DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	5/18/2026-5/21/2026
	FEI NUMBER 3013994264

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kimball A. Johnson, Principal Investigator

FIRM NAME	STREET ADDRESS
Kimball A. Johnson, M.D.	250 E Ponce De Leon Ave Ste 800
CITY, STATE, ZIP CODE, COUNTRY Decatur, GA 30030-3438	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 WE OBSERVED:
Protocol (b) (4) , "(b) (4)
(b) (4) ."

OBSERVATION 1

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

Specifically, 3 of 4 enrolled subjects received IP doses exceeding protocol-allowed limits, with subject (b) (6), (b) (7)(C) experiencing headache, abdominal pain, and fatigue. This occurred in the following subjects:

Subject ID	Baseline BMI	Maximum Allowed Dose	Visit	Date	Dose Received
(b) (6), (b) (7)(C)		(b) (4)	Visit 10	(b) (6), (b) (7)(C)	(b) (4)
			Visit 11		
			Visit 12		
			Visit 13		
			Visit 14		
			Visit 15		
			Visit 16		
			Visit 17		
			Visit 18		
			Visit 19		
			Visit 20		

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Brandy D Brown, Investigator
Peyton L Sloan, Investigator

X Brandy D Brown Investigator Signed By: BRANDY D. BROWN - S Date Signed: 05-21-2026 11:19:11

DATE ISSUED
5/21/2026

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Decatur, GA 30030-3438	Clinical Investigator

(b) (6), (b) (7)(C) (b) (6), (b) (7)(C) (b) (4) Visit 10 (b) (6), (b) (7)(C) (b) (4)

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Brandy D Brown, Investigator
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X Brandy D Brown
Investigator
Signed By: BRANDY D. BROWN - S
Date Signed: 05-21-2026 11:19:11

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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."