FDA NEWS RELEASE

Coronavirus (COVID-19) Update: Daily Roundup, March 24, 2020

For Immediate Release:

March 24, 2020

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA is facilitating access to convalescent plasma, antibody-rich blood products that are taken from blood donated by people who have recovered from the COVID-19 virus, that could shorten the length, or lessen the severity, of the illness. The agency will be using multiple pathways to support these efforts and has posted information for investigators (/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-inds) wishing to study convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of single patient emergency Investigational New Drug Applications for individual patients. The FDA also is actively engaging with researchers to discuss the possibility of collaboration on the development of a master protocol for the use of convalescent plasma, with the goal of reducing duplicative efforts.
- In response to this evolving public health emergency and continued filtering facepiece respirator (FFR or respirator) shortages, FDA has concluded based on the totality of scientific evidence available that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety (as described under section II Scope of Authorization) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized respirators listed in Exhibit 1 are authorized for use in healthcare settings by healthcare personnel (HCP) when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.
    - Letter of Authorization (https://www.fda.gov/media/136403/download)
    - Non-NIOSH Approved Respirator EUA FAQ (/medical-devices/emergency-situations-medical-devices/non-niosh-approved-respirator-eua-faq)
- The FDA issued a Consumer Update (/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments) advising consumers to be beware of fraudulent coronavirus tests, vaccines and treatments. The FDA is particularly concerned that deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It's likely that the products do not do what they claim, and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications. There are no FDA-approved products to prevent COVID-19. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. The agency warns not to take any form of chloroquine unless it has been prescribed by a health care provider and obtained from legitimate sources.
- Diagnostics update: In certain emergencies, the FDA can often quickly issue an emergency use authorization (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) for diagnostic tests based on FDA's rolling review of data and where the request meets certain criteria. In the COVID-19 pandemic, the FDA has worked with more than 190 test developers who have said they will be submitting applications to make tests that detect the virus. To date, 16 emergency use authorizations have been issued for nation-wide use, including one (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019) today. Under our laboratory developed test policy (https://www.fda.gov/media/135659/download) during COVID-19, the FDA has been notified by more than 65 laboratories.
- The FDA issued a Letter to Industry (https://www.fda.gov/media/136383/download) that includes steps the Center for Devices and Radiological Health (CDRH) has taken to prioritize work that advances the nation's response during the Coronavirus Disease 2019 (COVID-19) public health emergency. These steps seek to address the impact of COVID-19 public health emergency on day-to-day operations in CDRH and in the medical device industry, while ensuring that government and private sector efforts to respond to this national emergency receive the highest priority.

- The FDA provided flexibility to veterinarians (/news-events/press-announcements/coronavirus-covid-19-update-fda-helps-facilitate-veterinary-telemedicine-during-pandemic) who want to utilize telemedicine to prescribe certain drugs for animals by temporarily suspending enforcement of portions of the federal veterinarian-client-patient relationship requirements. This helps veterinarians continue to care for animals while minimizing person-to-person contact between veterinary staff and the animal owner or caretaker, allowing for the social distancing that is so important in limiting the further spread of coronavirus.
- The FDA explained how the agency is working with experts around the world to find ways to prevent and treat COVID-19, including collaborating with international organizations to facilitate the development of a vaccine: FDA Voices: FDA and EMA Collaborate to Facilitate SARS-CoV-2 Vaccine Development (/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-and-ema-collaborate-facilitate-sars-cov-2-vaccine-development).
- The FDA took action to increase U.S. supplies to support the U.S. response to COVID-19 by providing instructions to manufacturers (https://content.govdelivery.com/bulletins/gd/USDHSCBP-282c648?wgt_ref=USDHSCBP_WIDGET_2?utm_source=csms.cbp.gov&utm_medium=csms.cbp.gov&utm_term=undefined&utm_content=undefined&utm_campaign=(not%20set)&gclid=undefined&dclid=undefined&GAID=1278996374.1567630590) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) importing personal protective equipment and other devices. The agency is engaging with importers and others involved in the import trade community during this pandemic to facilitate the entry of needed products, including PPE, into the U.S. These instructions to importers clarify the types of PPE that can be imported without engaging with FDA. They also include information about the type of information importers can submit to facilitate their entries.
- The FDA provided an update, FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19 (/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-offers-assurance-about-food-safety-and-supply-people-and-animals-during-covid-19), to explain that the U.S. food supply remains safe for both people and animals. There is no evidence of human or animal food or food packaging being associated with transmission of the coronavirus that causes COVID-19. Additionally, overall, retail supply chains remain strong, and the FDA is working with food manufacturers and grocery stores to closely monitor the human food supply chain for any shortages. The same is true for animal food. The FDA is monitoring the availability of foods for livestock and pets. There are no shortages, and no current disruptions in the pet and livestock food supply chain.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- Coronavirus Disease 2019 (COVID-19) (/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19)

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