U.S. FOOD & DRUG ADMINISTRATION

Coronavirus Q&As for Consumers

The FDA is working to address the coronavirus disease 2019 (COVID-19) outbreak and keep you and your family informed on the latest developments. Here are answers to some frequently asked questions from consumers about vaccines.

Q: Are there any vaccines or other medical products available to prevent COVID-19?

A: Yes. On Dec. 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the use of the Pfizer-BioNTech COVID-19 Vaccine.
Additionally, the FDA is working with other vaccine developers, researchers, and manufacturers to help expedite the development and availability of medical products such as additional vaccines and antibodies, and drugs to prevent or treat COVID-19.

The FDA has scheduled a public meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) at 9 a.m. Thursday, Dec. 17, to discuss a request for an EUA of another COVID-19 vaccine. The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform.
To watch the web conference meeting, visit:

- YouTube
- Twitter
- Webcast
- Facebook

Although the VRBPAC members provide advice to the agency, which may include advice on the safety and effectiveness data submitted in the EUA request, final decisions on whether to authorize the vaccine for emergency use are made by the FDA. Read this Consumer Update to learn more about how advisory committees help the FDA make sound decisions based on the best science available, and watch this video to learn about EUAs.
For information about vaccine clinical trials for COVID-19, visit clinicaltrials.gov and the COVID-19 Prevention Network. Note: The information on clinicaltrials.gov is provided by the sponsor or principal investigator of a clinical trial. The listing of a study on the site does not reflect evaluation or endorsement of the trial by the Federal government.
Read more about what the FDA is doing to mitigate the effects of COVID-19.

Q: What is the FDA's role in approving vaccines, and what is being done to produce a COVID-19 vaccine?

A: The FDA regulates vaccines. Vaccines undergo a rigorous review of laboratory, clinical, and manufacturing data to ensure the safety, effectiveness, and quality of these products. Vaccines approved for marketing may also be required to undergo additional studies to further evaluate the vaccine and often to address specific questions about the vaccine's safety, effectiveness, or possible side effects.

On Dec. 11, 2020, the FDA issued an Emergency Use Authorization for the use of the Pfizer-BioNTech COVID-19 Vaccine. The issuance of an EUA is different than an FDA approval (licensure) of a vaccine.

In determining whether to issue an EUA for a product, the FDA evaluates the available evidence and assesses any known or potential risks and any known or potential benefits. And if the benefit-risk assessment is favorable, the product is made available during the public health emergency. Once a manufacturer submits an EUA request for a COVID-19 vaccine, the FDA then evaluates the request and determines whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the vaccine that is available to the agency.

In addition to supporting product development for high priority COVID-19 vaccines, the FDA continues to expedite clinical trials for additional vaccine candidates, providing timely advice to and interactions with vaccine developers.

For more information about COVID-19, visit:

- FDA: Coronavirus Disease 2019 (COVID-19)
- COVID-19 Vaccines
- CDC: Coronavirus (COVID-19)