



February 7, 2022

FDA Approves Second COVID-19 Vaccine: Moderna (SpikeVax)

Background & Current Status^{1,2:}

- On December 18, 2020, the U.S Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Moderna COVID-19 Vaccine for prevention for COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.
- In the August 12, 2021 revision, FDA authorized for emergency use a third dose of the Moderna COVID-19 vaccine administered at least 1 month following the two dose regimen of this vaccine in individuals 18 years of age or older who have undergone solid organ transplantation, or individuals 18 years of age or older who have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
- In the October 20, 2021 revision, FDA authorized for emergency use the administration of a single booster dose of Moderna COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. Additionally, FDA authorized the administration of a single booster dose of the Moderna COVID-19 Vaccine as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine.
- In the November 19, 2021 revision, FDA authorized the use of Moderna COVID-19 Vaccine as a single booster dose in individuals 18 years of age or older at least 6 months after completing the primary series of this vaccine, and authorized the vaccine as a single booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine in individuals 18 years of age or older. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.
- In the January 7, 2022 revision, FDA revised the authorized dosing interval of the homologous booster dose to at least five (5) months after completion of the primary series of this vaccine.
- **On January 31, 2022, the FDA approved a second COVID-19 vaccine. The vaccine has been known as the Moderna COVID-19 Vaccine; the approved vaccine will be marketed as Spikevax for the prevention of COVID-19 in individuals 18 years of age and older.**
 - ❖ *Spikevax has the same formulation as the EUA Moderna COVID-19 Vaccine and is administered as a primary series of two doses, one month apart. Spikevax can be used interchangeably with the EUA Moderna COVID-19 Vaccine to provide the COVID-19 vaccination series.*
 - ❖ *Moderna COVID-19 Vaccine remains available under EUA as a two-dose primary series for individuals 18 years of age and older, as a third primary series dose for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 18 years of age and older at least five months after completing a primary series of the vaccine. It is also authorized for use as a heterologous (or "mix and match") single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine.*

Vaccine Efficacy & Safety Data^{1:}

The approval of Spikevax is based on the FDA's evaluation and analysis of follow-up safety and effectiveness data from the ongoing randomized, placebo-controlled, blinded clinical trial that supported the December 2020 EUA for the Moderna COVID-19 Vaccine and information from post EUA experience to further inform safety and effectiveness.

The updated analyses to determine effectiveness of Spikevax included 14,287 vaccine recipients and 14,164 placebo recipients 18 years of age and older who did not have evidence of SARS-CoV-2 infection prior to receiving the first dose. The data used for the analyses were accrued before the Omicron variant emerged. These data demonstrated that Spikevax was 93% effective in preventing COVID-19, with 55 cases of COVID-19 occurring in the vaccine group and 744 COVID-19 cases in the placebo group. The vaccine was also 98% effective in preventing severe disease.

The FDA's safety analysis of Spikevax included approximately 15,184 vaccine recipients and 15,162 placebo recipients 18 years of age and older, more than half of these participants were followed for safety outcomes for at least four months after the second dose. Approximately 7,500 participants originally assigned to receive Spikevax in the blinded phase of the clinical trial completed safety follow-up for at least 6 months after the second dose.

The most commonly reported side effects by clinical trial participants were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, nausea/vomiting, swollen lymph nodes under the arm and fever.

Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following vaccination with the Moderna COVID-19 Vaccine and has determined that the data demonstrate increased risks particularly within seven days following the second dose, with the observed risk highest in males 18 through 24 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The [Spikevax Prescribing Information](#) includes a warning about these risks.

Current EUA Fact Sheets^{4,5}:

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

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

Mandatory Requirements under the Emergency Use Authorization²:

- Use Moderna COVID-19 Vaccine only in authorized patients described in the respective Fact Sheets.
- Communicate to recipients or caregivers, as age appropriate, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to receiving Moderna COVID-19 Vaccine.
- Include vaccination information in the local jurisdiction’s Immunization Information System or other system.
- 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 children, and
 - Cases of COVID-19 that result in hospitalization or death.
- Respond to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Moderna COVID-19 Vaccines to recipients.
- *Federal, Tribal, and Urban programs are all encouraged to **put “IHS” into field #26 of the form.***

References:

1. Food and Drug Administration. FDA News Release. [Coronavirus \(COVID-19\) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine](#). Published online on January 31, 2022.
2. Food and Drug Administration. [Moderna COVID-19 Vaccine Letter of Authorization](#). Issued January 31, 2022.
3. Food and Drug Administration. Moderna COVID-19 Vaccine: FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE. Revised: January 31, 2022.
4. Food and Drug Administration. Moderna COVID-19 Vaccine: FACT SHEET FOR RECIPIENTS & CAREGIVERS. Revised: January 31, 2022.