DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER (b) (6) 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: (b) (6) Telephone: (b) (6) Industry Information: www.fda.gov/oc/industry	06/24/2024-06/29/2024, 07/01/2024-07/02/2024 FEI NUMBER 3020223359

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Umesh Shaligram Executive Director, Manufacturing and R&D

FIRM NAME	STREET ADDRESS
Serum Institute of India Pvt. Limited Manjari Site	105-110, Manjari Bk, Pune Zone 3, Maharashtra 412307, India
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Pune, India 411 028	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:

OBSERVATION 1

Requalification of the (b) (4) used to (b) (4) the filling (b) (4) filling line and (b) (4)) where COVID vaccine is filled into syringes is inadequate. Specifically, the maximum load runs performed during re-qualification of the (b) (4) failed your acceptance criterion for observing positive (b) (4) in 2022 and during (b) (4) requalification run in 2023. In addition, positive (b) (4) were found in the same nearby locations during requalification of the (b) (4) of the vial filling line in 2023 and 2024. A thorough investigation was not conducted to identify a root cause of the positive (b) (4) and confirm the ability of your (b) (4) to (b) (4) areas where positive (b) (4) were found.

OBSERVATION 2

With the current acceptance criteria of the (b) (4), there is insufficient data to support that the current cleaning of the (b) (4) can assure no (b) (4) between vaccine products when the same (b) (4) are used in production with different (b) (4).

OBSERVATION 3

There is insufficient data in the (b) (4) validation study to support comparable (b) (4) performance with respect to (b) (4) of (b) (4) for (b) (4) uses of (b) (4) and (b) (4) uses of (b) (4). In addition, the (b) (4) for the (b) (4) (b) (4) was not evaluated in the study. This deficiency was previously identified during the last inspection in April 2022, and you committed to have the completed (b) (4) report by December 31, 2022. However, at the time of this inspection, the study has still not been completed.

OBSERVATION 4

There is a lack of (b) (4) data in the qualification report for (b) (4) reference standard lot # (b) (4). The (b) (4) is used to (b) (4) of this reference standard and serves as supportive information for the (b) (4) for the release of (b) (4) and drug product. Moreover, no investigation was included in the

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qualification report regarding the failure of producing valid test results for (b) (4) for the working (b) (4) reference standard.

OBSERVATION 5

DEV-003-2024-0049 detected on January 29, 2024 indicated a critical defect, (b) (4) (b) (4) was observed during AQL of (b) (4), batch (b) (4). Your firm failed to fully investigate and implement an effective corrective action/preventative action after identifying (b) (4) of (b) (4) for (b) (4) contributed to this critical defect.

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."