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 orabioinspectionalcorrespondence@fda.hhs.gov	5/18/2023-5/26/2023* FEI NUMBER 3002806949

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nigel C. Hilton, VP Manufacturing & Site Head

FIRM NAME	STREET ADDRESS
Seqirus Vaccines Limited	Gaskill Road, Liv
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Liverpool, LIV, L24 9GR United Kingdom	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:

1. Failure to conduct investigations into unexplained discrepancies.

   Specifically, during the review of the calibration certificate for the (b) (4)), used for the (b) (4) testing of the (b) (4) for the bulk formulated (b) (4) of Fluad. We observed that the September 2021 Calibration Certificate "As Found" data had not met the acceptance criteria for the (b) (4) measurement (b) (4) acceptance criteria). Your firm failed to follow procedure as documented in DOC-000134669 v8.0 *Execution of Maintenance,* in that quality unit was not notified and no investigation was initiated to determine impact on product since September 2020. Between April 23, 2021 - September 15, 2021, your firm manufactured and shipped (b) (4) formulated bulk FLUAD Quadrivalent batches to the US.

2. Lack of corrective action for trends observed during the (b) (4) Test of the Monovalent Bulk Drug Substance sample (b) (4).

   Specifically,

   There is an ongoing trend of investigations for (b) (4) observed in the (b) (4) sample for (b) (4) of the Fluad Monovalent Bulk Drug Substance for Influenza Vaccine. The investigation into 18 monovalent bulk drug substance batches is investigated under Master Deviation QE000436.

   Per Doc 000166303 V39 Determination of Sample (b) (4), the (b) (4) Test

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lewis K Antwi, Investigator Susan M Jackson, Investigator - Team Biologics	X Susan M Jackson Investigator - Team Biologics Signed By: Susan M. Jackson -S Date Signed: 05-26-2023 10:34:21	5/26/2023

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FIRM NAME Seqirus Vaccines Limited	STREET ADDRESS Gaskill Road, Liv
CITY, STATE, ZIP CODE, COUNTRY Liverpool, LIV, L24 9GR United Kingdom	TYPE ESTABLISHMENT INSPECTED Vaccine Manufacturer

is a release specification for Fluad Monovalent Bulk Influenza Drug Substance. The Monovalent Bulk Drug Substance sample ((b) (4)) must conform to (b) (4)

A. Per the BLA 125510, a criterion was not established and or specified in the approved application for (b) (4) (i.e., (b) (4), (b) (4), & (b) (4) etc.). However, Doc 000077011, Control in the Event of (b) (4) Detected in (b) (4) Containers or Sample Container, identifies, (b) (4) (b) (4) detected during the (b) (4) assay as (b) (4) for the monovalent bulk drug substance.

B. Per Master Deviation Investigation QE000436, sixteen (16) of eighteen (18) batches did not meet your Product Quality Specification per Doc 000188223 v 13 for (b) (4); however, the (b) (4) investigation was classified as minor per Doc 000077011, Control in the Event of (b) (4) in (b) (4) Containers or Sample Container and 16 are within your routine quarantine usage decision (quarantine not due to (b) (4)). Examples of Monovalent Bulk batches are as follows: (b) (4).

C. The root cause (QE-000436) for the (b) (4) in the monovalent bulk drug (b) (4) (b) (4) sample has been attributed to external supplier, specifically the manufacturer of the (b) (4) (b) (4) with (b) (4) containers. The (b) (4) supplier investigation is ongoing, however there is no assurance that the Fluad Monovalent bulk is representative of the Quality Control samples taken for release testing of the monovalent drug substance batches.

The firm continues to use the same supplier of the (b) (4) with (b) (4) containers as cited in the June 2017 FDA 483 for (b) (4). The corrections put in place to respond to the previous corrective action for (b) (4) in (b) (4) sample for (b) (4) have not been effective for the 2023/2024 Northern Hemisphere manufacturing campaign.

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*DATES OF INSPECTION

5/18/2023(Thu), 5/19/2023(Fri), 5/22/2023(Mon), 5/23/2023(Tue), 5/24/2023(Wed), 5/25/2023(Thu), 5/26/2023(Fri)

X Lewis K Antwi
Investigator
Signed By: 2001796124
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EMPLOYEE(S) SIGNATURE
Lewis K Antwi, Investigator
Susan M Jackson, Investigator - Team Biologics

X Susan M Jackson
Investigator - Team Biologics
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Date Signed: 05-26-2023 10:34:21

DATE ISSUED
5/26/2023

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."