



COVID-19 U.S. REGULATORY UPDATES

On January 31, a public health emergency was declared by the U.S. Department of Health and Human Services due to the coronavirus (COVID-19) outbreak. Since then, numerous key FDA regulatory actions have occurred, which have been provided as [daily roundups on the FDA website](#) and which we summarize below.

EMERGENCY USE AUTHORIZATIONS (EUAS)

Emergency Use Authorization is an expedited pathway that allows interstate distribution of medical countermeasures during a public health crisis such as the COVID-19 pandemic. The most current list of medical devices authorized for emergency use is posted to FDA's website.¹ Briefly, FDA has targeted the following medical device types for EUAs:

- > In vitro diagnostic tests
- > Lab developed tests
- > COVID-19 antibody tests
- > Personal protective equipment (PPE) (e.g. disposable filtering faceplate respirators)
- > Sterilization and decontamination systems
- > Ventilators (including their accessories as well as other devices that can be modified for use as ventilators)

In addition, FDA has issued EUAs for three drug products (remdesivir, propofen 0.5% and multi-filtrate PRO for CRRT). FDA had also issued an EUA for hydroxychloroquine; however, this EUA was withdrawn in June 2020, due to lack of effect and serious cardiac adverse events.²



FDA GUIDANCE

FDA continues to issue guidances for immediate implementation pertaining to various premarket and postmarket activities for certain medical products during the COVID-19 pandemic. An updated list of guidances is posted to FDA's website, with 51 COVID-related guidances published to date.³ Briefly, some key guidances are described below:

- > Development and use of diagnostic tests and corresponding regulatory requirements, including emergency use authorization requests⁴
- > Conduct of clinical studies during the COVID pandemic, including various measures to protect the safety of study participants⁵
- > Postmarket adverse event reporting for drugs, biologics, medical devices, combination products and dietary supplements during the COVID pandemic, considering the anticipated workforce reduction⁶

¹ <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices>

² <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>

³ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>

⁴ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help>

⁵ <https://www.fda.gov/media/136238/download>

⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic>



- > Temporary modifications of 510(k)-cleared non-invasive, vital sign-measuring devices to allow remote monitoring in a home environment, with the goal of reducing the risk of COVID exposure for patients⁷
- > Temporary modifications and repurposing of respiratory devices including ventilators to facilitate greater availability of these device types, with FDA exercising enforcement discretion and encouraging manufacturers to submit EUA requests⁸
- > Compounding of hand sanitizers and the use of alcohol produced by non-drug companies (distillers) for use in the manufacture of hand sanitizers, to address the shortage of hand sanitizers⁹
- > Enforcement policies for face masks, respirators, gowns and gloves during the COVID pandemic^{10 11}
- > EUA recommendations pertaining to decontamination and bioburden reduction systems for face masks and respirators¹²
- > Expanded access requests for the treatment of individual patients with investigational drugs and biologics¹³
- > An enforcement policy for non-invasive remote patient monitoring devices¹⁴
- > Recommendations to health care providers, investigators and blood establishments on the administration, study and collection of investigational convalescent plasma from individuals who have recovered from COVID-19 (COVID-19 convalescent plasma)¹⁵
- > Effects of COVID-19 on meetings with industry and the Medical Device User Fee Amendments (MDUFA) timelines and goals¹⁶
- > Notification to FDA of discontinuance or interruption in the manufacture of devices, including devices that are life-supporting, life-sustaining or intended for use in emergency medical care or during surgery¹⁷
- > COVID-19 vaccine development and licensure¹⁸



⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during>

⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus>

⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-manufacture-alcohol-incorporation-alcohol-based-hand-sanitizer-products-during>

¹⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>

¹¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health>

¹² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks>

¹³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-review-individual-patient-expanded-access-requests-investigational>

¹⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during>

¹⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-covid-19-convalescent-plasma>

