

Dept. of Health Services: Urges vaccination as the Moderna Covid-19 vaccine gains full FDA approval

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The U.S. Food and Drug Administration (FDA) granted its full approval of the Moderna COVID-19 vaccine. The vaccine will now be marketed under the name Spikevax for the prevention of COVID-19 in people 18 years of age and older.

“The FDA fully approved the Pfizer COVID-19 vaccine last August for those 16 and older and now has done the same with the Moderna vaccine for those 18 and older. These approvals are further confirmation that these vaccines are effective and safe,” said DHS Secretary-designee Karen Timberlake. “We urge those folks that have waited to get vaccinated to do so now and join their nearly 3.7 million fellow Wisconsinites who have received their COVID-19 vaccine.”

This is the same vaccine people have been getting for months. In order to grant full approval, the FDA required extensive data on safety and effectiveness, inspection of manufacturing facilities, and a comprehensive review of all clinical and real-world use. The full approval means that even more data were gathered and analyzed following the grant of emergency use authorization in December 2020 to further confirm that this vaccine works and is safe. All of the COVID-19 vaccines are extremely effective at preventing serious illness, hospitalization, and death – including from the Delta and Omicron variants.

The Moderna vaccine was the second COVID-19 vaccine to receive emergency use authorization (EUA) in the U.S. This authorization came after the Moderna product underwent rigorous clinical trials and an expedited review process to ensure the safety and efficacy of the vaccine. FDA granted the application for full approval through a [priority review\(link is external\)](#) designation, and reviewed updated data

from the clinical trial which supported the EUA and included a longer duration of follow-up in a larger clinical trial population.

“The FDA’s decision to issue full approval to the Moderna vaccine reinforces what we have known since the initial emergency use authorization – this vaccine is safe and effective,” said Stephanie Schauer, Ph.D., Division of Public Health Immunization Program Manager. “This is another important milestone and builds on evidence that the Moderna vaccine is safe and effective for everyone ages 18 and up. It’s more important than ever that everyone who is eligible to get vaccinated get vaccinated so we can keep ourselves, our kids, our friends, family, and neighbors safe.”

People who are unvaccinated are urged to get vaccinated as soon as they can. The COVID-19 vaccines are free, safe, and widely available in Wisconsin. To find a vaccination location near you, visit [Vaccines.gov\(link is external\)](#) or call 211 or 877-947-2211.

For up-to-date information about Wisconsin’s COVID-19 response, visit the [DHS COVID-19 webpage](#) and follow @DHSWI on [Facebook\(link is external\)](#), [Twitter\(link is external\)](#), or dhs.wi on [Instagram\(link is external\)](#) for more information on COVID-19.