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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

July 15, 2020

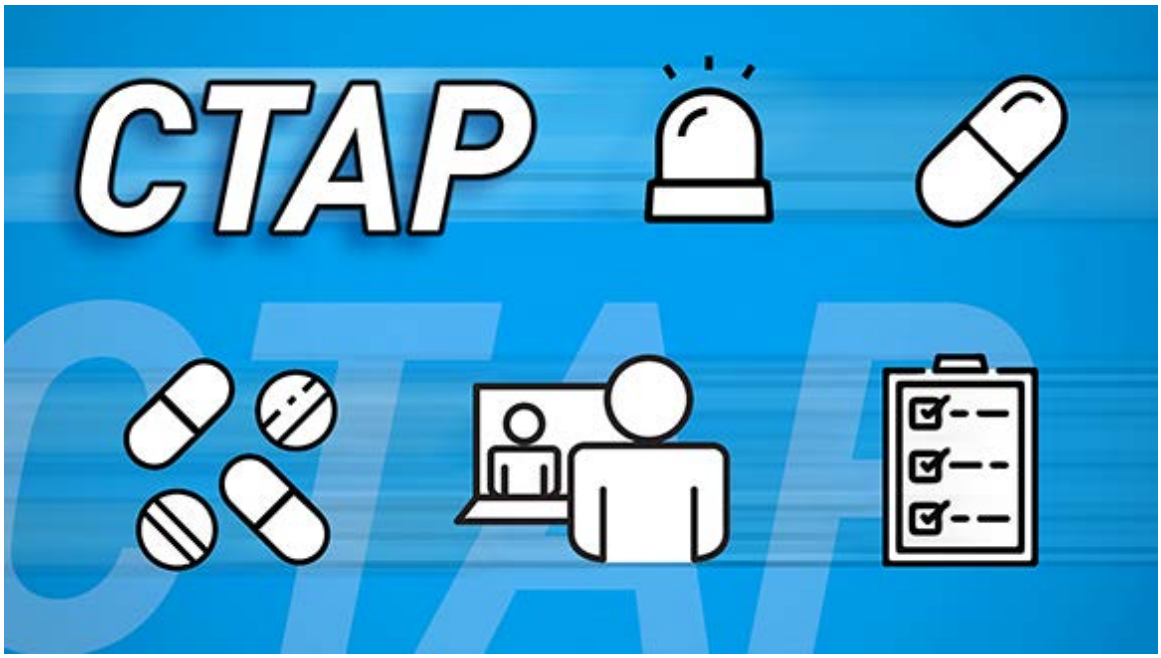
Coronavirus Disease 2019 (COVID-19) Update

FDA is an active partner in the coronavirus disease (COVID-19) response, working closely with our government and public health partners across the U.S. Department of Health and Human Services, and with our international counterparts. Actions by the FDA in our ongoing response to the COVID-19 pandemic since our last MCMi email update on July 8, 2020 include:

Coronavirus (COVID-19) Updates:

- July 14, 2020: Daily Roundup: FDA actions on treatment acceleration, drug compounding, warning letters, hand-sanitizer quiz, therapeutics, and more
- July 10, 2020: FDA prepares for resumption of domestic inspections with new risk assessment system
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA



A Behind the Scenes Look at How FDA is Working to Facilitate COVID-19 Treatments

When the FDA learned of the novel coronavirus (COVID-19) and its potentially devastating effects, we acted swiftly to set the regulatory stage for drug and biologics manufacturers to develop products to treat this serious disease. To meet this urgent need, the FDA created the Coronavirus Treatment Acceleration Program (CTAP) to enable the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to leverage cross-agency scientific resources and expertise to bear on COVID-19 therapeutic development and review.

