

The FDA is working to address the coronavirus disease (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 and drugs:

Q: What is the FDA doing to respond to the COVID-19 pandemic?

A: The FDA, along with other federal, state, and local agencies and public health officials across the country and internationally, plays a critical role in protecting public health during the COVID-19 pandemic. FDA staff are working round-the-clock to support development of [medical countermeasures](#) and are providing regulatory advice, guidance, and technical assistance to advance the development and availability of vaccines, therapies, diagnostic tests and other medical devices for use diagnosing, treating, and preventing this novel virus. The FDA continues to monitor the human and animal food supply and take swift action on fraudulent COVID-19 products.

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. There are currently no vaccines available for the prevention of COVID-19.

Vaccines undergo a rigorous review of laboratory and clinical data to ensure the safety and effectiveness 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.

The FDA is expediting clinical trials for vaccines by providing timely advice to and interactions with vaccine developers. The FDA is also supporting product development and scaling up of manufacturing capacity for high priority vaccines for COVID-19. [Vaccine developers can find more info about the review process here.](#)

Q: What does it mean to be an FDA-approved drug?

A: FDA approval of a drug means that the agency has determined, based on substantial evidence, that the drug is effective for its intended use, and that the benefits of the drug outweigh its risks when used according to the product's approved labeling. The drug approval process takes place within a structured framework that includes collecting clinical data and submitting an application to the FDA. [Learn more about the FDA's Drug Review Process.](#)

Q: What is the FDA's role in regulating potential treatments during a public health emergency?

A: The FDA carries out many activities to protect and promote public health during a public health emergency, including helping to accelerate the development and availability of potential treatments, maintaining and securing drug supply chains, providing guidance to food and medical device manufacturers, advising developers on clinical trial issues during a public health emergency, and keeping the public informed with authoritative health information.

The FDA is committed to supporting the development of new drugs, and the potential repurposing of existing drugs, to address COVID-19 by working with potential drug makers and sponsors to rapidly move products into clinical trials, while helping to ensure that trials are properly designed and safe. Read more about FDA efforts to [accelerate treatments](#) and other [actions related to coronavirus](#).

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