DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

MEMORANDUM

Date: April 01, 2025

From: (b) (6)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To: The file: STN 125817/0

Subject: Review of Lot Release Protocol (LRP) Template for COVID-19 Vaccine, Adjuvanted, included in STN 125817/0

Through: (b) (6) /FDA
(b) (6) /CBER/FDA

Applicant: Novavax, Inc.

Product: COVID-19 Vaccine, Adjuvanted
Trade Name: Nuvaxovid

Summary: The LRP template for COVID-19 Vaccine, Adjuvanted, submitted in amendment 125817/0.103 on March 26, 2025, is acceptable for use.

1 General Information

1.1 CMC Review Identifiers and Dates

1.1.1 **Biologics License Application STN:** 125817/0

1.1.2 **Submission received by CBER:** April 01, 2024

1.1.3 **Review completed:** April 01, 2025

1.1.4 **Material Reviewed:** BLA 125817/0

1.1.5 Related Master File, INDs and BLAs: STN 125817/0

2 Review

2.1 Documents Reviewed

The LRP template for COVID-19 Vaccine, Adjuvanted, submitted on April 05, 2024, in amendment 125817/0.4

The LRP template for COVID-19 Vaccine, Adjuvanted, submitted on October 31, 2024, in amendment 125817/0.42

The LRP template for COVID-19 Vaccine, Adjuvanted, submitted on March 05, 2025, in amendment 125817/0.82

The LRP template for COVID-19 Vaccine, Adjuvanted, submitted on March 11, 2025, in amendment 125817/0.88

The LRP template for COVID-19 Vaccine, Adjuvanted, submitted on March 19, 2025, in amendment 125817/0.97

The firm's response for Information Request submitted on March 26, 2025, in amendment 125817/0.103

2.2 Review

An LRP template was not provided with the initial submission on April 01, 2024. An IR was sent by OVRR(b) (6) on April 04, 2024, asking Novavax, Inc. to submit an LRP template. The firm submitted an LRP template on April 05, 2024, in amendment 125817/0.4. The firm proactively submitted an updated LRP template on October 31, 2024, in amendment 125817/0.42. The updated LRP template contained minor changes in the formatting of the tables. The updated LRP template was reviewed by (b) (6) and (b) (6) with

comments on the formatting, and to add endotoxin and sterility test result details using the provided CBER table templates. An IR was sent to the firm on February 27, 2025, to address these comments.

A response was submitted on March 05, 2025, in amendment 125817/0.82. This revised LRP template was reviewed by (b) (6) and (b) (6) with further comments on the formatting, such as numbering the electronic signature page as page 1 of 1, with the next page being the start of the actual LRP template and general comments on adding a separate lot release section for the Drug Substance, with each row in the table to represent a single lot release test which should include the name, specification, date and test result. An IR was sent to the firm on March 07, 2025, to address these comments.

A response was submitted on March 11, 2025, in amendment 125817/0.88. This revised LRP template was reviewed by (b) (6) and OVRR(b) (6) with comments. Comments included harmonizing the unit for the endotoxin test from to EU/mL and IU/mL to only EU/mL, adding adventitious agents test results of the (b) (4) for each lot and adding biological assay information, such as positive control lot numbers, acceptance criteria and test results to the LRP template. An IR was sent to the firm on March 17, 2025, to address these comments.

A response was submitted on March 19, 2025, in amendment 125817/0.97. This revised LRP template was reviewed by (b) (6) and OVRR(b) (6) with no comments.

(b) (6) did have additional comments to the firm pertaining to general lot release that were sent to the firm on March 25, 2025: CBER asked the firm (1) to submit 40 units of each Drug Product lot for CBER testing prior to receiving each new lot release protocol, (2) for the firm's manufacturing plan showing a weekly estimate of the number of lots produced, the expected dates of sample delivery and LRP submissions to CBER, prior to approval of each "strain-change" supplement application, and (3) for the firm to acknowledge that CBER lot release activities may take up to 30 working days; the firm needs to consider this in their distribution plan.

A response to this request was submitted on March 26, 2025, in amendment 125817/0.103. The firm stated they will request a teleconference to discuss a proposal to submit representative lots (not commercial lots) for testing. The firm's response was reviewed by (b) (6) and (b) (6) with no comments.

3 Conclusions

The lot release protocol template for COVID-19 Vaccine, Adjuvanted, submitted in amendment 125817/0.103 on March 26, 2025, is acceptable for use. This template may be used for future lot release submissions.