

February 1, 2022

From: Kansas Department of Health and Environment – Division of Public Health

To: COVID-19 Vaccine Providers

RE: FDA Approves Moderna COVID Vaccine

The Food and Drug Administration (FDA) announced on Monday, January 31, 2022, the approval of the Moderna COVID-19 vaccine. The vaccine has been brand named "Spikevax." 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.

The [FDA Press Release](#) from the FDA quotes Acting FDA Commissioner Janet Woodcock, MD "The FDA's approval of Spikevax is a significant step in the fight against the COVID-19 pandemic, marking the second vaccine approved to prevent COVID-19. The public can be assured that Spikevax meets the FDA's high standards for safety, effectiveness and manufacturing quality required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated."

Kansas COVID-19 vaccine providers are reminded under the current federal provider agreements that off-label use is not permitted. Spikevax and Moderna COVID-19 vaccines are interchangeable and approved for use in persons 18 and older. We have not been provided with any timeline when the distribution channels will begin to see the name Spikevax on vials of vaccine. Please remember and provide education to your patients that the approved vaccine is the same vaccine currently available and as first authorized under the Emergency Use Authorization in December 2020.