DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	3/10/2025-3/18/2025* FEI NUMBER 3002888623

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gregory Glasier, Head of Site Quality

FIRM NAME	STREET ADDRESS
Sanofi Pasteur Limited	1755 Steeles Ave W
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
North York, Ontario, M2R 3T4	Vaccine 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:

DRUG SUBSTANCE (COMPONENT)

The design of your firm's bioburden sample collection process allows for leaking/spilling of (b) (4) (b) (4) during collection.

On 11 MAR 2025, two operators were observed taking bioburden samples of (b) (4) (b) (4) as it flows through (b) (4) This occurs in a Class (b) (4) environment. (b) (4) was observed leaking profusely from the (b) (4) The (b) (4) another bottle was completed (as required), and leaking occurred as well. An interview of one of the operators revealed that such leaking occurs all the time and occurs for the sampling of (b) (4) as well (b) (4) (b) (4). Both the (b) (4) are used to make sterile (b) (4) which is used for adsorption of a given (b) (4) The (b) (4) is indicated on batch records for batch (b) (4) regarding the manufacturing of Aluminum Phosphate Suspension, (b) (4) but leaking/spilling of (b) (4) is not indicated.

***DATES OF INSPECTION**
3/10/2025(Mon), 3/11/2025(Tue), 3/12/2025(Wed), 3/13/2025(Thu), 3/14/2025(Fri), 3/17/2025(Mon), 3/18/2025(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lewis K Antwi, Investigator Gene D Arcy, Investigator - Team Biologics	X Gene D Arcy Investigator - Team Biologics Signed By: 1300159963 Date Signed: 03-18-2025 10:16:23	3/18/2025

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X Lewis K Antwi
Investigator
Signed By: 2001796124
Date Signed: 03-18-2025 10:17:06

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Lewis K Antwi, Investigator
Gene D Arcy, Investigator - Team Biologics

X Gene D Arcy
Investigator - Team Biologics
Signed By: 1300159963
Date Signed: 03-18-2025
10:16:23

DATE ISSUED
3/18/2025

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."