## FDA Authorized Versus Approved Vaccines

*Updated: Aug. 3, 2021*

## Talking Points

**FDA authorized vaccines and FDA approved vaccines follow similar paths before being determined safe and effective, with some differences**

- The FDA grants an authorization or approval for a vaccine only if it is proven safe and effective after phase 3 clinical trials conducted on thousands of people, and when its benefits outweigh any risks.
- Emergency Use Authorization (EUA) allows the FDA to authorize the use of unapproved medical products like vaccines, to diagnose, treat or prevent life-threatening conditions when there are no adequate, approved and available options.
- With an EUA, scientists follow people for at least 2 months after they are given the vaccine to observe its safety and efficacy.
- With FDA approval, scientists follow persons for at least 6 months after they are given the vaccine to ensure that the vaccine is effective.
- Most serious side effects, if they occur after a vaccine, typically occur 6 to 8 weeks after vaccination.

**The FDA's Emergency Use Authorization is a mechanism used to make medical products (such as vaccines) available quickly during a public health emergency**

- EUA submission requires manufacturers to submit safety and efficacy data from vaccine clinical trials.
- This includes all data accumulated from phase one and two studies and at least two months of data from the phase three study, as well as quality and consistency data.
- These data are then evaluated by the FDA and independent groups.

**Currently, all three COVID-19 vaccines used in the United States (Moderna, Pfizer and Johnson & Johnson) have been granted Emergency Use Authorization by the FDA**

- Pfizer/BioNTech applied to the FDA for full approval of its vaccine in early May 2021
    - The FDA has granted priority review designation to the Pfizer/BioNTech application for full approval and the FDA decision should come soon.
- Moderna applied for full approval in June 2021.
- Johnson & Johnson (J&J) is expected to apply for FDA approval soon.

**Emergency Use Authorization for the Moderna, Pfizer and J&J vaccines means the FDA has determined they are "safe and effective" for their intended use**

- Due to urgent public health risks of COVID-19, EUA allowed for a faster authorization process by the FDA and other national scientists to make the vaccines available to the public as early as possible.
- All of the same steps needed for a full approval by the FDA were still followed; no shortcuts were taken.
- With input from the FDA, manufacturers decide whether and when to submit an EUA request to FDA.
- Full approvals typically can take a year or more to occur.

**The FDA still requires that all three phases of a clinical trial are followed, whether it is for an EUA or for an approval**

- For the Pfizer, Moderna and J&J vaccines, 30,000 to 40,000 people were included in the trials for each vaccine.
- Scientists still reviewed all the data from the vaccine clinical trials to ensure the vaccines were safe and effective.
- Even with an EUA, vaccine makers are still required to continue to observe the vaccinated for additional months and after some time they can submit additional follow-up data to request full approval under Biologics Licensure Application (BLA).

## 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):**
A phase 3 clinical trial w/ 2 months of monitoring data after vaccination vs. ~~a~~ phase 3 clinical trial w/ at least 6 months of data. That's one of the main differences between Emergency Use Authorization vs. full approval of COVID-19 vaccines. FDA says all 3 vaccines are safe & effective.

All three #COVID19 vaccines used in the U.S. (Moderna, Pfizer and Johnson & Johnson) have been granted Emergency Use Authorization by @US_FDA and are considered safe and effective. #getvaccinatednow

@US_FDA's Emergency Use Authorization is how medicines get to the public quickly during health emergencies. The Moderna, Pfizer and J&J #COVID19 vaccines all followed this normal process. No shortcuts were taken. The FDA considers all three safe and effective.

**Facebook**
Emergency Use Authorization for the Moderna, Pfizer and J&J vaccines means the FDA has determined they are safe and effective for their intended use. To secure their EUAs, the Moderna, Pfizer and J&J #COVID19 vaccines all required complete Phase 1 & 2 clinical trial data, plus two months of Phase 3 clinical trial data. That data was evaluated by the FDA and other scientists. This normal EUA process is how medicines, like these vaccines, are quickly made available during public health emergencies.

Currently, all three #COVID19 vaccines used in the United States (Moderna, Pfizer and J&J) have been granted Emergency Use Authorization by the FDA. Pfizer and Moderna have already applied for full FDA approval. J&J is expected to apply for FDA approval soon. Those waiting to be vaccinated should consider that full FDA approval can take a year or more. Public health officials do not recommend waiting for a full FDA approval, all 3 currently authorized vaccines were considered safe and effective by the FDA.

The FDA still requires that all three phases of a clinical trial are followed, whether it is for an EUA or for an approval. For the Pfizer, Moderna and J&J vaccines, 30,000 to 40,000 people were included in the trials for each vaccine. Scientists still reviewed all the data from the vaccine clinical trials to ensure the vaccines were safe and effective. #COVID19

## Additional Resources

FDA Emergency Use Authorization for Vaccines Explained
FDA Development & Approval Process
FDA article on regulatory terminology
Public Health Collaborative: https://publichealthcollaborative.org/faq/
Children's Hospital of Philadelphia Vaccine Education Center: https://www.chop.edu/centers-programs/vaccine-education-center/making-vaccines/prevent-covid
NBC News – Vaccine Mandates: https://www.nbcnews.com/politics/white-house/vaccine-mandates-more-likely-once-fda-grants-full-approvals-health-n1274288
Huffington Post article
Science Magazine article
Kaiser Family Foundation COVID-19 Vaccine Monitor: June 2021

CNN article
New York Times article