

## **Spikevax (COVID-19 Vaccine, mRNA)**

**What data did FDA evaluate to support the September 11, 2023, approval of the following:**

- **a single dose for individuals 12 through 17 years of age**
- **a single dose for individuals 18 years of age and older**

The effectiveness of a single dose of Spikevax for individuals 12 years of age and older, regardless of prior COVID-19 vaccination status, is supported by FDA's previous determination of the effectiveness of Spikevax in individuals 18 years of age and older and FDA's analysis of immune response data from a clinical study among approximately 250 individuals 12 through 17 years of age who were COVID-19 unvaccinated, had evidence of prior SARS-CoV-2 infection, and received a single dose of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). The immune responses of these study participants were compared to the immune responses among approximately 300 study participants 18 through 25 years of age who had no evidence of prior SARS-CoV-2 infection and received two doses of Spikevax (Original monovalent), one month apart. The immune response data demonstrated that individuals who had prior evidence of infection responded adequately to a single dose of vaccine.

The safety of a single dose of Spikevax for individuals 12 through 17 years of age, regardless of prior COVID-19 vaccination status, is supported by FDA's previous determination of the safety of Spikevax in individuals 18 years of age and older. In addition, FDA evaluated data from a clinical study among approximately 2,500 individuals 12 through 17 years of age who received two doses of Spikevax and of these approximately 1,400 received a third dose of Spikevax. Additionally, FDA evaluated data from a clinical study among approximately 380 individuals 12 years through 17 years of age who were COVID-19 unvaccinated, had evidence of prior SARS-CoV-2 infection, and received a single dose of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). Among participants 12 through 17 years of age in these studies, the most commonly reported side effects were pain at the injection site, fatigue, headache, muscle pain, and underarm swelling/tenderness.

The data accrued with the Moderna COVID-19 Vaccine, Bivalent are relevant to Spikevax because these vaccines have a similar manufacturing process.