DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71-5128 Silver Spring, MD 20993-0002 240-402-8906	5/20/2024-5/24/2024
	FEI NUMBER 3025119430

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shalini S. Iyengar, Clinical Investigator

FIRM NAME	STREET ADDRESS
Shalini Iyengar, MBBS	Hexham General Hospital, Corbridge Road
CITY, STATE, ZIP CODE, COUNTRY Hexham, Northumberland, NE46 1QJ United Kingdom	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

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:
The observation listed on this FORM FDA 483 is related to the GlaxoSmithKline Biologicals SA study protocol 212494 (RSV OA=ADJ-006) entitled, "A Phase 3, randomized, placebo-controlled, observer blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination doses of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above."

OBSERVATION 1
Failure to prepare or maintain adequate and accurate case histories with respect to observations and data pertinent to the investigation.

Specifically, the chain of custody is not fully documented for the (b) (4) samples that were used for the study endpoint for evaluation of vaccine efficacy.

a) You destroyed the (b) (4) Confirmation forms, which documented when the (b) (4) samples would be (b) (4).

b) You failed to maintain (b) (4) documenting the (b) (4) confirmation sent to your staff members who are no longer employed at your site. (b) (4) documentation confirmed the date the (b) (4) would (b) (4) (b) (4) from subjects.

c) For (b) (4) out of (b) (4) "(b) (4) Processing and Shipping Log" records I reviewed, signatures for staff certifying the time (b) (4) were processed, placed into the (b) (4) r, and shipped to the laboratory for analysis appear to vary from the delegation of (b) (4) log. The logs are the only remaining

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kristin M Abaonza, Investigator	X Kristin M Abaonza Investigator Signed By: Kristin M. Abaonza -S Date Signed: 05-24-2024 09 59:38	5/24/2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71-5128 Silver Spring, MD 20993-0002 240-402-8906	5/20/2024-5/24/2024
	FEI NUMBER 3025119430

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shalini S. Iyengar, Clinical Investigator

FIRM NAME	STREET ADDRESS
Shalini Iyengar, MBBS	Hexham General Hospital, Corbridge Road
CITY, STATE, ZIP CODE, COUNTRY Hexham, Northumberland, NE46 1QJ United Kingdom	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

documentation that document chain of custody for the (b) (4) samples prior to shipment.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Kristin M Abaonza, Investigator

Kristin M Abaonza
Investigator
Signed By: Kristin M. Abaonza -S
Date Signed: 05-24-2024
09 59:38
X

DATE ISSUED
5/24/2024

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."