We're excited to say that there are now more than 510 drug development programs in planning stages, and as of today, the agency has reviewed more than 230 trials of potential therapies for COVID-19. *(July 14, 2020)*

Read more: FDA Voices

Related links:

- Coronavirus Treatment Acceleration Program (CTAP) - On July 14, 2020, FDA updated the CTAP webpage and posted key materials to provide information about CTAP's purpose, strategy and operations. Specifically, this update included posting a dashboard showing crucial statistics related to the development of potential COVID-19 therapeutics.
- New web page: Ensuring the Safety of Patients in Clinical Trials Studying Investigational New Drugs to Prevent or Treat COVID-19 *(July 14, 2020)*
- Coronavirus (COVID-19) | Drugs
- Coronavirus (COVID-19) | CBER-Regulated Biologics

FDA Insight Podcast

Join Dr. Anand Shah, FDA's Deputy Commissioner for Medical and Scientific Affairs, and other FDA leaders as they provide their **insight** into issues facing the agency – including the COVID-19 pandemic and other emerging topics. New episodes on Tuesdays!

- Ep. 1: Fighting COVID-19 at the FDA
- Ep. 2: All About COVID-19 Testing
- Ep. 3: Food Safety and COVID-19
- Ep. 4: **New!** Clinical Trials and Treatments for COVID-19

Emergency Use Authorization (EUA) Updates

EUAs to improve air flow, provide relief from shortness of breath in asthma patients
FDA issued an EUA (PDF) to Electrocore Inc., for its GammaCore Sapphire Non-invasive Vagus Nerve Stimulator. This stimulator is intended for use at home or in health care settings to treat adult patients with known or suspected COVID-19 who are experiencing worsened asthma-related shortness of breath and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by the patient's healthcare provider. The device improves airflow and provides relief from exacerbated asthma-related shortness of breath in such patients. The device is placed on either side of the patient's neck for two consecutive two-minute stimulations at the onset of respiratory distress or shortness of breath for up to 24 stimulations every 24 hours. *(July 10, 2020)*

FDA also added Circadiance, under the umbrella EUA for ventilators, for its SleepWeaver Prevent CPAP Mask. The product is a CPAP mask that was modified by combining it with an N95. *(July 8, 2020)*

Diagnostic test EUAs
To date, FDA has currently authorized 179 tests under EUAs, which include 148 molecular tests, 29 antibody tests, and 2 antigen tests. *Also see: Coronavirus Testing Basics*

Related links:

- FAQs on Testing for SARS-CoV-2 (frequently updated)
- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices

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Events

- **Today! July 15, 2020:** Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests - FDA will host a virtual Town Hall for clinical laboratories and commercial manufacturers that are developing or have developed diagnostic tests for SAR-CoV-2, 12:15 p.m. - 1:15 p.m. ET. FDA will host additional town halls in this series on Wednesdays in July.
- **July 21, 2020:** Save the date for the next event in the webinar series Respirators for Health Care Personnel Use during COVID-19 Pandemic.

Information for industry

Health care providers

- Home-Use Blood Glucose Meters Used in Hospitals and Long-Term Care Facilities During the COVID-19 Pandemic - FDA recognizes that home-use blood glucose meters may be used by patients with diabetes who are hospitalized due to COVID-19 or by those who reside in long-term care facilities (nursing homes, skilled nursing facilities, and assisted living facilities) to check their own blood glucose levels and provide the readings to the health care personnel caring for them. The FDA has updated these frequently asked questions to recognize that these devices may be used in long-term care facilities as well as hospitals. *(July 10, 2020)*

Biologics

- Study of antibody response to SARS-CoV-2 spike proteins could help inform vaccine design - FDA scientists have identified specific areas on the so-called spike proteins on the surface of the COVID-19-casuing virus that appear to be key to triggering strong protective antibody responses in rabbits exposed to the virus. The virus uses one part of the spike protein to attach to a cell and another to fuse with the cell membrane, enabling the virus to infect the cell. The scientists studied antibody response to SARS-CoV-2 spike proteins, which could help inform vaccine design by increasing our understanding of the various triggered antibody responses. *Also see the article in Science Translational Medicine (July 10, 2020)*

The FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid COVID-19 response efforts. FDA has issued more than 50 COVID-19-related guidances to date.

COVID-19-Related Guidance Documents

In case you missed it

- Coronavirus Disease 2019 (COVID-19) Resources for Health Professionals
- COVID-19 Educational Resources
- FDA Updates on Hand Sanitizers with Methanol *(updated July 10, 2020)*

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