U.S. Centers for Disease Control and Prevention Recommends Novavax COVID-19 Vaccine, Adjuvanted as a Booster in Adults

October 19, 2022

Today the U.S. Centers for Disease Control and Prevention (CDC) <u>recommended</u> the use of the Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373) as a booster for adults. This recommendation gives people ages 18 years and older the option to receive the Novavax COVID-19 Vaccine, Adjuvanted as a booster instead of an updated (bivalent) Pfizer-BioNTech or Moderna booster if they have completed primary series vaccination but have not previously received a COVID-19 booster, and if they cannot or will not receive mRNA vaccines.

According to CDC data, almost 50 percent of adults who received their primary series have yet to receive their first booster dose. Offering another vaccine choice may help increase COVID-19 booster vaccination rates for these adults. Novavax is also conducting ongoing trials further exploring the immunogenicity and safety of the Novavax COVID-19 Vaccine, Adjuvanted to expand its use as a booster.

The FDA has granted emergency use authorization for the Novavax COVID-19 Vaccine, Adjuvanted as a <u>first booster in</u> <u>adults aged 18 and older</u>, and as a two-dose primary series in <u>adults aged 18 and older</u> and in <u>adolescents aged 12 through 17</u>

<u>Doses</u> of the Novavax COVID-19 Vaccine, Adjuvanted are now available in the U.S. and can be located on <u>Vaccines.gov</u>.

Use of the Novavax COVID-19 Vaccine, Adjuvanted in the U.S.

The Novavax COVID-19 Vaccine, Adjuvanted vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) as a primary series in individuals 12 years of age and older. The Novavax COVID-19 Vaccine, Adjuvanted vaccine is also authorized to provide a first booster dose at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to 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 to 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.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Please click to see the Novavax COVID-19 Vaccine, Adjuvanted Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information.

Please click to see the Fact Sheet for Recipients and Caregivers.

References

1. Centers for Disease Control and Prevention. COVID-19 Vaccinations in the United States. Available at https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop. Accessed October 2022.