Full FDA Approval – Pfizer COVID-19 Vaccine **Updated: Aug. 25, 2021**

The FDA approved the Pfizer-BioNTech COVID-19 Vaccine for persons 16-years and older on August 23, 2021

- The Pfizer-BioNTech vaccine will now be called Comirnaty for marketing purposes; it is the same vaccine, and no changes were made to it
- It is still recommended to give the two-dose series: 3 weeks apart
- The full approval is for persons 16 years and older to prevent COVID-19 disease
- Janet Woodcock, MD with the FDA defined full approval as "meet[ing] the high standards for safety, effectiveness and manufacturing quality the FDA requires of an approved product"

The FDA granted full approval for the Pfizer-BioNTech COVID-19 Vaccine based on safety and effectiveness data from clinical trials as well as manufacturing information submitted by Pfizer-BioNTech

- ***Results of studies on effectiveness for the full FDA approval:***
  - In persons 16 years of age and older, approximately 20,000 people received the vaccine, and approximately 20,000 people received a placebo
  - The vaccine was found to be 91.3% effective in preventing symptomatic COVID-19 infection (77 infected from the vaccine group and 833 infected in the placebo group)
  - The study will be ongoing for a total of 2 years
- ***Studies on Safety for the full FDA approval:***
  - Approximately 22,000 people were vaccinated, and approximately 22,000 received placebo
  - Over half (approximately 25,000 people) were followed for four months after the second vaccine dose
  - Approximately 12,000 people were followed for at least six months after the second vaccine dose
  - The most common side effects in both groups were pain, redness and swelling at the injection site, headache, fatigue, muscle pain, chills, joint pain and fever. This was similar to what was observed during the clinical trials
- The FDA determined the totality of the available data presented clear evidence the vaccine may be effective in preventing COVID-19 and the known and potential benefits outweigh the known and potential risks of the vaccine's use in millions of people 16 years of age and older.

Full approval by scientists and experts at the FDA took three months to complete

- Review of hundreds of thousands of pages of expanded safety and efficacy data since the Emergency Use Authorization in December 2020

- Review of safety/effectiveness of the vaccine under real-world conditions
- Inspection of manufacturing facilities that make the vaccine
- The FDA's analysis of the data and a risk/benefit analysis

The FDA EUA and Full FDA Approval of the Pfizer-BioNTech COVID-19 vaccine followed different timelines but the same rigorous requirements and process

- The EUA of the Pfizer vaccine for persons 16 years and older was based on studies of over 18,000 people who received the actual vaccine and over 18,000 people who received a placebo
- The vaccine was found to be 95% effective in preventing COVID-19 disease
- Participants were followed for two months after receiving the second dose of either the actual vaccine or placebo
- EUA does not mean the vaccine was experimental. All the experimental work (clinical trials) was done just as with a full approval
- The EUA is still in effect for those 12-15 years old and those immunocompromised persons 12 years and older authorized for a third dose

The FDA is committed to reviewing data from ongoing studies of the vaccine over the next several years, including observing for:

- Further risk of myocarditis and pericarditis
- Long-term effects from the vaccine
- Ongoing studies of vaccination in pregnant people

With more safety and efficacy clinical data, more real-world data and ongoing tracking of the more than 165 million vaccinated people in the U.S., the full FDA approval of the Pfizer BioNTech vaccine has implications for public health

- There may be more widespread employer (public and private) vaccine mandates in the workplace
- More statewide, city and local vaccine mandates (for employees and others)
- More widespread school and college vaccine mandates for students

The CDC has published considerations related to myocarditis and pericarditis risk after vaccination with the Pfizer COVID-19 vaccine

- The observed risk is higher among males under 40 years of age than among females and older males
- The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that symptoms have resolved in most individuals
- Some individuals did require intensive care support
- Information is not yet available about potential long-term health outcomes

Full FDA approval will probably NOT influence/speed up the process for approval of childhood vaccines, according to some experts

- The Emergency Use Authorization is still in effect for those 12-15 years old and those immunocompromised persons 12 years and older authorized for a third dose
    - These groups did not receive full FDA approval on August 23, 2021
- Scientists are still collecting data on the proper dose, safety and efficacy of the vaccine in those under 12 years of age
- With a full FDA approval, some doctors could use the vaccine "off label"

- Off-label use is complicated, and scientists caution doctors that there is insufficient data for some populations/scenarios
- Some scientists warn against off-label use and tell doctors to wait for ACIP/CDC recommendations

Anyone who wishes to be vaccinated against COVID-19 may do so with three vaccines available, including those from Pfizer, Moderna and Johnson and Johnson

- All three vaccines have been rigorously tested, undergoing clinical trials that involved tens of thousands of people
- The FDA determined COVID-19 vaccines from Pfizer, Moderna and J and J were safe and effective, and each was granted EUA
- Since being granted EUA, all three vaccines have been administered to hundreds of millions of people in the U.S. and ongoing studies continue to be reviewed by the FDA
- Ask your doctor if you have questions about any of the vaccines and to learn how to schedule your vaccination

The Pfizer-BioNTech COVID-19 Vaccine was the first to receive EUA, and therefore the first to receive Full Approval from the FDA

- The FDA required those in clinical trials, and others vaccinated since the clinical trials ended, to be followed for several months in order to apply for Full FDA Approval
- A review of this data was needed for the FDA to grant Full Approval
- Pfizer was the first to accumulate that data
- Moderna and J and J's vaccines received their EUAs after Pfizer, with Moderna having sent data to the FDA in support of its Full FDA Approval application

Social Media Posts

Talking points, like those above, are meant for just that — talking. They shouldn't be used verbatim in print, email or social media.

