DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	2/9/2026-2/17/2026*
	FEI NUMBER 3028672933

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Erica C. Forsyth, Executive Director, Clinical Operations

FIRM NAME	STREET ADDRESS
BeOne Medicines USA, Inc.	311 Pennington Rocky Hill Road, Building 51
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pennington, NJ 08534-2130	Corporate Office

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:

OBSERVATION 1

Failure to ensure the study is conducted in accordance with the protocol and/or investigational plan.

Specifically,

Subject [redacted] (b) (6) was enrolled into Study [redacted] (b) (4) on July 20, 2023 without the testing of the subject's viral hepatitis C serologic markers at screening, per Protocol Amendment 1.0, Section 6.12.6, Hepatitis B and C Eligibility Testing. The protocol's Exclusion Criterion #8b requires a confirmation of hepatitis C status prior to enrollment, however, Subject [redacted] (b) (6) 's hepatitis C testing was not performed until August 9, 2023, twenty days after Subject enrollment into the study and administration of investigational product.

Subject [redacted] (b) (6) 's consent, required by country-specific laws, to ship the subject's fresh tumor biopsy was not obtained by the clinical site and as such, the subject's biopsy was never shipped to a central laboratory to confirm the pathology diagnosis of [redacted] (b) (4) per Protocol Amendment 2.0, Section 6.9.1, Sample Collection Guidance. Subject [redacted] (b) (6) 's fresh tumor biopsy was collected on December 20, 2023, the subject was enrolled and administered the investigational product on January 2, 2024, and died on [redacted] (b) (6) post-enrollment.

*DATES OF INSPECTION

2/09/2026(Mon), 2/10/2026(Tue), 2/11/2026(Wed), 2/12/2026(Thu), 2/13/2026(Fri), 2/17/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jay B Shah, Investigator X Jay B Shah Investigator Signed By: 2003178113 Date Signed: 02-17-2026 16:10:52	2/17/2026

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EMPLOYEE(S) SIGNATURE

Jay B Shah, Investigator

X Jay B Shah
Investigator
Signed By: 2003178113
Date Signed: 02-17-2026
16:10:52

DATE ISSUED
2/17/2026

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."