DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place. Suite 5900 Detroit, MI 48207 (313) 393-8100	01/28/2026 - 02/24/2026* FEI NUMBER 3030530655

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kevin Rosenthal, Vice President, Site Head.	
FIRM NAME RayzeBio, Inc	STREET ADDRESS 5850 W. 80th Street
CITY, STATE, ZIP CODE, COUNTRY Indianapolis, IN 46278	TYPE ESTABLISHMENT INSPECTED 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

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. Your firm's procedure SOP-00013 ("Batch Review and Release Process," v. 5, effective 10/31/2025) for shipping drug products under quarantine is inadequate. The procedure allows shipment of sterile injectable drug products to end customers before the completion of analytical tests and quality review of batch manufacturing records, but it does not specify the steps to be taken if the product fails to meet finished product quality specification(s). This procedure does not ensure the quality of products prior to distribution.

B. Your firm lacked a procedure for recalls that details the steps to follow, within the shelf life of the products, in the case of batch failures due to analytical test failures or manufacturing deviations.

C. Per SOP-00012 ("Corrective and Preventive Action (CAPA) Handling," v. 2, effective 04/14/2025), Quality Assurance (QA) is responsible for tracking CAPA quality events, and CAPA due dates can be extended during the Implementation phase with appropriate justification. A review of the firm's list of CAPAs revealed that many remain open past their due dates without justification. For example:

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1. CAPA-00217 was initiated to address missed pipettes calibration. CAPA-00217 was opened on 08/11/2025 to verify that pipettes were either calibrated or retired and to assess the need for a process change surrounding the calibration of pipettes. Neither action was performed, and CAPA-00217 remains open without a justification with a past due date of 11/14/2025.

2. CAPA-00218 was initiated 08/13/2025 to address overdue calibration work orders, have overdue equipment calibrated, and the calibration work order documentation completed. CAPA-00218 remains open without justification and has a past due date of 10/31/2025.

3. CAPA-00222 was initiated on 08/18/2025 to address overdue maintenance work orders, including overdue schedules for (b) (4) , and (b) (4) preventive maintenance (PM) for HVAC equipment PM work orders; (b) (4) system (b) (4) in Suite (b) (4) and Suite (b) (4); refrigerators, freezers, incubators, and stability chambers in micro and analytical labs; and BSCs and fume hoods in QC micro/sterility and production rooms. CAPA-00222 remains open without justification and has a past due date of 11/30/2025.

4. CAPA-00215 was initiated on 08/08/2025 to activate all freezer and refrigerator assets and their associated PM schedules active in the (b) (4) (b) (4) . This CAPA was initiated following the failure to perform preventative maintenance for freezers and refrigerators per the recommended frequency. CAPA-00215 remains open without justification and has a past due date of 09/12/2025.

5. CAPA-00214 was initiated on 08/08/2025 to have all HVAC assets and their associated PM schedules active in the (b) (4) . CAPA-00214 remains open without justification and has a past due date of 09/12/2025.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed. Such procedures shall include validation of all aseptic and sterilization processes.

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Specifically,

A. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the aseptic process. Your firm failed to provide supportive data for the initial validation of the process confirmation batches. For example:

1. Per the firm's procedure SOP-00155 ("Aseptic Process Simulations (Media Fills)," v. 1, effective 05/28/2025), for initial validation, a minimum of (b) (4) successful media fills are required to consider the line aseptically validated. Your firm claims the process is validated in Suite (b) (4); however, your firm failed to validate a minimum of (b) (4) (b) (4) successful media fills in Suite (b) (4) as described in the following table:

Media Fill Batch Number	Date Performed	Media Fill Result
(b) (4)	(b) (4)	Invalidated
		Pass
		Pass
		Invalidated
		Pass
		Pass
		Invalidated
		Pass
		Pass
		Invalidated

