FDA RESPONSE TO COVID-19: WHAT YOU NEED TO KNOW

The U.S. Food and Drug Administration continues to play a critical role in accelerating medical products to diagnose, treat and prevent COVID-19. Working together with clinicians, health care organizations and other partners, FDA is committed to meeting the challenge of COVID-19.

For more information access www.fda.gov/coronavirus

Diagnostic and Antibody Testing

During the COVID-19 pandemic, the FDA oversees the validity of tests developed by others through the Emergency Use Authorization (EUA) process. The agency is working diligently with manufacturers to meet the urgent need to authorize COVID-19 tests. FDA is taking the necessary steps to ensure that the tests developed for clinical use in the United States provide accurate and reliable results and to help provide timely access to such tests.

Vaccine Development

FDA is working closely with federal partners, vaccine developers, researchers, manufacturers, and experts across the globe to help expedite the development and availability of vaccines to prevent COVID-19. FDA intends to use regulatory flexibility to help ensure the most efficient and timely development of safe and effective vaccines to prevent COVID-19.

Therapeutics

FDA created the Coronavirus Treatment Acceleration Program (CTAP), a new program designed to expedite the development of potential COVID-19 therapies, using every tool at the agency's disposal. Several therapies are currently being tested in clinical trials to evaluate whether they are safe and effective in combating COVID-19. For more information visit the CTAP program web page.

Medical Product Supply

FDA is helping to expedite the development and availability of medical products needed to diagnose, treat, and prevent this disease. FDA has been monitoring the worldwide demand and helping to mitigate supply chain disruptions caused by the COVID-19 pandemic. FDA is also working to help increase the availability of personal protective equipment (PPE) and other critical devices that patients and those on the front lines of the U.S. response rely upon.

Fraudulent Products

FDA exercises its regulatory authority to protect consumers from companies and individuals selling products with false or misleading claims to prevent, treat, mitigate, diagnose, or cure COVID-19, including by issuing warning letters and pursuing civil and criminal enforcement actions, where appropriate.
See Fraudulent Coronavirus Disease 2019 (COVID-19) Products for more information.

FDA

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