

What FDA's full approval of Pfizer-BioNTech COVID-19 vaccine means

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What's the news: The Food and Drug Administration (FDA) granted full approval to the Pfizer-BioNTech COVID-19 vaccine. This is the first COVID-19 vaccine to receive full approval and will be marketed as Comirnaty. The vaccine is fully approved for use in individuals ages 16 and older to prevent COVID-19 disease.

However, the Pfizer COVID-19 vaccine is still available under emergency use authorization for adolescents 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

“Although the three widely available vaccines for COVID-19 have been shown safe and highly effective through intense study and research, the FDA’s announcement Monday should instill confidence in those who, until now, have been wary of the emergency use designation given to these vaccines,” said AMA President Gerald E. Harmon, MD. “The message could not be more clear: This vaccine is safe and highly effective in preventing severe illness, hospitalization and death due to COVID-19.”

This is the result of months of work, robust data evaluation and a thorough, comprehensive review process that has protected more than 100 million Americans from severe COVID-19 complications. It is a milestone and major step forward in the worldwide effort to end this pandemic.

“Today’s news marks a critical moment for people who were concerned about getting vaccinated due to the vaccines being authorized for emergency use. With millions of data points on the vaccine’s safety and efficacy over nearly nine months of vaccinations, every ‘i’ is dotted and every ‘t’ is crossed. This vaccine is safe, it prevents severe COVID-19, hospitalization, and deaths, and it will save your life,” says a joint statement from the AMA, American Hospital Association and American Nurses Association that applauds FDA full approval of the Pfizer COVID-19 vaccine.

Pfizer-BioNTech also plans to ask the FDA to approve a third dose as a booster shot. This is something the Biden administration has been advocating for, aiming for booster shots to be available to all eligible Americans beginning Sept. 20, pending review by the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices.

Why it's important: More than 60% of the total U.S. population has had at least one dose of a COVID-19 vaccine. Yet many Americans remained concerned about getting vaccinated, even as the highly contagious and dangerous Delta variant continues to spread.

But full approval for this mRNA COVID-19 vaccine by Pfizer may be just what some Americans needed to be convinced that the shots are safe and effective. That's because, in a survey from the Kaiser Family Foundation, 30% of unvaccinated people said they were waiting for COVID-19 vaccines to receive full approval before taking the next step to get vaccinated.

"We are there now; this vaccine is fully approved. If uncertainty was holding you back, now is the time to act. And if you still have questions about the vaccines or about COVID-19, please consult your health care professional," the joint statement says. "Science, data and thorough research have given us the tools to defeat COVID-19. With the Delta variant surging, there has never been a better time to get vaccinated."

With full FDA approval and licensing, the AMA supports greater and stronger use of vaccine mandates by public and private sector employers and other organizations for the populations recommended to receive the vaccine by the Advisory Committee on Immunization Practices. Major companies such as Walt Disney and Walmart have already expressed to their employees that they must get fully vaccinated against COVID-19 by this fall. The Pentagon also noted they would make vaccinations mandatory for service members following the FDA's full approval of Pfizer's COVID-19 vaccine.

Learn more: The FDA and CDC will continue to monitor and evaluate any safety concerns that are identified. Additionally, the FDA requires Pfizer-BioNTech to conduct post-marketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty. Pfizer has also committed to additional safety studies on pregnant individuals and infant outcomes after receiving Comirnaty during pregnancy.

The FDA has updated its fact sheet for physicians and other health professionals administering the Pfizer COVID-19 vaccine to include information for full approval of Comirnaty.

Additionally, the CDC offers information for physicians and other health professionals on the Pfizer-BioNTech COVID-19 vaccine overview and safety.

The AMA has developed frequently-asked-questions documents on COVID-19 vaccination covering



safety, allocation and distribution, administration and more. There are two FAQs, one designed to answer patients' questions, and another to address physicians' & COVID-19 vaccine questions.

To learn more about COVID-19 vaccine developments, visit the AMA vaccine resource guide.