DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	4/13/2026-4/27/2026* FEI NUMBER 3011908561

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ghiath M. Mikdadi, M.D., Clinical Investigator

FIRM NAME	STREET ADDRESS
Ghiath M. Mikdadi, M.D.	16033 Doctors Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hammond, LA 70403-1479	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:
Observations included on this form are related to the following clinical trials, (b)(4) abbreviated as (b)(4), and A phase (b)(4) abbreviated as (b)(4)

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

Specifically,

A. Subjects were enrolled in the (b)(4) and (b)(4) studies who did not meet all eligibility criteria for study enrollment. All subjects subsequently received the investigational product (IP).

1. Four out of 13 subjects reviewed of the 32 subjects enrolled in the (b)(4) study did not meet all eligibility criteria.

Subject Number	Eligibility Criterion	Reason Eligibility Not Met	Screening Date	Randomization/First IP Dose Date
(b) (6), (b)	Inclusion	Subject not on (b)(4) at	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)

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EMPLOYEE(S) SIGNATURE
Dana M Klimavicz, Investigator

X Dana M Klimavicz Investigator Signed By: DANA M. KLIMAVICZ Date Signed: 04-27-2026 09:18:50

DATE ISSUED
4/27/2026

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FIRM NAME Ghiath M. Mikdadi, M.D.	STREET ADDRESS 16033 Doctors Blvd
CITY, STATE, ZIP CODE, COUNTRY Hammond, LA 70403-1479	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

	criteria 4	screening		
(b)(6), (b)(7)(C)	Inclusion criteria 4	Subject not on optimized (b)(4) dose for (b)(4)	(b)(4)	
	Inclusion criteria 4, Exclusion Criteria 5	Subject not on (b)(4) at screening. Subject taking exclusionary medication at screening		
	Inclusion criteria 4	Subject not on high intensity (b)(4) (b)(4) dose and did not enter (b)(4) optimization period		

2. Two out of 10 subjects enrolled in the (b)(4) study did not meet all eligibility criteria.

Subject Number	Eligibility Criterion	Reason Eligibility Not Met	Screening Date	Randomization/ First IP Dose Date
(b)(6), (b)(7)(C)	Exclusion 1	Subject was taking exclusionary medication at screening	5/12/25	5/27/25
	Inclusion 7, Exclusion 14	Subject did not meet any option for inclusion 7, systolic blood pressure	2/12/26	3/4/26

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Dana M Klimavicz, Investigator X Dana M Klimavicz Investigator Signed By: DANA M. KLIMAVICZ Date Signed: 04-27-2026 09:18:50	DATE ISSUED 4/27/2026

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		was (b)(4) Hg at Visit 2		

B. (b)(4) laboratory values for subjects in the (b)(4) study were available to blinded staff.

(b)(4) laboratory values for Subject (b)(6), (b) were documented in the Month 27, 12/4/24 visit notes. At this visit, the subject was prescribed a prohibited medication, (b)(4) Study treatment was not discontinued when the prohibited medication was initiated.

***DATES OF INSPECTION**
4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu), 4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed), 4/27/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Dana M Klimavicz, Investigator	X Dana M Klimavicz Investigator Signed By: DANA M. KLIMAVICZ Date Signed: 04-27-2026 09:18:50	4/27/2026

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."