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	5/27/2026-6/3/2026*
	FEI NUMBER 3020928491

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Adedayo Akinbi, CEO

FIRM NAME	STREET ADDRESS
Annovex Pharma, Inc.	7403 Lockport Pl Ste C-D
CITY, STATE, ZIP CODE, COUNTRY Lorton, VA 22079-1569	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, your firm failed to ensure that the laminar airflow hoods used for the production of sterile and non-sterile drug products were maintained in a state of adequate control.

During the (b) (4) cleanroom certification conducted on January 28, 2026, all(b) (4) laminar airflow hoods at your facility were found to be operating outside the acceptable airflow velocity range at the time of certification, as documented by the as-found FAIL designation in Certification Report #02647-20260128RT01:

(b) (4)

Your firm did not initiate an investigation or quality related event in response to these findings and did not conduct a product impact assessment for sterile and non-sterile drug products produced in these laminar airflow hoods since the previous (b) (4) certification in July 2025.

~~The following sterile drug products produced in these laminar airflow hoods remain within their assigned beyond use dates and may still be in distribution:~~

- ~~NAD+ (Nicotinamide Adenine Dinucleotide) Injection 200 mg/mL 10 mL fill, Lot~~

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christina K Theodorou, Investigator X Christina K Theodorou Investigator Signed By: CHRISTINA K. THEODOROU -S Date Signed: 06-18-2026 14:33:18	6/18/2026

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~~26.04.00000016 BUD September 19, 2026~~

- ~~NAD+ (Nicotinamide Adenine Dinucleotide) Injection 200 mg/mL 6 mL fill, Lot 6.04.00000011 BUD September 13, 2026~~

OBSERVATION 2

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically, your firm has not conducted annual product reviews for any drug product in your portfolio. Your Quality Assurance Manager confirmed that no annual product reviews have been completed and that the standard operating procedure governing the conduct of annual product reviews has not been approved and remains in draft form.

The following drug products have been in commercial production for more than one year without an annual product review being conducted:

- Lorazepam 0.25 mg/0.125 mL Oral Solution — commercially produced since November 28, 2023 (b) (4) batches to date)
- Lorazepam 0.5 mg/0.25 mL Oral Solution — commercially produced since November 28, 2023 ((b) (4) batches to date)
- Phenylephrine Hydrochloride Injection 0.1 mg/mL — commercially produced since January 29, 2024 ((b) (4) batches to date)

***DATES OF INSPECTION**

5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri), 6/01/2026(Mon), 6/02/2026(Tue), 6/03/2026(Wed)

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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."