U.S. Centers for Disease Control and Prevention Expands Recommendation for Novavax COVID-19 Vaccine, Adjuvanted to Adolescents Aged 12 Through 17

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- Novavax's vaccine is the first protein-based vaccine to receive Emergency Use Authorization for adolescents and adults in the U.S.
- Vaccines are available and can be located on Vaccines.gov

Today the U.S. Centers for Disease Control and Prevention (CDC) recommended expanding the use of Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373) as a two-dose primary series for active immunization to prevent coronavirus disease 2019 caused by the severe acute respiratory syndrome coronavirus 2 to adolescents aged 12 through 17. The Interim Clinical Considerations on its website have been updated accordingly.

The recommendation follows the emergency use authorization (EUA) granted for use in adolescents aged 12 through 17 by the U.S. Food and Drug Administration on <u>August 19, 2022</u>, and the EUA granted for adults aged 18 and older on <u>July 13</u>, 2022. The CDC previously recommended use of the vaccine in adults aged 18 and older.

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

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

The Novavax COVID-19 Vaccine, Adjuvanted has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA) to provide a two-dose primary series to individuals 12 years of age and older to prevent Coronavirus Disease 2019 (COVID-19).

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.

Authorized Use

The Novavax COVID-19 Vaccine, Adjuvanted is authorized for use under an Emergency Use Authorization (EUA) to provide a two-dose primary series for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

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.