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	5/11/2026-5/15/2026
	FEI NUMBER 3012367823

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Xiankai Sun, Director

FIRM NAME	STREET ADDRESS
University of Texas Southwestern Medical Center, The	2201 Inwood Dr
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75235	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer / PET Drug Producer

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

You did not follow procedures to investigate the cause(s) of the nonconforming batch(s) of a PET drug product.

Specifically,

A. A Corrective Action/Preventive Action (CAPA) initiated on May 07, 2019 (CAPA Index Number 0010, documented on Form FA013, Version 2) to address elevated microbial counts in the ISO 7 production room, including the identification of Stenotrophomonas spp., a Gram-negative organism, during active air sampling conducted on May 01, 2019 (b)(4) of Clean Room result: 19 CFU/m³; action level: (b)(4)), has not been formally closed. Specifically, Section 7.0 (Follow-Up) of Form FA013 — which requires the Regulatory Affairs Officer or designee to verify that all corrective and preventive actions were completed and to document whether the event was successfully addressed and recurrence prevented — has not been completed or signed. The form remains unsigned in the Follow-Up section as of the date of this inspection. SOP 029.A013 (CAPA — Corrective Action Preventive Action, Version 2), Section 6.5.13, requires that upon completion of all corrective and preventive actions, the Regulatory Affairs Officer or their designee must verify that all tasks were completed by signing and dating the Follow-Up section.

B. For maintenance batch (b)(4) (manufactured (b)(4)), sterility testing was not initiated, and the failure to initiate sterility testing was not separately investigated. An abnormal occurrence report (Form FA020) was filed on April 20, 2023, documenting that the (b) (4) Chromatograph (b) (4) system suitability failed due to a retention time shift (observed retention time: (b)(4) ; historical retention time: approximately (b)(4)), and that the (b) (4) column had not been changed since 2017. The FA020 documents that a new column was ordered as corrective action. No separate investigation of the failure to initiate sterility testing was conducted, and no corrective or preventive action was documented. SOP 029.A013 (Version 2) states that CAPA procedures apply to all ANDA processes.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Shelby N Turner, Investigator

X Shelby N Turner Investigator Signed By: SHELBY N. TURNER -S Date Signed: 05-15-2026 13:58:50

DATE ISSUED
5/15/2026

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C. The firm's written CAPA procedures (SOP 029.A013, Version 2) do not define the criteria for determining when a CAPA (Form FA013) is required as opposed to an abnormal occurrence or out-of-specification report (Form FA020). The SOP does not contain a documented threshold or decision framework for this distinction. Additionally, no documented basis exists for exempting (b)(4) batches from CAPA requirements under SOP 029.A013. When asked, the Regulatory Affairs Officer acknowledged that no written threshold or policy stating an exemption for (b)(4) batches currently exists in the CAPA SOP.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shelby N Turner, Investigator	X Shelby N Turner Investigator Signed By: SHELBY N. TURNER -S Date Signed: 05-15-2026 13:58:50	5/15/2026

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."