2. The firm's validation master plan (Document# TD-00001, "Indianapolis Site Validation Master Plan," version 4, effective 05/13/2025) claims validated media fill parameters for worst-case conditions that lack supporting data from media fill runs in manufacturing Suites (b) (4) and (b) (4). The Validation Master Plan stated the following parameters: (b) (4)-vial batch size, (b) (4) (b) (4) vial size, (b) (4) fill volume, (b) (4) clean hold time, (b) (4) filling time, and (b) (4) (b) (4) aseptic processing time. However, these parameters were not demonstrated in the actual media fill runs performed as described below:

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a. For Suite (b)(4) (Room (b)(4)) process confirmation batches:
   - Media fill (b)(4), performed on (b)(4) had a (b)(4) fill time
   - Media fill (b)(4), performed on (b)(4), had a batch size of (b)(4) vials, a (b)(4) clean hold time, a (b)(4) filling (dispensing) time, and a (b)(4) aseptic processing time.
   - Media fill (b)(4), performed on (b)(4), had a (b)(4) final product vial size, a (b)(4) fill volume, and a (b)(4) clean hold time.

b. For Suite (b)(4) (Room (b)(4)) process confirmation batches:
   - Media fill (b)(4), performed on (b)(4), had a (b)(4) final product vial size, a (b)(4) and (b)(4) fill volume, a (b)(4) clean hold time, a (b)(4) filling (dispensing) time, and a (b)(4) aseptic processing time.
   - Media fill (b)(4), performed on (b)(4), had a (b)(4) (b)(4) clean hold time.
   - Media fill (b)(4), performed on (b)(4), had a (b)(4) final product vial size, and a (b)(4) fill volume

B. **The following observations were made during review of the most current smoke study (air flow visualization):**

1. The following activities were not evaluated during the smoke studies for vial filling in Suite (b)(4): the drug product bulk transfer from the Formulation Chamber ((b)(4)) to the Dispensing/Filling Chamber ((b)(4)) and the final product vial transfer from (b)(4) to (b)(4) Chamber (b)(4).
2. The smoke study was not performed in (b)(4) Chamber (b)(4) and (b)(4) Chamber (b)(4), both of which have an ISO 5 classification.

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3. Operators did not move slowly and deliberately. Rapid operator movements within the aseptic area were observed in both the smoke study videos and routine production operations.
4. Assessment of the inside surfaces of the (b) (4) in Suite (b) (4) and Suite (b) (4) could not be made because your firm placed (b) (4) on the interior walls, preventing evaluation of the (b) (4) walls' state of repair, presence of scratches, and air flow assessment at the bottom.

C. Your firm lacks post-batch cleaning procedures to prevent contamination. SOP-00098 ("Cleaning Procedure: (b) (4) ISO 5 (b) (4) ," v2, effective 04/11/2025) requires only pre-batch cleaning of the (b) (4) (ISO 5) and production room (ISO 7). Batch records confirm no post-batch cleaning is performed. No risk assessment or justification supports this practice.

D. On 02/02/2026, during the set-up and aseptic fill for (b) (4) lot (b) (4) , in Suite (b) (4) (Room (b) (4), we observed the following:

1. During cleaning and set-up, production operators were observed donning non-sterile coveralls and non-sterile head hoods. Operators opened the (b) (4) (both the Formulation Chamber and the Filling/Dispensing Chamber) and leaned their upper bodies inside to clean the back wall.

2. Operators did not consistently follow unidirectional wiping as required by SOP-00098 (v2, effective 04/11/2025), which specifies wiping vertical surfaces from (b) (4) . Instead, operators were observed wiping in multiple directions, including (b) (4) and (b) (4) (b) (4)

3. Operators did not move slowly and deliberately. Rapid operator movements within the aseptic area were observed.
4. During aseptic fill, aseptic operators were observed manipulating vials, including removing mis-oriented vials and carrying vials for filling. No forceps are used inside the (b) (4) to

handle vials (empty, being filled, or filled). Only operators' fingertips are monitored, not the rest of the fingers or hands.

5. To open the (b) (4)-chamber door between the Formulation Chamber and (b) (4) Chamber, the operator touched four locations: the (b) (4) Chamber door button to unlock the door, the door handle to manually open it, the other side of the door facing the (b) (4) Chamber, and the tray above the rail to bring material into the formulation chamber. Only the (b) (4) Chamber door button is monitored; the other three locations are not. A similar observation was noted in the smoke studies.

