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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

June 24, 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 17, 2020 include:

Coronavirus (COVID-19) Updates:

- June 23, 2020: Daily Roundup: FDA actions on food safety, the CURE Drug Repurposing Collaboratory, and more
- June 23, 2020: Testimony: Oversight of the Trump Administration's Response to the COVID-19 Pandemic, by FDA Commissioner, Stephen M. Hahn, MD and other HHS officials
- June 23, 2020: Consumer Update: Getting Smarter about Food Safety: The Pandemic and Lessons Learned
- June 23, 2020: FDA Maintains the Pace of Meeting Its Goals on Applications for Medical Products During the Pandemic

- June 23, 2020: New FDA Insight podcast - Episode 1: Fighting COVID-19 at the FDA - FDA Commissioner Dr. Stephen Hahn, and FDA Deputy Commissioner for Medical and Scientific Affairs Dr. Anand Shah discuss FDA's COVID-19 efforts, including the drug development process for a COVID-19 treatment (13:40)
- June 19, 2020: FDA advises consumers not to use hand sanitizer products manufactured by Eskbiochem, due to the potential presence of methanol (wood alcohol), a substance that can be toxic when absorbed through the skin or ingested
- June 18, 2020: FDA Takes Additional Action to Harness Real-World Data to Inform COVID-19 Response Efforts
- June 17, 2020: FDA Issues Warning Letters to Companies Inappropriately Marketing Antibody Tests, Potentially Placing Public Health at Risk
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

3D Printing in FDA's Rapid Response to COVID-19

The FDA continues to take creative and flexible approaches to address access to critical medical products in response to COVID-19. In partnership with academic researchers, non-traditional manufacturers, communities of makers, and individuals who are banding together to support and fill local and national needs, the FDA is actively engaged and is developing ways to support these groups seeking to help their communities. Our goal is to help expand the availability of relevant products in ways that are consistent with the FDA's public-health mission.

For example, the FDA is working in partnership with the National Institutes of Health (NIH), the Veterans Administration (VA), and America Makes to support non-traditional manufacturing approaches (e.g., 3D printing), to address devices shortages including personal protective equipment (PPE). Through this

partnership, 3D-printable designs for COVID response are assessed by the VA, and the NIH posts them on its 3D Print Exchange. The FDA has, among other things, provided information on labeling and testing for face shields and face masks. On June 19, 2020, the FDA posted a web update that documents how this partnership has contributed to the number of medical devices—including PPE—and parts available to support the COVID-19 response since its launch 10 weeks ago. For example, 31 community-submitted designs passed the testing performed by VA clinics and were given clinically reviewed status. In addition, this effort has so far matched more than 272,000 3D-printed face shields and more than 230,000 3D-printed face masks with health care providers and others in need. The FDA has issued a temporary policy for face masks and respirators during the COVID-19 public-health emergency.

View the new 3D printing update

Emergency Use Authorization (EUA) Updates

Certain COVID-19 serology/antibody tests should not be used
FDA **recommends** that clinical laboratories and health care providers stop using COVID-19 antibody tests listed on FDA's **"removed" test list.** The "removed" test list includes:

- tests where significant clinical performance problems were identified that cannot be or have not been addressed by the commercial manufacturer in a timely manner,
- tests for which an Emergency Use Authorization request has not been submitted by a commercial manufacturer of a serology test within a reasonable period of time as outlined in the FDA's guidance, and
- tests voluntarily withdrawn by the respective commercial manufacturers. *(June 19, 2020)*

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, FDA has authorized 145 tests under EUAs, which include 122 molecular tests, 22 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)
- Contacts for Medical Devices During the COVID-19 Pandemic

Events

- **Today! June 24, 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*
- **July 7, 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:**
  - FDA updated the guidance, Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency, to facilitate notification regarding device manufacturing interruptions or discontinuance. The FDA updated this guidance to include a list of device types and corresponding product codes that FDA recommends manufacturers consider in determining whether a notification under Section 506J of the FD&C Act is required during the COVID-19 pandemic. *Also see: Medical Device Supply Chain Notifications During the COVID-19 Public Health Emergency (June 19, 2020)*
  - Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers *(June 22, 2020)*
  - Non-contact Temperature Assessment Devices During the COVID-19 Pandemic *(June 19, 2020)*
- **Drugs:**
  - FDA is partnering with the Critical Path Institute (C-Path) and the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH), on the CURE Drug Repurposing Collaboratory (CDRC). CDRC will provide a forum for the exchange of clinical practice data to inform potential new uses of existing drugs for areas of high unmet medical need, advancing research in these areas. CDRC will focus on capturing relevant real-world clinical outcome data through the FDA-NCATS CURE ID platform. In a pilot project focused on COVID-19, CDRC will use data collected via the CURE ID platform to aggregate global clinician treatment experiences to identify existing drugs that demonstrate possible treatment approaches that should be studied further. *(June 23, 2020)*

- **Guidance for industry:**
  - On June 17, 2020, the FDA issued a guidance for industry entitled, Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency. The COVID-19 pandemic has impacted clinical development and ongoing clinical trials across investigational product areas. Public health measures to control the virus may impact the ability to collect data, for example, if trial participants are not able to visit clinical sites for endpoint assessments. To help ensure that the trial will provide interpretable findings with correct statistical quantification of uncertainty, this guidance addresses statistical considerations for proposed changes to trial conduct due to the COVID-19 pandemic that may impact the analysis and interpretation of the primary or key secondary endpoints in the trial.
- 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

- **New toolkit!** Convalescent Plasma Fact Sheets and Toolkit for Health Professionals *(June 19, 2020)*
- Coronavirus Disease 2019 (COVID-19) Resources for Health Professionals
- COVID-19 Educational Resources
- FDA COVID-19 Response At-A-Glance Summary *(PDF, updated June 18, 2020)*

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