

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

300 River Place, Suite 5900
Detroit, MI 48207
(313) 393-8100 Fax: (313) 393-8139

DATE(S) OF INSPECTION

4/7/2026-4/15/2026*

FEI NUMBER

3043348785

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kristen M. Pettit, Clinical Investigator

FIRM NAME

Kristen M. Pettit, M.D.

STREET ADDRESS

1600 Huron Pkwy

CITY, STATE, ZIP CODE, COUNTRY

Ann Arbor, MI 48109-5001

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 Protocol (b)(4),

OBSERVATION 1

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

Specifically,

(A) Investigational Product Complaints

The study Pharmacy Manual requires the investigator report "a complete description of the product complaint" and provide expiration dates.

Defective investigational product (b)(4) were destroyed at the site pharmacy before the Sponsor could evaluate them:

- (b)(4) (Subject (b)(6), (b)(7)(C)): Destroyed 7/10/2023, reported 10/19/2023
- (b)(4) (Subject (b)(6), (b)(7)(C)): Destroyed 11/25/2024, reported 9/23/2024
- (b)(4) (Subject (b)(6), (b)(7)(C)): Destroyed 10/10/2024, reported 1/3/2025
- (b)(4) (Subject (b)(6), (b)(7)(C)): Destroyed 9/10/2024, reported 1/3/2025

The investigator did not implement procedures to preserve evidence of product defects before destruction. (b)(4) were destroyed at the site and were not returned to Sponsor for investigation. Sponsor closure letters confirm (b)(4) were not received.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Dina A Tallman, Investigator

Dina A Tallman
Investigator
Signed By: DINA A. TALLMAN -S
Date Signed: 04-15-2026
15:37:29

X

DATE ISSUED

4/15/2026

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Product complaint reports were incomplete. Expiration dates were reported as "Unknown Date."

(B) (b)(4) Eligibility Assessment

The primary study efficacy endpoint is (b)(4) eligibility during Weeks (b)(4) (Protocol Amendment 3.1, Section 6.2.1). (b)(4) eligibility is defined as a confirmed (b)(4) (b)(4)% that is (b)(4) percentage points higher than baseline (b)(4), with confirmation required within (b)(4) (Section 9.6.1).

The primary study efficacy endpoint is (b)(4) eligibility during Weeks (b)(4) (Protocol Amendment 3.1, Section 6.2.1). (b)(4) is defined as a confirmed (b)(4) (b)(4)% that is (b)(4) percentage points higher than baseline (b)(4), with confirmation required within (b)(4) (Section 9.6.1).

Subject (b)(6), (b)(7)(C) had (b)(4) values for:

- Week 0 (b)(6), (b)(7)(C): 42.8%
- Week 28 (b)(6), (b)(7)(C): 47.1% (b)(4) percentage points higher than baseline)

No confirmatory (b)(4) test was ordered or performed within the required (b)(4) timeframe.

Subject (b)(6), (b)(7)(C) had (b)(4) values for:

- Week 0 (b)(6), (b)(7)(C): 41.1%
- Week 4 (b)(6), (b)(7)(C): 45.5% (b)(4) percentage points higher than baseline)
- Week 16 (b)(6), (b)(7)(C): 45.0% (b)(4) percentage points higher than baseline)
-

No confirmatory (b)(4) tests were ordered or performed within the required (b)(4) timeframe for either Week (b)(4) or Week (b)(4) values.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Dina A Tallman, Investigator	Dina A Tallman Investigator Signed By: DINA A. TALLMAN -S Date Signed: 04-15-2026 15:37:29 X	DATE ISSUED 4/15/2026

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(C) Incorrect Randomization Stratification

The protocol requires subjects be stratified by (b)(4) at randomization. Two of eleven subjects (18%) were incorrectly stratified at randomization:

(1) **Subject** (b)(6), (b)(7)(C) was mis-stratified as " (b)(4) + (b)(4) " during randomization on (b)(6), (b)(7)(C). Although medical records from (b)(4) confirm (b)(4) was discontinued in January 2022, the subject was not correctly assigned to the " (b)(4) only" stratum.

(2) **Subject** (b)(6), (b)(7)(C) was mis-stratified as " (b)(4) only" on (b)(6), (b)(7)(C). Despite an active prescription and medical records confirming continuous (b)(4) since age (b)(4) (b)(4) incorrectly recorded no prior cytoreductive therapy. The actual therapy was " (b)(4) + (b)(4) "

(D) Failure to Follow Protocol-Mandated Subject Withdrawal Criteria

Subject (b)(6), (b)(7)(C) met protocol-mandated withdrawal criteria (b)(4) from baseline, confirmed at 8 weeks per Protocol Amendment 5, Section 8.3.2), but continued study treatment.

Week 36 (b)(6), (b)(7)(C): (b)(4) (b)(4) (baseline: (b)(4))
Week 44 (b)(6), (b)(7)(C): (b)(4) (b)(4) - Persistent at (b)(4) weeks

A progress note by the CI dated (b)(6), (b)(7)(C) does not document the elevated (b)(4), withdrawal criteria, or decision to continue treatment. Justification was documented retrospectively by the physician assistant (PA) on 3/31/2025 (85 days later).

OBSERVATION 2

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

Specifically,

For **Subject** (b) (6), (b) (7)(C), concomitant medication data entered into the electronic data capture (EDC) system was inaccurate.

EDC Entry Period	EDC Frequency	Actual Frequency per source records
9/11/2023 - 4/22/2024	(b)(4)	
4/22/2024 - 8/20/2024		

The primary efficacy endpoint assessment period (Week (b)(4), ending 10/9/2023) falls within the 9/11/2023 - 4/22/2024 EDC entry period. Based on the inaccurate EDC data, Subject (b) (6), (b) (7)(C) was erroneously classified as a non-responder for the primary efficacy endpoint (Criterion 9: (b)(4)). The CI electronically signed the primary efficacy analysis on 2/20/2025.

***DATES OF INSPECTION**

4/07/2026(Tue), 4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/15/2026(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Dina A Tallman, Investigator	Dina A Tallman Investigator Signed By: DINA A. TALLMAN -S Date Signed: 04-15-2026 15:37:29 X	DATE ISSUED 4/15/2026

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."