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To: Maine Immunization Program Providers

From: Maine Immunization Program

Subject: The FDA Approves Second COVID-19 Vaccine

Date: January 31, 2021

The U.S. Food and Drug Administration has 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 met the FDA's rigorous standards for safety, effectiveness and manufacturing quality required for approval. The Moderna COVID-19 Vaccine has been <u>available under</u> emergency use authorization (EUA) for individuals 18 years of age and older since December 18, 2020.

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.

Please see the full press announcement here.