U.S. FOOD & DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b) (6) ANALYTICAL METHOD REVIEW MEMO

To: BLA STN 125817/0

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

Through: (b) (6)
CBER

(b) (6)
/CBER

Product: Nuvaxovid (Novavax COVID-19 Vaccine, Adjuvanted)

Applicant: Novavax

Subject: Review of Analytical Methods used for Nuvaxovid (Novavax COVID-19 Vaccine, Adjuvanted) (b) (4) Drug Product (DP) and Lot Release

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Recommendation: Approval

Summary:
The following analytical method used for lot release of Nuvaxovid, and its associated analytical method validation were reviewed:

1. Identity SARS-CoV-2 rS by (b) (4)

Conclusion:
The analytical method reviewed for the Nuvaxovid (b) (4) DP was found to be adequate for its intended use.

Documents Reviewed:
Information in sections of the original submission that describe control of (b) (4) DP (3.2.S.4, and 3.2.P.5, respectively), including descriptions of (b) (4) DP specifications, analytical procedures of (b) (4) DP and validation of these analytical procedures were reviewed. Responses to Information Request (IR) received on May 25, 2024, in Amendment 23 (Amendment 125817/0.23) as well as responses to IR received on November 1, 2024, in Amendment 43 (Amendment 125817/0.43) were also reviewed.

Background:
On April 1, 2024, Novavax submitted an original Biologics License Application (BLA), STN 125817/0, for Nuvaxovid (Novavax COVID-19 Vaccine, Adjuvanted), for active immunization to

prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

The active ingredient of Nuvaxovid is SARS-CoV-2 recombinant spike (rS) glycoprotein produced and purified from Spodoptera frugiperda (Sf9) insect cells. SARS-CoV-2 rS stabilized in its prefusion conformation forms trimers and assembles into nanoparticles, which binds with high affinity to the human angiotensin-converting enzyme 2 (hACE2) receptor.

SARS-CoV-2 rS Wuhan is the antigen component of a vaccine for use against SARS-CoV-2, while the SARS-CoV-2 rS Omicron XBB.1.5 and Omicron JN.1, respectively, is the antigen component of a vaccine for use against the evolving SARS-CoV-2.

Nuvaxovid contains 5 micrograms (mcg) of SARS-CoV-2 rS adjuvanted with 50 mcg of saponin-based Matrix-M adjuvant per dose. The finished product is presented as a dispersion for injection in a multidose vial containing 5 doses of 0.5 mL each. Nuvaxovid is administered intramuscularly as a single dose (0.5 mL).

Review:

Identity SARS-CoV-2 rS by (b) (4)

Introduction

(b) (4) is an identity test to detect and discriminate SARS-CoV-2 rS variants. It involves (b) (4) treatment of SARS-CoV-2 rS, resulting in the formation of (b) (4) . Because (b) (4) identifies the SARS-CoV-2 rS variants via identification of unique (b) (4) of each variant, it is better than (b) (4) analysis which needs several months or longer to generate specific antibodies for each variant.

Method

(b) (4)

4 pages have been determined to be not releasable: (b)(4)

(b) (4)

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Test Summary

All the validation acceptance criteria for (b) (4) DP samples were fulfilled. Identity of all samples (SARS-CoV-2 rS Wuhan, XBB.1.5, BA 5, JN.1 (b) (4) DP) subjected to specificity testing was confirmed and identity was not confirmed in challenge molecules and in Formulation Buffer, in accordance with acceptance criteria.

Conclusion

The method of Identity SARS-CoV-2 rS by (b) (4) was well described and the validation test results complied with the predefined acceptance criteria. Therefore, the method is appropriately validated and is suitable for its intended use.