DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

(b) (6) **ANALYTICAL METHOD REVIEW MEMO**

To: Biologics License Application, STN 125817/0

From: (b) (6)

Through: (b) (6)

Sponsor: Novavax Inc.

Subject: Suitability of lot-release test methods for Novavax COVID-19 Vaccine, Adjuvanted (Nuvaxovid) (b) (4) Drug Product

Recommendation: Approval

Executive Summary:
Analytical methods used for lot release of Nuvaxovid were reviewed by (b) (6) Their review memoranda are attached to this cover letter.

Conclusion:
The analytical methods and their validations and/or qualifications reviewed for the Nuvaxovid (b) (4) drug product were found to be adequate for their intended use.