DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	3/30/2026-4/3/2026
	FEI NUMBER 3042222477

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Diana T. Widicus, M.D., Clinical Investigator

FIRM NAME	STREET ADDRESS
Diana T. Widicus, M.D.	1118 W Legacy Pointe Dr
CITY, STATE, ZIP CODE, COUNTRY Springfield, IL 62711-6444	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:
For study protocol (b)(4)

OBSERVATION 1

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

Specifically,

1) Seventeen (17) out of twenty-eight (28) subjects reviewed had inaccurate serious adverse event (SAE) and adverse event (AE) data transcribed from the paper source into the electronic case report form (eCRF). The following are examples of these discrepancies:

Subject ID	AE/SAE Description	Source Document	EDC/Data Listing
(b) (6), (b) (7)(C)	SAE: Metastatic Squamous Cell Carcinoma	Start Date: 6/20/20231	Start Date: 6/20/2023
	SAE: Pathological fracture of spine due to neoplastic disease	Start Date: No start date End Date: 12/12/2023	Start Date: (b) (6), (b) (7)(C) End Date: No End Date
	AE: Low magnesium	End date: 12/20/2023; Outcome: Recovered/Resolved	No end date; Outcome: Not recovered/not resolved

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Vidhi J Jani, Investigator	X Vidhi J Jani Investigator Signed By: 2004378950 Date Signed: 04-06-2026 10:37:27	4/6/2026

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	AE: Pain in right foot	Outcome: Recovering/Resolving	Outcome: Not recovered/Not resolved
	AE: Left shoulder pain	Start: 3/16/2023; End: 3/23/2023	Start: 3/23/2023; End: 3/30/2023
(b) (6), (b) (7)(C)	AE: Low potassium levels	End date: 2/4/2022; Outcome: Recovering/Resolving	No end date; Outcome: Recovering/Resolving
(b) (6), (b) (7)(C)	AE: Heartburn	End date: 4/9/2021; Outcome: Recovered/Resolved	No end date; Outcome: Not recovered/Not resolved
	AE: Rectal Bleeding	End date: 2/18/2025; Outcome: Recovered/Resolved	No end date; Outcome: Not recovered/not resolved
(b) (6), (b) (7)(C)	AE: Depression	End date: 5/20/2022; Outcome: Recovered/Resolved	No end date; Outcome: Not recovered/not resolved
	AE: Right Lower Back Pain	Start date: 2/18/2022	Start date: 2/22/2022
(b) (6), (b) (7)(C)	AE: Second degree heart block, Mobitz type 1	Outcome: Recovering/Resolving	Outcome: Not recovered/not resolved
	AE: Concussion	Severity: Moderate	Severity: Mild
(b) (6), (b) (7)(C)	AE: Lower Respiratory Infection	End date: 11/9/2022	End date: 10/19/2022
	AE: Upper Respiratory Infection	Start date: 1/13/2024	Start date: 1/12/2024
(b) (6), (b) (7)(C)	AE: Vomiting	Outcome: Not recovered/ Not resolved	Outcome: Recovered/ Resolved

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(b) (6), (b) (7)(C)	AE: Shooting pain on face	Start Date: 11/24/2015	Start Date: 11/24/2021
	AE: Diaphragm injury from cardiac ablation	No start date	Start Date: (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C)	AE: Worsening Back Pain	Outcome: Incomplete	Outcome: Not Recovered/ Not Resolved
(b) (6), (b) (7)(C)	AE: Worsening Back Pain	End date: 1/27/2025 Outcome: Recovered/ Resolved	No end date; Outcome: Not recovered/ Not resolved
	AE: Dizziness when standing up	Start date: 5/27/2022	Start date: 2/3/2023

2) End date for SAE related to Kidney Infection for subject (b) (6), (b) (7)(C) was not reported to the sponsor.

3) AE records were not accurately maintained. For instance, four SAEs for subject (b) (6), (b) (7)(C) end dates were initially documented as 2/2/2022. These dates were subsequently crossed out to indicate the SAEs had not ended, with the correction dated 2/2/2022. However, the adverse event form was not initiated until 10/23/2022, approximately 8 months after the documented correction date.

4) The primary efficacy study endpoint, (b)(4) for Subject (b) (6), (b) (7)(C), was missing from the source record.

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	Vidhi J Jani, Investigator X Vidhi J Jani Investigator Signed By: 2004378950 Date Signed: 04-06-2026 10:37:27	4/6/2026

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."