6. Cleaning deficiencies were observed when production operators cleaned the tray and rail system inside the (b) (4) Chamber and (b) (4) Chamber, which by design include hard-to-reach areas.

7. The operator did not clean between the fingers of the (b) (4) for the Filling Main Chamber, while the instructions in the MBR, along with SOP-00098, version 2, effective 04/11/2025, require wiping the entire surface of each (b) (4) to ensure thorough coverage of all areas, including (b) (4).

E. Physical (b) (4) testing is not performed for the (b) (4) for (b) (4) and (b) (4) (b) (4) in the Suite (b) (4) manufacturing line, and (b) (4) and (b) (4) in the Suite (b) (4) manufacturing line. Per SOP-00110 ("(b) (4) Testing," v1, effective 07/08/2025), (b) (4) (b) (4) testing comprises two phases: visual inspection and testing using the (b) (4) (b) (4) testing unit. Additionally, the MBR requires (b) (4) -batch (b) (4) testing. However, (b) (4) are not (b) (4) tested before and after each fill during routine manufacturing.

F. The (b) (4) for (b) (4) and (b) (4) in the Suite (b) (4) manufacturing line, and (b) (4) and (b) (4) in the Suite (b) (4) manufacturing line, were not changed at the frequency specified per SOP-00116, "Operation of (b) (4) ISO 5 (b) (4)," v3, effective

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11/07/2025. The (b) (4) for both Suites (b) (4) and (b) (4) were not replaced during the last three certifications performed in (b) (4), and (b) (4)

G. During packaging operations for (b) (4) lot (b) (4), an operator was observed repeatedly touching the sterile stopper with non-sterile gloves after touching the trash can. The (b) (4) seal is crimped around the stopper from the sides, and the vial lacks a (b) (4) (b) (4) cap.

OBSERVATION 3
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. The firm's environmental monitoring and personnel monitoring procedures are inadequate. For example:

1. Your firm failed to analyze raw Environmental Monitoring data for patterns (e.g., increasing CFUs) that indicate a loss of control in aseptic areas. Data trending is not performed and compiled (b) (4) in accordance with procedures SOP-00044 ("Environmental Monitoring," v1, effective 06/24/2025) and SOP-00191 ("(b) (4) Trending and Reporting").

2. Environmental monitoring points are not scientifically justified or located in critical areas, failing to detect potential sources of contamination. No risk assessment study was performed to define sampling locations and frequencies of monitoring in ISO 5 and ISO 7 areas.

3. The Formulation (b) (4) Chamber and Dispensing (b) (4) Chamber were qualified with ISO 5 classification during Installation and Operational Qualification for Suite (b) (4) and Suite (b) (4) (b) (4) ISO 5 (b) (4). However, your environmental monitoring program monitors these two (b) (4) chambers as ISO 6 areas without adequate justification.

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4. On February 2, 2026, during aseptic fill operations for lot (b) (4) in Suite (b) (4) (Room (b) (4)), an operator touched four locations when transferring material between the (b) (4) Chamber and the Formulation Chamber: the (b) (4) Chamber door button (monitored), the door handle, the door's (b) (4) chamber-facing side, and the tray above the rail where the operator pulled the tray (all three unmonitored). This practice was also observed during smoke studies.

5. There is no personnel monitoring occurring above the shoulders, although aseptic operators were observed during set up activities leaning inside the aseptic formulation and filling chambers from their waist up to their head.

6. On February 2, 2026, during aseptic fill operations for lot (b) (4) in Suite (b) (4) (Room (b) (4)), the operators' fingertips were sampled without (b) (4) the finger as required by the firm's procedure SOP-00043 ("Viable Surface Testing", v 1, effective 06/24/2025).

7. The firm does not monitor the inside of ISO 7 cleanroom transfer carts used for carrying (b) (4) Materials (b) (4) that are loaded into the (b) (4) Formulation (b) (4) Chamber and (b) (4) Materials (b) (4) that are loaded into the (b) (4) Dispensing (b) (4) Chamber.

