Aug. 23, 2021

To All COVID-19 Vaccine Providers,

Today, the U.S. Food & Drug Administration (FDA) granted full approval of the Pfizer-BioNTech COVID-19 vaccine for ages 16 and older. The vaccine will now be marketed as **Comirnaty** for the prevention of COVID-19 disease. Individuals ages 12-15 can continue to safely receive the vaccine under the emergency use authorization (EAU).

The Pfizer vaccine has been available under EUA for individuals age 16 and older since Dec. 11, 2020, and the emergency authorization was expanded to include individuals ages 12-15 on May 10, 2021. Today's approval is for those 16 years old and older because that age group has been studied the longest.

"Full approval of this safe, effective COVID-19 vaccine can give Ohioans an added layer of confidence when choosing to be vaccinated. The Pfizer COVID-19 vaccine was built upon decades of research on mRNA vaccines, and was thoroughly researched and tested in one of the largest vaccine clinical trials in history," said Ohio Department of Health Director Bruce Vanderhoff, MD. "The world's most comprehensive vaccine safety monitoring system has closely observed the more than 200 million doses that have been administered in the United States, including more than 6 million doses administered in Ohio. This action by the FDA validates the confidence of so many physicians, scientists, and public health experts in the safety and efficacy of the Pfizer COVID-19 vaccine."

As COVID-19 cases climb nationwide, the Ohio Department of Health urges vaccine providers to seize this opportunity to help build confidence among the vaccine hesitant about the safety of the vaccines.

ACTIONS FOR OHIO COVID-19 VACCINE PROVIDERS

- Please review and share updated FDA resources for the Pfizer COVID-19 vaccine, now known as Comirnaty.
    - Comirnaty Prescribing Information
    - Comirnaty package insert
    - Cormirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA
    - Frequently Asked Questions about Comirnaty COVID-19 Vaccine
- According to a recent Kaiser Family Foundation (KFF) poll, three in 10 unvaccinated adults said they would be more likely to get vaccinated if the vaccines currently authorized for emergency use received full approval from the FDA. Please share today's news with your patients and members of your community and urge them to get vaccinated with a safe, effective, and now fully approved vaccine for the best protection against COVID-19.
    - Please use all possible communication channels to reach those who are not yet vaccinated, including websites and social media, in-app/MyChart messaging, and voice and text messaging.
- Please ensure you have a steady supply of Pfizer-BioNTech COVID-19 vaccine available on site. Providers can order vaccine through the ImpactSIIS Vaccine Ordering Management System (VOMS) 24 hours a day, seven days a week.
    - The Pfizer vaccine can be ordered in increments of 1,170 for direct shipment from the manufacturer.

    - The Ohio Department of Health also offers repackaging of the vaccine into smaller order sets in 30-dose increments from the Receipt, Store, and Stage (RSS) Warehouse.
    - Ultra-cold storage is not required for the Pfizer vaccine. The vaccine can be stored at standard freezer temperatures for 14 days and standard temperatures for up to 31 days. See Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary for complete storage and handling information.
- Please work with your community partners to increase efforts to offer special vaccination opportunities for businesses, organizations, colleges, and schools to make receiving the Pfizer vaccine as convenient as possible.
- Please continue to reinforce the safety and effectiveness of Pfizer COVID-19 vaccine for adolescents ages 12-15, as well as those 16 years and older for whom Comirnaty has been fully approved.

MESSAGING: EXPLAINING EUA VS. FULL APPROVAL

Today's news offers an opportunity to educate the public about the difference between an EUA and full approval, and why Ohioans should feel confident about the safety of the vaccines following this approval process.

- EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product.
- The FDA has granted EUAs for three COVID-19 vaccines (Pfizer, Moderna, Johnson & Johnson). The Pfizer vaccine was the first of the COVID-19 vaccines to receive an EUA on Dec. 11, 2020, the first to apply for full approval, and now the first to receive full approval.
- A manufacturer must submit an application for full licensure. The application builds on the data and information that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process and inspections at the sites where vaccine is made. Vaccine applications have the equivalent of hundreds of thousands of pages of data and other information – more than what is submitted as part of an EUA.
- For the EUA, the FDA requires at least half of the participants of the original studies to be followed for at least two months post-vaccination. This is because most vaccine-related side effects occur right after vaccination. Full FDA approval requires participants in the original studies to be followed for at least six months. Reviewers look at data from the same study participants collected over a longer time period. All adverse events are examined.
- The Pfizer COVID-19 vaccine is now the first FDA-approved COVID-19 vaccine. This means the Pfizer vaccine has successfully completed the agency's standard process for reviewing all medical products.
- Today's approval is for ages 16 and older because that age group has been studied the longest. The EUA for 16 and older was issued in December 2020, but the EUA for ages 12-15 was granted five months later in May.
- Moderna, which received its EUA one week following Pfizer, also has applied for full FDA approval of its COVID-19 vaccine. Regulators are still reviewing Moderna's application.

- All COVID-19 vaccines currently authorized in the United States are effective in preventing severe disease, hospitalization, and death from COVID-19.
- Available data suggest COVID-19 vaccines offer protection against known circulating variants, including the Delta variant. Vaccination continues to be critical during this period of rapidly increasing cases and spread of variants of concern.

Thank you for your ongoing efforts to increase the number of Ohioans who are vaccinated.

If you have any questions or issues, please call the ODH Provider Call Center between 8 a.m. and 7 p.m. Monday through Friday at 1-844-9ODHVAX (1-844-963-4829) or email COVIDVACCINE@odh.ohio.gov.

Sincerely,
ODH COVID-19 Vaccination Provider Relations Team