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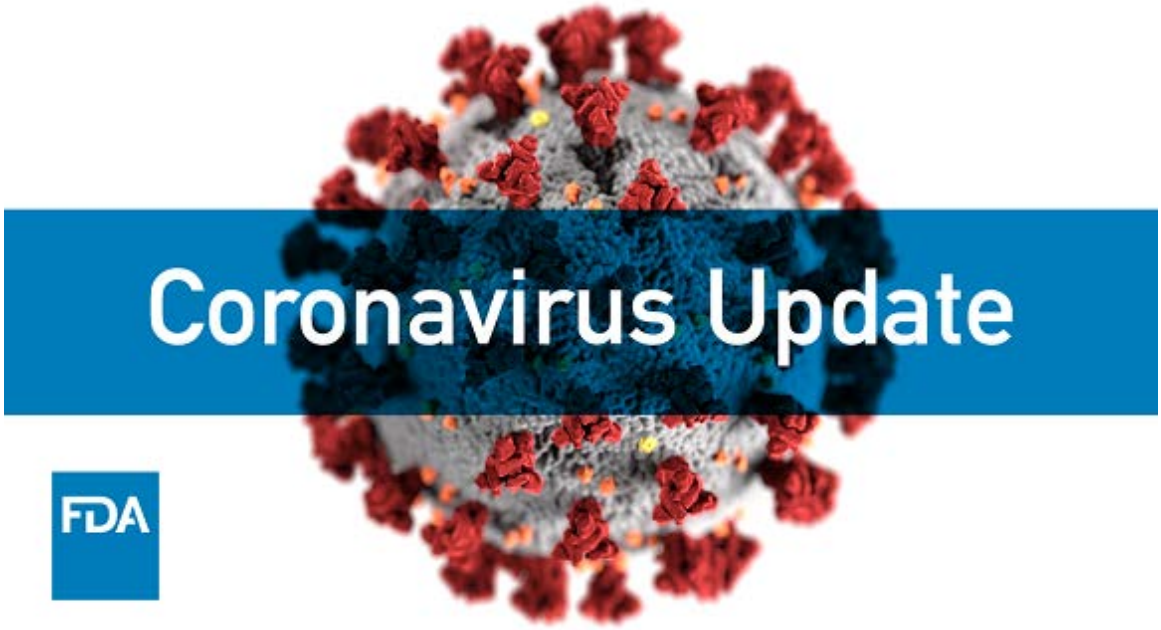
U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

April 1, 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 March 25, 2020 include:

Coronavirus (COVID-19) Updates:

- March 31, 2020 - Daily Roundup including information about diagnostics and new warning letters
- March 30, 2020 - Daily Roundup including new Emergency Use Authorizations (EUAs) and enforcement policies to help expand the availability and capability of sterilizers, disinfectant devices and air purifiers, and expand the availability of gowns and other protective apparel
- March 30, 2020 - FDA Continues to Accelerate Development of Novel Therapies for COVID-19 - *Also see: Coronavirus Treatment Acceleration Program (CTAP)*
- March 30, 2020: FDA expedites review of diagnostic tests to combat COVID-19

- March 29, 2020 - HHS accepts donations of medicine to Strategic National Stockpile as possible treatments for COVID-19 patients - FDA issues EUA for donated hydroxychloroquine sulfate, chloroquine phosphate
- March 28, 2020 - FDA takes further steps to help mitigate supply interruptions of food and medical products
- March 27, 2020 - Daily Roundup on topics including diagnostics, guidance for manufacturers to make sure that they continue to notify FDA of any permanent discontinuance or interruption of drug and biological product manufacturing in a timely manner, and a letter to stakeholders about the imminent threat to the health of consumers who may take chloroquine phosphate products used to treat disease in aquarium fish, thinking the products are interchangeable with FDA-approved drugs (used to treat malaria and certain other conditions in humans) that are being studied as a COVID-19 treatment for humans.
- March 27, 2020 - Consumer Update: Food Safety and Availability During the Coronavirus Pandemic
- March 27, 2020 - Consumer Update: Safely Using Hand Sanitizer
- March 27, 2020 - FDA takes action to help increase U.S. supply of ventilators and respirators for protection of health care workers, patients
- March 26, 2020 - Daily Roundup, including questions and answers related to consumer use of hand sanitizer during the COVID-19 public health emergency
- March 25, 2020 - Daily Roundup, including guidances for industry, and an EUA (PDF) for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories.