B. Your firm failed to perform periodic review of quality impactful alarms. Between 08/26/2024 and 03/21/2025, your facility reported 19,463 differential pressure, temperature and humidity alarms. Below are alarms from 03/10/2025 to 03/21/2025 only:

Alarm Type	# of alarms	Area
Differential Pressure (DP)	227	▪ Rooms (b) (4) (ISO7-ISO8) ▪ Rooms (b) (4) (ISO8-(b) (4)
Humidity and Temperature	38	▪ (b) (4) chamber (b) (4) Suite (b) (4) ▪ Suite (b) (4)
Humidity	38	▪ QC Micro Lab
	38	▪ QC Analytical Lab

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Alarm Type	# of alarms	Area
	38	▪ Packaging and Labeling Room ▪ Receiving Warehouse (b) (4) Room ▪ Receiving Warehouse (b) (4) Room ▪ Shipping Warehouse (b) (4) Room ▪ Shipping Warehouse (b) (4) Room

DEV-00117 (initiated on January 29, 2025, and closed on March 31, 2025) was created to revise Alarm Management SOP-00209 to include a Quality Impactful Alarm Periodic Review requirement. Deviation DEV-00183 (initiated on May 20, 2025, and closed on August 1, 2025) was created for failure to perform the (b) (4) alarm management review. SOP-00209 was not updated until December 16, 2025.
Additionally, CAPA-00106 and CAPA-00201 were initiated on December 9, 2024, and July 22, 2025, respectively, to address environmental monitoring alarms and procedural gaps. Both CAPAs remain open.

To date, no periodic review of quality impactful alarms has been performed.

C. The firm's procedure SOP-00195, "Cleanroom Certification," v 0, effective 04/11/2025, defines the ACPH Acceptance Criteria for ISO 7 rooms as (b) (4) and for ISO 8 rooms as (b) (4) and defines the Differential Pressure (Water Column) Acceptance Criteria for all cleanrooms as (b) (4) inches water column. Upon review of the 06/19/2025 cleanroom certification, the following four classified rooms were found to have failed to meet SOP-00195 criteria for differential pressure (DP) and/or air changes per hour (ACPH):

- Room (b) (4) (Sterility Room, ISO 7): 35 ACPH
- Room (b) (4) (Production Exit Corridor, ISO 7): 28 ACPH
- Room (b) (4) (De-Gowning Room, ISO 8): 16 ACPH, 0.008 inches water column
- Room (b) (4) (Waste (b) (4) , ISO 8): 19 ACPH, 0.021 inches water column

Your firm attributed the failure in Room (b) (4) (ISO 7) to a (b) (4) barrier but did not retest until the 12/10/2025 certification. For Rooms (b) (4) and (b) (4), your firm used different, scientifically unsupported ISO acceptance criteria (as evidenced by the Investigation Report Dev-00207, initiated 07/07/2025) and claimed the values were acceptable without justification.
Additionally, CAPA-00227 (initiated 08/21/2025) referenced USP <797> acceptance criteria and required updating SOP-00195 (version 0, effective 04/11/2025) with new criteria. However, SOP-00195 was not updated, and a scientifically unsupported ISO acceptance criteria were reused in the 12/10/2025 Cleanrooms Certification.

D. Your firm failed to initially qualify the ISO 5 Biological Safety Cabinet (BSC, (b) (4)) that hosts all sterility testing performed by the firm in Room (b) (4). Additionally, the firm failed to perform certification for the BSC during (b) (4) and (b) (4) as required by the firm's procedure, SOP-00195, titled "Cleanroom Certification," v. 0, effective 04/11/2024. Your Principal Engineer confirmed that the firm relies mainly on the (b) (4) monitoring that is performed during the conduct of sterility testing.

