



Our Reference: EUA 28237

March 28, 2023

Novavax, Inc.  
Attention: Kathleen Callahan, M.S.  
21 Firstfield Road  
Gaithersburg, MD 20878

**Re:** EUA 28237 - Emergency Use Authorization of Novavax COVID-19 Vaccine, Adjuvanted, Reissued on October 19, 2022, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3); Request in Amendments received on March 2, 2023, March 23, 2023, and March 27 2023, to Update the Authorized Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) - (including Full EUA Prescribing Information) and the Carton and Vial labels for 5-Dose Vial with 6-hour in-use shelf-life after the first puncture when stored between 2°C to 25°C.

Dear Ms. Callahan:

This letter is to notify you that we have reviewed the requested changes and data to support the revisions to your Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Carton and Vial labels to include a 5-Dose Vial with 6-hour in-use shelf-life after the first puncture when stored between 2°C to 25°C, and that your request is granted.

We concur with the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Full EUA Prescribing Information to include the following new information:

## **2 DOSAGE AND ADMINISTRATION**

### Prepare for administration

This Section was revised to include the updated drug product presentations shown below:

- Novavax COVID-19 Vaccine, Adjuvanted is available in two presentations:
  - Multi-dose vial containing 5 doses of 0.5 mL each
  - Multi-dose vial containing 10 doses of 0.5 mL each

## **19 HOW SUPPLIED/STORAGE AND HANDLING**

This Section was revised to include the updated drug product presentations shown below:

The Novavax COVID-19 Vaccine, Adjuvanted is supplied in:

- Carton (NDC 80631-100-10) containing 10 multi-dose vials (NDC 80631-100-01). Each multi-dose vial contains 10 doses of 0.5 mL each.
- Carton (NDC 80631-102-10) containing 10 multi-dose vials (NDC 80631-102-01). Each multidose vial contains 5 doses of 0.5 mL each.

Related changes were also made to the EUA Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) (short version) for consistency. This EUA Fact Sheet has also been updated to include other minor editorial changes.

By submitting these amendments for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the October 19, 2022, letter authorizing the emergency use of Novavax COVID-19 Vaccine, Adjuvanted.

Sincerely,

--/S/--

David C. Kaslow, M.D.  
Director  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research