



October 20, 2022

## FDA Issues EUA for Novavax COVID-19 Vaccine Boosters

On October 19, 2022, the U.S. Food and Drug Administration (FDA) reissued the [Letter of Authorization](#) to authorize the use of Novavax COVID-19 Vaccine, Adjuvanted as a first booster dose (0.5 mL) to the following individuals at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine:

- **Individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and**
- **Individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.**

In addition, the FDA is revising the Fact Sheets for Novavax COVID-19 Vaccine, Adjuvanted, to reflect these changes.

On July 13, 2022, the U.S Food and Drug Administration (FDA) issued an [emergency use authorization \(EUA\)](#) for the Novavax COVID-19 Vaccine, Adjuvanted for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. On August 22, 2022, the FDA reissued the authorization to include individuals age 12 years through 17 years of age. On September 12, 2022 the FDA revised the conditions of authorization related to [Vaccine Adverse Event Reporting System \(VAERS\)](#) reporting requirements.

The Novavax COVID-19 Vaccine, Adjuvanted is administered as a two-dose primary series, three weeks apart. The vaccine contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual. The spike protein in this vaccine is produced in insect cells; the Matrix M-adjuvant contains saponin extracts from the bark of the Soapbark tree that is native to Chile.

### **Vaccine Efficacy & Safety Data**

In reissuing the Letter of Authorization, the FDA relied on safety and immunogenicity data from 1) an ongoing randomized, blinded, placebo-controlled phase 3 study of the vaccine conducted in the United States and Mexico and 2) an independent phase 2 study conducted in the United Kingdom.

In the open-label booster vaccination portion of the phase 3 study, 12,738 participants 18 years of age and older received a single booster dose of Novavax COVID-19 Vaccine, Adjuvanted (0.5 mL) at least 6 months after the two-dose primary series. Effectiveness of a booster dose of the Novavax COVID-19 Vaccine, Adjuvanted following a Novavax COVID-19 Vaccine, Adjuvanted primary series was based on assessment of neutralizing antibody titers determined by microneutralization assay (MN50) against the original SARS-CoV-2 strain. Immunogenicity analyses compared the MN50 titers following the booster dose to the MN50 titers following the primary series. A subset of 243 participants were included in the per-protocol immunogenicity analysis set, and did not have serologic or virologic evidence (if available) of SARS-CoV-2 infection up to 28-days post booster dose. Pre-specified immunogenicity non-inferiority analyses included an assessment of MN50 geometric mean titer (GMT) ratio and difference in seroconversion rates. Seroconversion for a participant was defined as achieving a 4-fold rise in MN50 from baseline (before the booster dose and before the first dose of the primary series). The analysis of the GMT ratio of MN50 following the booster dose compared to the primary series met the non-inferiority criteria for a booster response and point estimate. The lower limit of the two-sided 95% CI for the difference in seroconversion rates did not meet the non-inferiority criteria for a booster response.

Safety analyses included evaluation of solicited local and systemic adverse reactions within 7 days after a booster dose (n=238) and non-serious unsolicited adverse events within 28 days after a booster dose (n=298). Safety analysis also included evaluation of serious adverse events and adverse events of interest after a booster dose (n=12,738) with a median follow-up of 121-days post booster dose through data extraction of August 18, 2022.

In the independent Phase 2 study conducted in the UK, 114 participants aged 30 years and older with no history of laboratory-confirmed SARS-CoV-2 infection received Novavax COVID-19 Vaccine, Adjuvanted administered at least 84 days (median 105 days) after completion of the Pfizer-BioNTech COVID-19 Vaccine primary series. This multicenter, randomized, controlled Phase 2 trial investigated the immunogenicity of a single booster dose of Novavax COVID-19 Vaccine, Adjuvanted in participants who had received two doses of the Pfizer-BioNTech COVID-19 Vaccine as a primary vaccination series. Participants included adults aged 30 years and older with no history of laboratory-confirmed SARS-CoV-2 infection. The Novavax COVID-19 Vaccine, Adjuvanted was administered at least 84 days after completion of a Pfizer-BioNTech COVID-19 Vaccine primary series in 114 participants. Neutralizing antibody titers measured by a microneutralization assay were assessed prior to the booster dose and 28-days post-booster dose. A booster response to the Novavax COVID-19 Vaccine, Adjuvanted was demonstrated.

FDA's review of the currently available safety data did not identify specific safety concerns that would preclude issuance of an EUA. The FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of the Novavax COVID-19 Vaccine, Adjuvanted outweigh its known and potential risks as a first booster dose for the prevention of COVID-19 in such individuals.

### **Current EUA Fact Sheets**

As a convenience, Fact Sheets for the Novavax COVID-19 Vaccine are accessible below:

- ❖ [Healthcare Providers](#)
- ❖ [Recipients and Caregivers](#)

### **Mandatory Requirements under the Emergency Use Authorization (all requirements must be met)**

- Use of Novavax COVID-19 Vaccine, Adjuvanted is authorized for use in individuals 18 years of age and older.
- The vaccination provider must communicate to the individual receiving the Novavax COVID-19 Vaccine, Adjuvanted or their caregiver, information consistent with the "[Fact Sheet for Recipients and Caregivers](#)" prior to the individual receiving the Novavax COVID-19 Vaccine, Adjuvanted.
- The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.
- The vaccination provider is responsible for mandatory reporting of the following to the [Vaccine Adverse Event Reporting System \(VAERS\)](#):
  - vaccine administration errors whether or not associated with an adverse event,
  - serious adverse events\* (irrespective of attribution to vaccination),
  - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
  - cases of COVID-19 that result in hospitalization or death.
- The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Novavax COVID-19 Vaccine, Adjuvanted to recipients.
- **Federal, Tribal, and Urban programs are all encouraged to put "IHS" into field #26 of the form.**

### **References:**

1. U.S. Food and Drug Administration. Emergency Use Authorization, Novavax COVID-19 Vaccine. Published online on October 19, 2022.