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	3/9/2026-3/13/2026
	FEI NUMBER 3042366712

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey R. Hoodin, M.D., Principal Investigator

FIRM NAME	STREET ADDRESS
Jeffrey R. Hoodin, M.D.	11011 S 48th St Ste 108
CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85044-1787	TYPE ESTABLISHMENT INSPECTED CI

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 WE OBSERVED:
OBSERVATION 1
Failure to prepare or maintain adequate and accurate case histories with respect to observations and data pertinent to the investigation.

As the Principal Investigator for the study protocol (b) (4) you failed to prepare and maintain adequate and accurate case histories recording all observations and other data pertinent to the investigation for each enrolled subject.

Specifically,

1. Per Protocol (b) (4) questionnaires must be reviewed by the investigator at the time of each visit. Review of the (b) (4) assessment audit trail history report from (b) (4) (Electronic Clinical Outcome Assessments) revealed that study coordinators administered and reviewed a total of 76 (b) (4) assessments. These study coordinators were neither the investigator nor delegated on the site delegation log to perform investigator reviews of (b) (4) assessments.
   - You stated on March 12, 2026 that prior to May 1, 2025 you administered (b) (4) questionnaires under multiple study coordinators login credentials because you did not have (b) (4) access.
   - After being granted (b) (4) access on May 1, 2025, audit trail history revealed multiple study coordinators continued administering (b) (4) assessments on 12 separate occasions.

   These practices constitute a failure to comply with the protocol requirement that (b) (4) questionnaires must be reviewed by the investigator at the time of each visit.

2. The study records contain conflicting and irreconcilable accounts regarding whether a (b) (4) procedure was performed on Subject #(b) (6), (b) (7)(C) These discrepancies demonstrate inadequate documentation of procedures actually performed, inaccurate and inconsistent record-keeping, and failure to maintain records that would enable accurate reconstruction of study conduct.

   Timeline of Conflicting Documentation Regarding (b) (4) Procedure Performance:

   a) **Site's Response to Sponsor Dated April 21, 2025**: You stated in your letter, it was verbalized to the CRA that subject #(b) (6), (b) (7)(C) underwent the (b) (4) procedure without providing informed consent. In this letter, you acknowledged that the (b) (4) procedure was performed, that the subject used the equipment, that study staff failed to collect the required

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lan T Tran, Investigator Andra Lepnis, Investigator	X Lan T Tran Investigator Signed By: 2003788887 Date Signed: 03-13-2026 08:02:04	3/13/2026

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consent, and that the subject subsequently declined to participate in the (b) (4) procedure.

b) **Site's Response to Sponsor Dated May 21, 2025**: You stated that the (b) (4) procedure was performed under the assumption that the general study consent covered this procedure. You further acknowledged that it was later clarified that a separate consent form was required for the (b) (4) procedure.

c) **Site's Note-to-File Dated August 07, 2025**: You documented that all enrolled subjects were offered to participate in the (b) (4) Consent Addendum, but all subjects declined.

d) **FDA Inspection (March 09, 2026 to 11-Mach 12, 2026)**: When questioned on March 10, 2026 and again on March 11, 2026, you denied having (b) (4) equipment at the site and denied performing the (b) (4) procedure on any subject.

These contradictory statements across multiple documented communications demonstrate a failure to maintain adequate and accurate records as required by applicable regulations.

3. **Subject** (b) (6), (b) (7) (C) - The case history contains contradictory documentation regarding the timing and completion of inclusion/exclusion criteria assessments:

a) (b) (4) **Documentation:**
- On (b) (6), (b) (7)(C) (screening visit), the study coordinator disabled the inclusion/exclusion criteria questions in (b) (4), with no results recorded.
- All entries remained marked as "(disabled)" until February 4, 2025, when they were "(enabled)" and responses of "Yes," "No," or "N/A" were entered.
- You electronically signed the Inclusion/Exclusion document on February 4, 2025.

b) **Timeline Inconsistencies:**
- The subject was randomized on (b) (6), (b) (7)(C), despite incomplete inclusion/exclusion criteria documentation.
- Laboratory results were documented as reviewed by you on November 19, 2024.
- A separate electronic signature dated November 11, 2024, indicates you reviewed and agreed with all inclusion/exclusion criteria prior to reviewing the laboratory results necessary for eligibility determination.

c) **Critical Data Gap:**
- At the time of your November 11, 2024 electronic signature, laboratory results required for eligibility determination—including (b) (4) —were still pending central laboratory review and had not been received.

4. **Subject** (b) (6), (b) (7) (C) - The case history contains incomplete and retrospectively completed documentation of inclusion/exclusion criteria:

a) **Delayed Documentation of Eligibility Criteria:**
- On (b) (6), (b) (7)(C) (screening visit), the study coordinator disabled the inclusion/exclusion criteria

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questions in (b) (4) with no results recorded.
- All entries remained marked as "(disabled)" for 54 days until January 14, 2025, when they were "(enabled)" and responses of "Yes," "No," or "N/A" were entered.
- Subject was randomized on (b) (6), (b) (7)(C) before signing off on the Inclusion/Exclusion on January 14, 2025.

5. **Subject** (b) (6), (b) (7)(C) - Medical records were not adequately reviewed and verified prior to enrollment to confirm eligibility:

   a. **Failure to Verify Eligibility Prior to Enrollment**: The subject was enrolled on (b) (6), (b) (7)(C), prior to documented verification of medical records to confirm compliance with eligibility criteria #42, which requires a (b) (4) The subject's medical records were signed as being reviewed November 22, 2024, after the subject's enrollment on (b) (6), (b) (7)(C).

   b. **Inadequate Documentation of Prior Medication Washout**: Subject was randomized (b) (6), (b) (7)(C). A progress note documented by a study coordinator on August 14, 2025 in (b) (4) states "(b) (4) (b) (4)" There is no clear documentation of when stop dates for (b) (4) were verified in either (b) (4) or (b) (4).

OBSERVATION 2
An investigation was not conducted in accordance with the signed statement of investigator and investigational plan.

Protocol (b) (4)

You enrolled subjects who did not meet the protocol-specified eligibility criteria.

Specifically,

1. **Enrollment of Ineligible Subjects: Inclusion Criterion #3 - (b) (4) Requirements**

   The protocol requires subjects diagnosed with (b) (4) to have a screening (b) (4) at Visit 1. **Subject** (b) (6), (b) (7)(C) with (b) (4) enrolled on (b) (6), (b) (7)(C), with a screening (b) (4) which is (b) (4) the required minimum of (b) (4)

2. **Failure to Adjust Prohibited Concomitant Medication Per Protocol Requirements**

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You failed to (b) (4) as required by the protocol which requires that (b) (4) at Visit 3 for subjects receiving this medication. **Subject** (b) (6) was taking (b) (4) at screening on (b) (6), (b) (7)(C) . At Visit 3 on (b) (6), (b) (7)(C), the (b) (4) dose was not reduced as required by the protocol.

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Andra Lepnis, Investigator

X Lan T Tran
Investigator
Signed By: 2003788887
Date Signed: 03-13-2026
08:02:04

DATE ISSUED
3/13/2026

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."