion Criterion 6.b compliance cannot be confirmed.

C. Protocol Deviations Not Documented

The exclusion criteria observations for Subject (b) (6), (b) (7)(C) and Subject (b) (6), (b) (7)(C) were not

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documented in the protocol deviation log as deviations from the investigational plan.

The missing (b) (4) or (b) (4) measurements for the nine subjects were not documented as protocol deviations or as data collection failures.

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."