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 Attention: (b) (6) Telephone: (b) (6) Industry Information: www.fda.gov/oc/industry	07/10/2023 to 07/18/2023
	FEI NUMBER 3017847976

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jakub Kronovetr, Site Director

FIRM NAME	STREET ADDRESS
Novavax CZ	Bohumil 138
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
281 63 Jevany CZ	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 (I) (WE) OBSERVED:

1. There is inadequate data in the (b) (4) and (b) (4) validation report approved on April 24, 2023 to support the maximum proposed number of (b) (4) uses for the (b) (4) and (b) (4) uses for the (b) (4) used for the (b) (4) of (b) (4). The deficiencies are as follows:
a. The (b) (4) for the (b) (4) was evaluated only up to (b) (4) uses of (b) (4)
b. The critical quality attributes such as (b) (4), (b) (4) and (b) (4) were not evaluated as In-Process Controls for each batch after (b) (4) and only (b) (4) was evaluated for each batch after (b) (4) (b) (4)
c. The (b) (4) and (b) (4) were not evaluated during the (b) (4) of the (b) (4) and (b) (4)
2. There is a lack of data to support the use of (b) (4) reference standard (b) (4) for the potency determination of (b) (4) batches for the (b) (4) and (b) (4) by the (b) (4) method.

3. The proposed maximum holding times for the process intermediates including (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) and (b) (4) have not been validated for the (b) (4) manufacturing process at production scale.

4. Vendor performed Disinfectant efficacy studies failed to include environmental isolates from the facility. Firm provided a disinfectant effective study protocol (b) (4) that will include facility isolates for the study.

(b) (6)
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(b) (6)

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5. Corrective action was not always taken in a timely manner to prevent the repeated recurrence for (b) (4) integrity failures, for example:

(b) (4) used in production process and equipment are currently visually inspected (b) (4) ; however, current visual inspection procedure had failed to prevent multiple (b) (4) integrity failures (A total of 25 deviations related to (b) (4) integrity test failures were reported from August 2021 to April 2023), and CAPA to introduce pre-use (b) (4) integrity test has not been introduced in a timely manner to prevent the re-occurrence of integrity failures.

6. Current procedures for (b) (4) and (b) (4) of (b) (4) are deficient. For example:

No (b) (4) time limit is specified in the procedures for time between (b) (4) product removed from (b) (4) and (b) (4) or (b) (4) In addition, (b) (4) validation to (b) (4) is pending for concurrent validation.

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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 judgement, 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."