DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	10/28/2024-11/1/2024
	FEI NUMBER 3016888173

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Naren S. Kadaba, VP of Manufacutring and Site Head

FIRM NAME	STREET ADDRESS
Kite Pharma, Inc.	9021 Bennett Creek Blvd
CITY, STATE, ZIP CODE, COUNTRY Frederick, MD 21704-7639	TYPE ESTABLISHMENT INSPECTED Finished Product Drug Manufacturer

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:

OBSERVATION 1

All adverse experiences were not reported within 15 calendar day of initial receipt of the information.

Specifically,
From 04 MARCH 2022 through 14 OCTOBER 2024, 11 serious and unexpected adverse experiences were not reported to FDA within 15 calendar days of initial receipt of the information. These adverse experiences were reported to FDA from 17 to 159 calendar days of initial receipt of the information, including the following adverse experiences:

Case Number	Initial Date Received by Manufacturer	Date of Submission	Date Between Initial Receipt to Submission
(b)(4)		May 12, 2023	39
		April 26, 2023	21
		April 26, 2023	21
		June 8, 2023	28
		July 5, 2023	56
		August 18, 2023	17
		October 27, 2023	31
		January 19, 2024	33
		August 7, 2024	48
		April 2, 2024	47

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Peng Zhou, Investigator
Richard L Bartlett, Investigator
Lizaida Perez, Investigator

X Peng Zhou Investigator Signed By: 2002104695 Date Signed: 11-01-2024 18:00:37

DATE ISSUED
11/1/2024

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Frederick, MD 21704-7639	Finished Product Drug Manufacturer

(b)(4)	May 20, 2024	159

X Richard L Bartlett
Investigator
Signed By: Richard L. Bartlett -S
Date Signed: 11-01-2024 18:01:25

X Lizaida Perez
Investigator
Signed By: 2004213019
Date Signed: 11-01-2024 18:02:07

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Peng Zhou, Investigator
Richard L Bartlett, Investigator
Lizaida Perez, Investigator

X Peng Zhou
Investigator
Signed By: 2002104595
Date Signed: 11-01-2024
18:00:37

DATE ISSUED
11/1/2024

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."