OBSERVATION 4
There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet to any of its specifications

Specifically,

A. A review of the EMPQ (REC-00703, "Environmental Performance Qualification Summary Report," v0, approved 08/23/2024) showed that protocol deviations were inadequately investigated. Protocol Deviation Reports 11-16 identified 14 samples exceeding CFU action limits, totaling 315 CFUs. The Quality Unit failed to adequately investigate and implement corrective actions after identifying the CFUs, determine microorganism sources or trace them to

production operations, and evaluate potential quality impact on sterile drug product manufacturing.

B. A review of the firm's environmental monitoring excursions list (EME (b) (4)) for the period from 05/20/2025 to 01/20/2026 revealed that approximately 55 of 113 EME investigations remain open (37 in ISO 5 areas) without adequate investigation, with many investigations for excursions dating back to 10/06/2025 (n=18) not yet initiated. Multiple batches were released to market with unresolved excursions. For example:

- EME-2025-046: On 11/11/2025, an excursion notification was submitted in response to a personnel monitoring excursion of one (1) CFU (Action limit (b) (4) CFU), sampling date 11/04/2025, following the sterility testing in the Biological Safety Cabinet (ISO 5) in Room (b) (4) for lot (b) (4) and lot (b) (4). To date, no investigation has been initiated in response to this excursion. Both batches, lot (b) (4) (b) (4) and lot (b) (4), were released to the U.S. market.

- EME-2025-053: On 12/22/2025, an excursion notification was submitted in response to a (b) (4) monitoring excursion during the formulation activities of lot (b) (4) (b) (4) in the Formulation Chamber (ISO 5) in Room (b) (4) of one (1) CFU (Action limit (b) (4) CFU), sampling date 12/16/2025. To date, no investigation has been initiated in response to this excursion. Lot (b) (4) was released to the U.S. market.

- EME-2025-055: On 12/26/2025, an excursion notification was submitted in response to a (b) (4) monitoring excursion during the formulation activities of lot (b) (4) (b) (4) in the Formulation Chamber (ISO 5) in Room (b) (4) of one (1) CFU (Action limit (b) (4) CFU), sampling date 12/17/2025. To date, no investigation has been initiated in response to this excursion. Lot (b) (4) was released to the U.S. market.

- EME-2025-056: On 12/26/2025, an excursion notification was submitted in response to a (b) (4) monitoring excursion during the filling activities of lot (b) (4) in

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the Filling/Dispensing Chamber (ISO 5) in Room (b) (4) of one (1) CFU (Action limit (b) (4) CFU), sampling date 12/17/2025. To date, no investigation has been initiated in response to this excursion. Lot (b) (4) was released to the U.S. market.

- EME-2026-002: On 01/14/2026, an excursion notification was submitted in response to a viable active air monitoring excursion during the formulation activities of lot (b) (4) (b) (4) in the Formulation Chamber (ISO 5) in Room (b) (4) of two (2) CFU (Action limit (b) (4) CFU), sampling date 01/05/2026. Lot (b) (4) was rejected; however, no investigation has been initiated in response to this excursion.

OBSERVATION 5

Equipment are not cleaned, maintained, sanitized or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product.

Specifically,

Your firm uses (b) (4) cleaning for (b) (4) ISO 5 (b) (4) in Suite (b) (4) (Room (b) (4)) and Suite (b) (4) (Room (b) (4)) but has not established or validated a decontamination method (e.g., (b) (4) (b) (4) or (b) (4)). The firm's Validation Master Plan (TD-00001, v4, effective 05/13/2025) requires Installation and Operational Qualification (IQ/OQ) for the (b) (4) (b) (4) and (b) (4), referencing change control PC-00089, which was initiated on 03/25/2025 for (b) (4) implementation in ISO 5 spaces. No progress has been made since initiation, and your firm has provided no explanation or justification for failing to implement a validated sterilization method for the (b) (4)

OBSERVATION 6

Your firm failed to provide adequate system for cleaning and disinfecting the room and equipment to produce aseptic condition.

