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 orabioinspectionalcorrespondence@fda.hhs.gov	2/26/2024-3/6/2024* FEI NUMBER 3001314775

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Carsten Schneider, Site Head and Managing Director

FIRM NAME	STREET ADDRESS
GSK Vaccines GmbH	Emil-Von-Behring-Str. 76
CITY, STATE, ZIP CODE, COUNTRY Marburg, Hassia, 35041 Germany	TYPE ESTABLISHMENT INSPECTED Licensed biological drug 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:

OBSERVATION 1:

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

a. On 2/26/2024 during (b) (4) operation of MenA Vaccine batch (b) (4) using (b) (4) unit, and after exchanging (b) (4) located approximately (b) (4) vials, the grade (b) (4) operators did not reject the (b) (4) product vials located directly below the intervention. As per your SOP instruction# 9000085445-02, before carrying out a (b) (4) change, the line must be (b) (4) so that there are no vials in the (b) (4). However, the operators did not ensure that the (b) (4) line was (b) (4) to the intervention. In addition, there is not documentation available in the executed batch records to ensure that the operators (b) (4) the (b) (4) lines or reject the (b) (4) product vials (b) (4) the interventions. The firm has used the (b) (4) unit to (b) (4) RabAvert (batch (b) (4), Expiry (b) (4)) and MenA Vaccines (batch (b) (4) and Expiry (b) (4)) for US market.

b. On 3/6/2024, during set up operations of (b) (4) unit for MenA batch (b) (4), I observed the shoulder of Grade (b) (4) operator touch the Grade (b) (4) side of the (b) (4). No sanitization was performed on the Grade (b) (4) side of the (b) (4) before closing the (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Unnee Ranjan, Team Lead Investigator Thai D Truong, Investigator X Unnee Ranjan Team Lead Investigator Signed By: 2001565336 Date Signed: 03-06-2024 19:13:02	3/6/2024

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OBSERVATION 2:

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, investigation related to (b) (4) of Aluminum Hydroxide (b) (4) is not adequate. Aluminum Hydroxide is an adjuvant used for Infanrix, (b) (4), Pediarix, and Boostrix Vaccine products for US market. On 06Apr2023, (b) (4) and (b) (4) were observed on the (b) (4) of (b) (4), which is used for the (b) (4) of Aluminum Hydroxide bulk material (Deviation # 200991257). The root cause was identified as (b) (4) of (b) (4) due to (b) (4) contact with Aluminum Hydroxide suspension. Based on the investigation, you have identified that a contact time of more than (b) (4) can lead to (b) (4) parts. However, the investigation was not extended to other (b) (4) surfaces to re-evaluate the established dirty hold times of 72 hours for fixed equipment, such as but not limited to (b) (4), and (b) (4) for (b) (4) parts, such as not limited to (b) (4) utilized for Aluminum Hydroxide (b) (4) production.

OBSERVATION 3:

Separate or defined areas to prevent mix-ups are deficient.

Specifically, your firm failed to discard and/or transfer (b) (4) materials to a physical quarantine location to prevent the materials being used beyond (b) (4) dates. (b) (4) materials were observed to be stored in your (b) (4) on 2/27/2024. There was no clear demarcation between (b) (4) materials and (b) (4) or (b) (4) materials in your (b) (4). More than (b) (4) material batches (material lots) had been identified that are currently stored at the

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same location with your (b) (4) or (b) (4) materials in your (b) (4).

In addition, your written procedure LSOP-9000056691-12, "Execution of Destructions" requires that, "materials to be destroyed are (b) (4) in room (b) (4)" until physical destruction. There are more than (b) (4) material batches (material lots) identified with status "(b) (4)" that are currently stored in your (b) (4).

OBSERVATION 4:

Documents and (b) (4) used for distribution of the (b) (4) drug products are deficient.

Specifically, your firm failed to ensure correct (b) (4) were applied to (b) (4) drug product containers before release. The final (b) (4) on your containers that hold (b) (4) drug products contain incorrect expiration date. The expiration date on the (b) (4) was not based on the associated stability studies.

Furthermore, your documentations that accompanied with the (b) (4) drug product shipment, including the packing lists, contain incorrect information. The documents do not bear an expiration date determined by the associated stability studies and do not match with the expiration date on the container (b) (4) that hold (b) (4) drug products.

***DATES OF INSPECTION**
2/26/2024(Mon), 2/27/2024(Tue), 2/28/2024(Wed), 2/29/2024(Thu), 3/01/2024(Fri), 3/04/2024(Mon), 3/05/2024(Tue), 3/06/2024(Wed)

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X Thai D Truong
Investigator
Signed By: 0014274389
Date Signed: 03-06-2024 19:13:34

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Unnee Ranjan, Team Lead Investigator
Thai D Truong, Investigator

X Unnee Ranjan
Team Lead Investigator
Signed By: 2001565336
Date Signed: 03-06-2024 19:13:02

DATE ISSUED
3/6/2024

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."