¹⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices>

¹⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc>

¹⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>

FDA COMMUNICATIONS/DEVELOPMENTS

- > FDA issued a letter to health care providers¹⁹ with strategies to conserve PPE such as surgical masks (not including N95 respirators) and gowns, as well as surgical gloves²⁰. These letters contain FDA's recommended actions based on current supply levels and health care organizational needs.
- > As of May, FDA reported 144 active trials of therapeutic agents, with another 457 development programs for therapeutic agents in the planning stages. This includes the first FDA-approved IND for evaluation of a novel vaccine mRNA-1273, developed by Moderna, which is soon to initiate its Phase 3 trial. In addition, several drug treatments are being evaluated in clinical studies, including a Phase III trial of Gilead's remdesivir²¹, where FDA has recently issued warnings to health care providers regarding the potential for serious drug interactions.²²
- > FDA is working with regulatory bodies around the world to find ways to prevent and treat COVID-19, such as collaborations with the European Medicines Agency on vaccine development, including the type of preclinical studies needed and the data needed to address the theoretical potential for a vaccine to enhance disease²³.
- > FDA issued FAQ on 3D printing, given that 3D printing may be used to address PPE shortages during the COVID pandemic such as those reported for surgical and N95 masks. FDA cautioned manufacturers and users of 3D printed

PPE on the potential lack of effectiveness in providing a barrier to fluid and infection control and also provided recommendations to health care providers on the use of 3D printed masks, should they need to be used²⁴.

- > FDA announced a new program, the Coronavirus Treatment Acceleration Program, to develop and bring COVID treatments to affected patients in an expedited manner. Features of this program include reallocation of resources within FDA, including the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research providing guidance and reviewing documentation as well as a more interactive approach, where documentation such as for clinical studies can be reviewed more quickly with direct communication between researchers/developers and the appropriate FDA staff.²⁵
- > FDA issued a letter to health care providers stating its concerns regarding inadequate and inconsistent respiratory protection of certain respirators from China following testing by the National Institute for Occupational Safety and Health that failed to demonstrate a minimum particulate filtration efficiency of 95%. FDA subsequently reissued the corresponding EUA, indicating that these respirators were no longer authorized under the EUA.²⁶
- > FDA announced it would be participating in the COVID-19 Diagnostics Evidence Accelerator, utilizing analysis of data in real time to further develop diagnostics. FDA also participates in the companion COVID-19 Therapeutics Evidence Accelerator.²⁷

¹⁹ <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers>

²⁰ <https://www.fda.gov/medical-devices/letters-health-care-providers/medical-glove-conservation-strategies-letter-health-care-providers>

²¹ <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins>

²² <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-warns-newly-discovered-potential-drug-interaction-may-reduce>

²³ <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-and-ema-collaborate-facilitate-sars-cov-2-vaccine-development>

²⁴ <https://www.fda.gov/medical-devices/3d-printing-medical-devices/faqs-3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic>

²⁵ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-accelerate-development-novel-therapies-covid-19>

²⁶ <https://www.fda.gov/medical-devices/letters-health-care-providers/certain-filtering-facepiece-respirators-china-may-not-provide-adequate-respiratory-protection-letter>

²⁷ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-action-harness-real-world-data-inform-covid-19>



- > FDA issued warning letters to various companies for distributing and marketing unapproved products for COVID-19 and advised consumers not to purchase or use these products.²⁸
- > FDA warned consumers of the presence of methanol in some ethanol-based hand sanitizers because of toxicity risks if absorbed through the skin or ingested, which was further supported by reports of adverse events received by FDA. FDA published a list of hand sanitizer products and the companies that produce them to inform consumers of hand sanitizers with methanol, produced in the same facility as those with methanol, or those that have been recalled by the manufacturer or distributor.²⁹
- > FDA issued a drug safety communication warning against the use of hydroxychloroquine or chloroquine outside the hospital setting or clinical studies for prevention or treatment of COVID-19 due to the risk of heart rhythm problems including QT interval prolongation, ventricular tachycardia and ventricular fibrillation, as well as death.³⁰

NSF INTERNATIONAL

NSF International and Amarex Clinical Research (an NSF International company and a full-service, international clinical research organization), have regulatory and clinical trial experts who can provide support to your organization for COVID-19 related product development in the preclinical and clinical stages. This support includes regulatory filings, strategies and FDA interactions as well clinical trials support for diagnostics, respiratory devices, pharmaceuticals and biologics.

²⁸ <https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products>

²⁹ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol>

³⁰ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>

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