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Specifically,

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions. For example:

A. Your firm has not conducted disinfectant efficacy studies to demonstrate that the disinfectants used (b) (4), and (b) (4) can adequately reduce bioburden from Suite (b) (4) and Suite (b) (4) cleanroom surfaces. The firm failed to perform studies showing these disinfectants effectively inactivate or remove microorganisms (bacteria, fungi, yeast, molds, and bacterial spores) from Grade A surfaces composed of various materials including (b) (4), (b) (4), and (b) (4).

B. Per SOP-00037 ("Aseptic Technique," v0, effective 06/28/2024, section 5.1.4), operators must perform handwashing with antimicrobial soap and water before gowning. However, on 02/02/2026 during gowning observation for lot (b) (4), no sink was present in the Production Gowning Room (Room (b) (4)), and handwashing was not required for ISO 7 area entry. The Senior QA Specialist confirmed that handwashing is not required upon cleanroom entry; operators only apply (b) (4) to hands before donning gloves. Sinks are only available in the kitchen and restrooms.

OBSERVATION 7
Routine calibration of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

On 02/18/2026, I performed a review of your (b) (4) system used for the workflows and activities associated with preventive maintenance (PM) and calibration of equipment in the production and QC laboratory. The review revealed a total of (b) (4)

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FIRM NAME RayzeBio, Inc	STREET ADDRESS 5850 W. 80th Street
CITY, STATE, ZIP CODE, COUNTRY Indianapolis, IN 46278	TYPE ESTABLISHMENT INSPECTED Manufacturer

pipettes ((b)(4) pipettes owned by Production and (b)(4) pipettes owned by QC Analytical) that were overdue for calibration and had passed the allowable grace period of (b) (4) . No work orders had been generated in (b) (4) for the calibration of this equipment. Additionally, no deviation was created for missing the calibration due date (01/31/2026).

OBSERVATION 8
Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

Specifically,

Operators performing 100% manual visual inspection of (b) (4) finished vials lack adequate training per SOP-00134 (Visual Inspection Guidelines, v3, effective 11/21/2025). While the SOP defines three defect classifications (Critical, Major, Minor) covering (b)(4) total defect types including (b)(4) (b)(4) glass container defects, (b) (4) container closure defects, and (b) (4) content defects (with inherent, extrinsic, and intrinsic particulates), the qualification test (b)(4) only includes particulate defects. Operators are not qualified to identify the full range of defects or differentiate between the three particulate types.

OBSERVATION 9
Laboratory records do not include complete records of any testing and standardization of laboratory reference standards.

Specifically,

Your firm did not perform reference standard characterizations of the (b) (4) reference standard used in the final release testing of (b) (4) Your firm uses the reference standard (b) (4)

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place. Suite 5900 Detroit, MI 48207 (313) 393-8100	01/28/2026 - 02/24/2026* FEI NUMBER 3030530655

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Kevin Rosenthal, Vice President, Site Head.

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RayzeBio, Inc	5850 W. 80th Street
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Indianapolis, IN 46278	Manufacturer

(b) (4) lot# (b) (4) to conduct the (b) (4) purity, identity, and (b) (4) concentration determination by HPLC of (b) (4)

OBSERVATION 10

Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality. Your firm also failed to validate and establish the reliability of your component supplier's test analyses at appropriate intervals.

Specifically,

1. Your firm does not conduct identity testing of raw materials used in the production of (b) (4) (b) (4)
2. Your firm does not conduct testing on conformity of containers and closures to ensure that the manufacturer's results are valid and reliable, including sterility of these containers and closures.
3. Your firm has never performed supplier audits on any of the raw materials received at your facility.

OBSERVATION 11

Master production and control records lack a statement of theoretical yield including the maximum and minimum percentages of theoretical yield beyond which investigation is required.

Specifically,

The master batch record for the products (b) (4) Solution for (b) (4) does not have theoretical yield specifications at (b) (4) stage of the dug product.

***DATES OF INSPECTION:**
01/28/2026 (Wed), 01/30/2026 (Fri), 02/02/2026 (Mon), 02/03/2026 (Tue), 02/05/2026 (Thu), 02/06/2026 (Fri), 02/13/2026 (Fri), 02/18/2026 (Wed), 02/24/2026 (Tue).

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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."