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FDA APPROVES FIRST COVID-19 VACCINE

On August 23, 2021, the US Food and Drug Administration (FDA) granted full approval to the Pfizer-BioNTech COVID-19 Vaccine's Biologics License Application (BLA) for people 16 and older. Local Public Health Departments across Western Wisconsin hope that this approval increases vaccine confidence across the region. While approval was granted for 16 and older, individuals aged 12-15 can still receive the vaccine under the Emergency Use Authorization (EUA).

“This formal approval is another great signal that these vaccines are safe and effective. With the announcement of the Governor’s new reward program of \$100 for those who receive their first vaccine between now and September 6th, this is a great time for someone who was on the fence to call up their doctor, pharmacist, or local health department for an appointment,” said Health Officer Josie Knauber.

The announcement of the FDA’s full approval comes on the same day as an announcement from Governor Tony Ever’s that Wisconsin residents who get their first dose of any COVID-19 vaccine from a vaccine provider located in Wisconsin beginning August 20 through September 6 can receive a \$100 Visa Gift Card.

What is the difference between EUA and BLA:

Emergency Use Authorization (EUA): This is used during a public health emergency. To receive EUA, the product’s known potential benefits must be proven to outweigh the known potential risks. The product must go through three trial phases, have its data reviewed, and receive approval by FDA, ACIP, CDC, and WI DHS before the administration of vaccine can begin. COVID-19 vaccines currently under EUA in the United States include:

- Moderna for those 18 and older
- Johnson & Johnson/Janssen for those 18 and older
- Pfizer-BioNTech for those 12 through 15

Biologics License Application (BLA): Approved when substantial evidence of safety and evidence has been provided. COVID-19 Vaccines under BLA in the United States include:

- Comirnaty (Pfizer-BioTech) for those 16 and older

***The FDA has required that COVID-19 vaccines under EUA follow similar processes to BLA.**

Pfizer-BioNTech’s vaccine contains messenger RNA, which spurs the body to make a protein similar to the protein in the virus that causes COVID-19. Then the immune system can defend the body if exposed to the virus. The mRNA is only in the body for a short time. It does not become part of, or change, the body’s own genetic material.

With full approval, the Pfizer-BioNTech vaccine will now be called “Comirnaty.”

Cases continue to rise in Wisconsin and in the Northwestern region. It is important that people continue to be vaccinated and follow COVID-19 precautions. Vaccination is an important tool returning our lives to normal and rebuilding our economy and reducing the likelihood of hospitalization and death.

Wisconsin residents can locate vaccines near them through <https://www.vaccines.gov/> or by calling 211. ###