DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	4/27/2026-4/30/2026
	FEI NUMBER 3043129636

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Prithviraj Bose, MD, Clinical Investigator

FIRM NAME	STREET ADDRESS
Prithviraj Bose, M.D.	M.D. Anderson Cancer Center, Department Of Leukemia, Unit 428, 1515 Holcombe Blvd
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77030-4009	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 Study (b) (4) a review of 5 of 5 randomized subjects revealed the following:

OBSERVATION 1

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

Specifically, you did not ensure that all subjects met eligibility criteria before randomization in the study.

a. Subject (b) (6), (b) (7)(C) did not meet Inclusion Criteria #2, which requires inadequate control of (b) (4) defined as a (b) (4) total score of (b) (4) after a stable regimen of (b) (4) therapies is established, with no modifications for (b) (4). At the time of screening, this subject was taking (b) (4) on a regular basis and a (b) (4) on an as-needed basis, failing to satisfy the requirement. Despite not meeting this criterion, the subject was randomized into Part 2 of the study and started treatment with the study drug on (b) (6), (b) (7)(C)

b. Subject (b) (6), (b) (7)(C) was determined to be eligible for the study prior to all screening assessment results being available. A screening (b) (4) was not done within the protocol-required screening window. Despite this, the subject was randomized into Part 2 of the study and started

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Terri E Gibson, Investigator	X Terri E Gibson Investigator Signed By: Terri E. Gibson -S Date Signed: 04-30-2026 16:14:10	4/30/2026

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treatment with the study drug on (b) (6), (b) (7)(C)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Terri E Gibson, Investigator

X Terri E Gibson
Investigator
Signed By: Terri E. Gibson -S
Date Signed: 04-30-2026
16:14:10

DATE ISSUED
4/30/2026

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."