U.S. FOOD & DRUG ADMINISTRATION

Memorandum

DATE	March 21, 2025
FROM	(b) (6)
THROUGH	(b) (6)
THROUGH	(b) (6)
TO	(b) (6) 125817/0 (b) (6)
SUBJECT	(b) (6) Final Discipline Review Memo
SPONSOR	Novavax, Inc.
PRODUCT	NUVAXOVID (Novavax's COVID-19 Vaccine, Adjuvanted)
sBLA	STN 125817/0

FINAL SUMMARY STATEMENT

(b) (6) inspections were issued for two domestic clinical investigator (CI) sites participating in the conduct of Study 2019nCoV-301. The inspections did not reveal significant problems impacting the data submitted in support of this Biologics License Application (BLA).

BACKGROUND

(b) (6) inspection assignments were issued for two domestic CI sites that participated in the conduct the protocol entitled "A Phase 3, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant in Adult Participants ≥ 18 Years with a Pediatric Expansion in Adolescents (12 to < 18 Years)" (2019nCoV-301).

The sites were selected based on previous inspectional history, geographic location, and the data submitted in the BLA. The BLA review committee concurred with the sites selected for inspection. These inspections were conducted in accordance with FDA's

Compliance Program (CP) 7348.811, Inspection Program for CI and the inspection assignment included specific questions concerning the study protocol, and information submitted in the BLA was compared to source documents at the site. Study 2019nCoV-301 was conducted at 73 sites across The United States, enrolling a total of 2250 subjects. The two domestic CI sites inspected in support of this BLA covered approximately 7% of the subjects enrolled in the study.

INSPECTION SUMMARY AND OUTCOME

The inspections verified the data reported in the BLA, including but not limited to subject eligibility, protocol deviations, study drug administration, primary efficacy endpoint, and adverse events for all subjects enrolled at the inspected clinical sites. No significant objectionable inspectional findings were observed during the inspection. A Form FDA 483 was issued for one of the two inspected sites. The table below summarizes the (b) (6) inspections:

Site ID	Study Site Name and Location	Form FDA 483 Issued?	Final Inspection Classification
US012	**Velocity Clinical Research** Meridian, ID	Yes	No Action Indicated (NAI)*
US143	**Research Your Health** Plano, Texas	No	Voluntary Action Indicated (VAI)*

*Both classifications were changed by the Center. See details under Inspectional Findings.

Inspectional Findings:

The inspections did not reveal substantiative issues that impact the data submitted in the BLA. However, the following issues were discussed during the inspections and shared with the BLA review committee.

- Study site US012: A Form FDA 483 was issued for this site with three observations related to verbal confirmation of medical history, temperature excursions, and protocol deviation reporting to the Institutional Review Board. Our review of the EIR and the site's explanations to the observations listed on the Form FDA 483 revealed that initial observations were not substantiated. The final classification was downgraded from VAI to NAI by the Center.

- Study site US143: A Form FDA 483 was not issued however we noted that protocol deviations were not being recorded by the site personnel, but rather by the monitor during their review. The final classification was escalated from NAI to VAI by the Center.

Sponsor Issues:

No significant sponsor issues were noted.

FINANCIAL DISCLOSURE

The CI CP directs the FDA investigators to ask the CI if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouses and dependent children, and if and when the information was last updated. The information submitted to the BLA was verified at the inspected sites.

ADMINISTRATIVE FOLLOW-UP

No administrative follow-up is warranted at this time. Should you have any questions about the contents of this memo or any aspect of (b) (6), please contact me at (b) (6)

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