COVID-19 Updates from FDA

FDA Efforts to Connect Manufacturers and Health Care Entities: COVID-19 Response Public-Private Partnership

FDA entered a Memorandum of Understanding (MoU) with the Department of Veterans Affairs (VA) Innovation Ecosystem and the National Institutes of Health (NIH) 3D Print Exchange, to share data, and coordinate on open-source medical products for the COVID-19 response with other stakeholders such as America Makes. *(March 25, 2020)*

Learn more

Related links:

- **FAQs on 3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic** - Manufacturers and facilities may email COVIDManufacturing@fda.hhs.gov with questions.
- America Makes COVID-19 Health Care Needs and AM Capabilities Repository
- VA VHA Innovation Ecosystem: 3D Printing for COVID-19

- NIH 3D Print Exchange: COVID-19 Supply Chain Response

Emergency Use Authorization (EUA) Updates

Reminder: FDA Sets up 24/7 Hotline to Help Labs with Diagnostic Test Issues
FDA's 24/7 hotline (1-888-INFO-FDA, choose option *) is available for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs and media needed for transport and conservation of the samples.

22 diagnostic EUAs issued to date
In the COVID-19 pandemic, the FDA has worked with more than 160 test developers who have said they will be submitting applications to make tests that detect the virus. To date, 22 EUAs have been issued for nation-wide use. Under our laboratory developed test policy (PDF) during COVID-19, the FDA has been notified by more than 65 laboratories.

High Complexity Molecular-Based Laboratory Developed Tests
On March 31, 2020, FDA concluded (PDF) based on the totality of scientific evidence available that molecular-based laboratory developed tests (LDTs) that are authorized for use by the singular developing laboratory are appropriate to protect the public health or safety (as described under the Scope of Authorization (Section II)) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests. *More information*

Reissued Respirator EUAs

- March 29, 2020: FDA reissued an EUA for the Battelle Decontamination System for use in decontaminating compatible N95 respirators for reuse by health care personnel during the COVID-19 pandemic (initially issued March 28, 2020).
- March 28, 2020: FDA also reissued both the NIOSH-approved Respirator EUA (PDF) and the non-NIOSH approved Respirator EUA (PDF) to include N95 respirators that have been decontaminated with Battelle's new system under these EUA authorizations.

Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests

April 1, 2020: 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 also plans to hold virtual town halls for clinical laboratories and commercial manufacturers to help answer questions on **April 8, 15, 22, and 29**, from 1:15 p.m. - 2:15 p.m. ET.

Related links:

- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- Emergency Use Authorizations (Devices)
- Information for Laboratories Implementing IVD Tests Under EUA
- FDA Issues New Policy to Help Expedite Availability of Diagnostics *(February 29, 2020)*

Information for industry

- Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency *(March 30, 2020)*
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency *(March 29, 2020)*
- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic, updated with an appendix adding questions and answers *(March 30, 2020)* - For questions on clinical trial conduct during the COVID-19 pandemic, please email Clinicaltrialconduct-COVID19@fda.hhs.gov.
- Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry *(March 27, 2020)*
- The FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid coronavirus disease 2019 (COVID-19) response efforts. Please bookmark our new web page, COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders, for the latest information (button below).

COVID-19-Related Guidance Documents

In case you missed it

- Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions (www.fda.gov/coronavirusFAQ)
- Summary of FDA & EMA Global Regulators Meeting on Data Requirements Supporting First-in-Human Clinical Trials with SARS-CoV-2 Vaccines *(March 18, 2020)*
- Investigational COVID-19 Convalescent Plasma -Emergency INDs: Frequently Asked Questions

(PDF) *(March 26, 2020)*

- HHS/ASPR Strategic National Stockpile (SNS) Response to the COVID-19 Pandemic - As part of the ongoing response, the SNS is deploying personal protective equipment (PPE), including N95 respirators, surgical and face masks, face shields, gloves, and disposable gowns, to help prevent COVID-19 transmission in all 50 states, the nation's four largest cities, and U.S. territories and ventilators to areas in need. The SNS is also working with its partners across the federal government to coordinate logistics operations in order to leverage all available resources to support the COVID-19 response. *(March 29, 2020)*
- HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus *(March 6, 2020)*

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