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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

June 17, 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 June 10, 2020 include:

Coronavirus (COVID-19) Updates:

- June 16, 2020: Daily Roundup: FDA actions on an online portal for adverse event reporting on EUA devices or COVID-19-related guidance and more
- June 16, 2020: Facilitating Diagnostic Test Availability for Asymptomatic Testing and Sample Pooling
- June 16, 2020: FDA Revokes Emergency Use Authorization for Chembio Antibody Test
- June 15, 2020: FDA Warns of Newly Discovered Potential Drug Interaction That May Reduce Effectiveness of a COVID-19 Treatment Authorized for Emergency Use
- June 15, 2020: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine
- June 11, 2020: FDA Voices - Rare Disease Therapy Development and Access Remain Top FDA

Priorities During COVID-19

- June 10, 2020: FDA Authorizes First Next Generation Sequence Test for Diagnosing COVID-19
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

Pet Safety & COVID-19

Watch this new video and read the Consumer Update to learn more about keeping your pets safe during the COVID-19 pandemic.

Consumer Update & video: Q&A on COVID-19 & Pets

Emergency Use Authorization (EUA) Updates

FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine
On June 15, 2020, based on FDA's continued review of the scientific evidence available for hydroxychloroquine sulfate (HCQ) and chloroquine phosphate (CQ) to treat COVID-19, FDA has determined that the statutory criteria for EUA as outlined in Section 564(c)(2) of the Food, Drug, and Cosmetic Act are no longer met. Specifically, FDA

has determined that CQ and HCQ are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other serious side effects, the known and potential benefits of CQ and HCQ no longer outweigh the known and potential risks for the authorized use. This warrants revocation (PDF) of the EUA for HCQ and CQ for the treatment of COVID-19. *Also see: Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate (PDF, June 15, 2020)*

FDA Revokes Emergency Use Authorization for Chembio Antibody Test

On June 16, 2020, FDA revoked (PDF) the EUA of the Chembio Diagnostic System, Inc. (Chembio) DPP COVID-19 IgM/IgG System, a SARS-CoV-2 antibody test, due to performance concerns with the accuracy of the test. Antibody tests, a type of serological test, can help provide information on a person's and population's exposure to COVID-19.

FDA Warns of Newly Discovered Potential Drug Interaction That May Reduce Effectiveness of a COVID-19 Treatment Authorized for Emergency Use

On June 15, 2020, FDA warned health care providers about a newly discovered potential drug interaction related to the investigational antiviral drug remdesivir, which has received EUA for the treatment of hospitalized COVID-19 patients with severe disease. Based on a recently completed non-clinical laboratory study, the FDA revised the fact sheet for health care providers (PDF) that accompanies the drug to state that co-administration of remdesivir and chloroquine phosphate or hydroxychloroquine sulfate is not recommended as it may result in reduced antiviral activity of remdesivir. *Also see: Frequently Asked Questions on the EUA for Remdesivir for Certain Hospitalized Patients (PDF, updated June 15, 2020)*

New point of care test EUA

On June 10, 2020, FDA issued an EUA (PDF) for Cue Health Inc.'s Cue COVID-19 Test, authorized for use at the point of care (in patient care settings), giving patients more immediate access to test results. For more information, see the June 12, 2020 Daily Roundup.

Testing supply substitution strategies - reminder

FDA is offering a new resource, **Testing Supply Substitution Strategies** (1.5 MB). This 22-slide PowerPoint file contains detailed information to help support labs performing authorized COVID-19 tests. This interactive tool includes validated supply alternatives that labs can use to continue performing testing when there is a supply issue with some components of a test. To navigate through the strategies in the file, download the file, open it, and click Slide Show > From Beginning. *(June 3. 2020)*

Diagnostic test EUAs

To date, the FDA has authorized 140 tests under EUAs, which include 118 molecular tests, 21 antibody tests, and 1 antigen test. *Also see: Coronavirus Testing Basics*

Related links:

- What is an EUA? (video)

- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- EUA Authorized Serology Test Performance
- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices *(updated June 15, 2020)*
- FDA Combating COVID-19 with Medical Devices *(PDF, updated June 15, 2020)*
- Contacts for Medical Devices During the COVID-19 Pandemic

Events

- **Today! June 17, 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 June. *There is significant interest in this Town Hall. Connecting early is highly recommended. To ensure you are connected, please dial-in at 12:00 p.m. ET*
- **June 23, 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

- **Devices - new FAQs for industry:**
  - Hospital Beds, Stretchers, and Mattresses During the COVID-19 Public Health Emergency *(June 10, 2020)*
  - Adverse Event Reporting for Medical Devices Under EUA or Discussed in COVID-19-Related Guidance Documents *(June 15, 2020)*
- **Drugs and biologics:**
  - FDA and NIH have made updates to the CURE ID crowd-sourcing app to make it easier for healthcare providers to share — via mobile device or website — their experiences treating COVID-19 patients who are unable to be enrolled in a clinical trial. CURE ID's web-based repository lets providers share experiences with novel uses of existing drugs in treating difficult-to-treat infectious diseases. Healthcare providers worldwide are encouraged to share their COVID-19 treatment experiences via CURE ID.
- 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
- From CDC - Buyer Beware: How to Avoid Scams, Fraud, & Rumor During an Emergency

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