Talking points are most effective when you use your own language to share the basic information found in said content, sharing messages in a style of speech that is both expected and best understood by your audiences. For social media, that means keeping it short, conversational and not trying to tackle too much information at once. Stick to the most important details, and don't try to explain too much in a single post.

You wouldn't read Shakespeare to a fifth-grade class; instead, you would talk about the general themes of Shakespeare's stories and avoid the complicated language. We suggest a similar approach to using critical vaccine information on social media. For example:

Twitter (limited to 280 characters with spaces):

The @Pfizer @BioNTech_Group #COVID19 Vaccine received full approval from the @US_FDA on Aug. 23, 2021, for those 16 years and older. It will be marketed as Comirnaty, but it's the same vaccine and no changes were made to it. #vaccines

While the @US_FDA has granted full approval to the @Pfizer @BioNTech_Group #COVID19 vaccine for those 16 years and older, the Emergency Use Authorization remains in place for those 12-15 years of age. Speak with your doctor about your plan to get vaccinated.

Full @US_FDA approval for the @Pfizer @BioNTech_Group #COVID19 vaccine is the result of more data – clinical and real-world – as well as a larger, observable population having already received the vaccine as part of the FDA's rigorous process and requirements.

Facebook
The Pfizer-BioNTech #COVID19 Vaccine received full FDA Approval on Aug. 23, 2021, for those 16 years and older. The vaccine will be marketed as Comirnaty. It is the same Pfizer-BioNTech vaccine currently in use; no changes were made. However, with more time and data – clinical and real-world – the FDA's rigorous process and requirements were met for full approval. If you have questions or want to make a plan to get your vaccine, please contact your doctor right away.

A larger population of safety and effectiveness data, along with information provided by the manufacturer, played a significant role in the Aug. 23, 2021 decision to grant Full Approval by the FDA for the Pfizer-BioNTech #COVID19 Vaccine, which will be marketed as Comirnaty. Emergency Use Authorization by the FDA remains in effect for those 12-15 years of age and those immunocompromised persons 12 years and older authorized for a third dose

Full Approval by the FDA for the Pfizer-BioNTech #COVID19 Vaccine took three months of study by scientists and experts at the FDA who reviewed hundreds of thousands of pages of expanded safety and efficacy data dating back to December 2020. Their work included review of the vaccine's safety and efficacy under real-world conditions and inspection of the manufacturing facilities involved. Finally, the FDA also conducted its own risk/benefit analysis. The FDA ultimately determined known and potential benefits outweigh the known and potential risks of the vaccine's use in millions of people 16 years of age and older.

Additional Social Media Messaging from the Public Health Collaborative
(https://publichealthcollaborative.org/resources/resource-fda-approval-messaging-and-outreach-tools/#social-media)

Have you been waiting for full FDA approval to get vaccinated? It's time to schedule your appt! Now that the FDA has issued full approval for the first COVID-19 vaccine, we can all be even more confident that these vaccines work and are safe. Learn more: [*insert link to your local/state landing page]*

Rigorous testing, real-world data, tens of thousands in clinical trials, and billions of doses administered. That's how we know the COVID-19 vaccines are safe and effective — and now the first COVID vaccine has full FDA approval. Get yours today: [*link to local state landing page]*

After reviewing even more data about the first COVID-19 vaccine's safety and effectiveness, the FDA has issued full approval to the Pfizer vaccine. Join the millions who have already gotten a safe, effective, and free COVID-19 vaccine. *[link to local state landing page]*

As COVID-19 infections, hospitalizations, + deaths increase, the unvaccinated continue to be most at risk. The good news: the FDA has fully approved the first COVID-19 vaccine. Get yours today to protect yourself and your loved ones from the delta variant. *[link to local/state landing page]*

How can REACH recipients share this information in their communities:

1. Through listening sessions, focus groups, surveys and utilizing other needs assessment tools, find out what questions your communities may have regarding full FDA approval of a COVID-19 vaccine and develop messaging around the findings.

2. Use trusted messengers to share this information through various channels such as 'conversations in the community,' town hall gatherings, etc. Work with health care providers and other community partners and share resources with them that they can use to spread the message of the importance of COVID-19 vaccination and flu vaccination.

3. Continue to hold vaccine clinic events in your communities. You may reach those who were initially in the 'wait and see' group who were awaiting full FDA approval of a COVID-19 vaccine in order to get vaccinated.

4. Through media channels – print, TV, radio and social media.

Additional Resources

- Package insert – Comirnaty
- Fact sheet for Providers administering the vaccine
- Fact sheet for vaccine recipients
- Frequently asked questions
- NBC News article
- https://publichealthcollaborative.org/faq/#FDA-Approval
- One-pager from DeBeaumont: Communicating About FDA Approval to Build Confidence in COVID-19 Vaccines