

Guidance from the Department of Health and Human Services, the Department of Defense, and the Federal Emergency Management Agency on How You Can Help

We know that many of you are looking for specific COVID-19 information and ways to help, especially as these issues are time-sensitive. Below is a list of topic-specific resources provided by the Department of Health and Human Services (HHS), the Department of Defense (DoD), and the Federal Emergency Management Agency (FEMA).

DoD and FEMA:

Businesses: If a constituent company would like to produce, sell, or donate medical products to help with the COVID-19 response, they should consult <https://www.fema.gov/coronavirus/how-to-help>.

- The DoD's COVID-19 Joint Acquisition Task Force (JATF) has launched a "COVID-19 JATF Industry Portal" where interested vendors can fill out a short form to provide information on ways they can help support our nation's current response and continued resiliency. The Industry Portal is best accessed through the link on the main COVID-19 JATF web-page: <https://www.acq.osd.mil/jatf.html>
- The Defense Pricing and Contracting's (DPC) "Contracting with the Department of Defense" provides businesses that have not done business with the government in the past with a step-by-step approach to get started: https://www.acq.osd.mil/dpap/pacc/cc/docs/COVID-19/Contracting_with_DoD_COVID-19_Memo_and_Attachment_3.27.2020.pdf
- Visit the DPC COVID-19 page to view COVID-related material for the contracting community, including this announcement, at: <https://www.acq.osd.mil/dpap/pacc/cc/COVID-19.html>

Health and Human Services (HHS):

Personal Protective Equipment: If a constituent or health care provider has questions or is experiencing spot shortages of personal protective equipment or other supplies, they should call our toll-free line at 1-888-463-6332 (1-888-INFO-FDA), then choose option (*). The line is available 24 hours a day to help address difficulties obtaining supplies. Please note, however, that FDA does not control the production volume or distribution of medical devices.

Hand Sanitizer: If a constituent would like to manufacture or donate hand sanitizer, they should consult <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19> and, if they have questions, contact COVID-19-Hand-Sanitizers@fda.hhs.gov. Please also direct companies interested in producing hand sanitizer to FDA's latest guidance documents at the links below.

- [Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\) Guidance for Industry](#)

- [Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\)](#)
- [Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency](#)

Food: If a constituent in the food industry has a question for FDA, they may find information on common questions about food safety and COVID-19 at <https://www.fda.gov/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19>. If they need to contact FDA's Center for Food Safety and Applied Nutrition about a COVID-19 related question, they may do so by submitting a question [here](#).

COVID-19 Diagnostic Tests: For questions about development of COVID-19 diagnostic tests, there are several important resources your constituents may wish to use:

- **24/7 Hotline for Diagnostics:** If a constituent developer, lab, manufacturer or health care provider has questions about testing or is experiencing spot shortages of testing, personal protective equipment, or other supplies, they should call our toll-free line at **1-888-463-6332 (1-888-INFO-FDA)**, then choose **option (*)**. The line is available 24 hours a day to help address difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs, media needed for transport, and conservation of the samples – among other things. Please note, however, that FDA does not control the production volume or distribution of medical devices.
- **Frequently Asked Questions about COVID-19 Diagnostic Tests:** In response to questions from labs, manufacturers, health care providers, and others, FDA has generated FAQs and posted them on our website for all who are involved in test development for COVID-19s. FDA updates these FAQs on a rolling basis, often daily as issues arise. Your constituents can access these FAQs at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>.
- **Emergency Use Authorization (EUA) for COVID-19 Diagnostic Tests:** If your constituent needs additional information for completing the EUA template, would like to know how to submit Pre-EUA/EUA submissions to FDA, or wish to consider an alternative specimen type, they may contact the Division of Microbiology Devices at (301) 348-1778 or email CDRH-EUA-Templates@fda.hhs.gov. As noted above, *FDA must prioritize and is unable to provide information on the status of any individual submissions (this is generally confidential commercial information) and FDA would encourage congressional offices to reach out to specific developers for the status of any pending product submissions.*
 - The EUAs that have been issued for diagnostic tests, PPE, and ventilators are listed at <https://www.fda.gov/media/136702/download>.

Importation: Constituents who have a shipment of COVID-19 supplies held up at a port of entry should visit <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/importing-covid-19-supplies> for contact information and instructions. It includes an interactive map that importers can use to find the right office for their shipment, based on where the product is entering the United States. To speed assistance, they should provide the customs entry number (the 11-digit number they can get from their filer), the port of entry, and other shipment details. (Constituents who need assistance with import procedures regarding personal protective equipment or test kits should email COVID19FDAImportInquiries@fda.hhs.gov.)

Vaccines and Other Biological Product Candidates: Biological product sponsors, including vaccine developers, wishing to develop vaccines can email industry.biologics@fda.hhs.gov or call 1-800-835-4709 for further information.

Therapeutic Candidates: Developers who believe their investigational product may have activity against the COVID-19 virus and have relevant cell culture and/or animal model data may submit a Pre-IND (PIND)

application to the Agency as a “general correspondence” via the Pre-IND Consultation program. See <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-therapeutics-general-information-interested-stakeholders> or call 301-796-1500 for additional information on this program.

Drug Product Candidates: Inquiries regarding product development for proposed COVID-19 uses should be sent to COVID19-productdevelopment@fda.hhs.gov. Product sponsors can read more about the Coronavirus Treatment Acceleration Program at <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>. We also recommend they review [COVID-19 Therapeutics: General Information for Interested Stakeholders](#) for additional information.

Chloroquine/Hydroxychloroquine: There has been significant public interest in the drugs chloroquine and hydroxychloroquine. FDA has published an FAQ on the subject that may be of interest to your office and your constituents at <https://www.fda.gov/media/136784/download>.

Drug Shortages: FDA continues to take steps to monitor the supply chain. The Drug Shortage Staff within the FDA’s Center for Drug Evaluation and Research (CDER) has asked manufacturers to evaluate their entire supply chain, including active pharmaceutical ingredients, finished dose forms, and any components that may be impacted in any area of the supply chain due to the COVID-19 outbreak. If a constituent health care provider has questions or concerns about a drug shortage, related or unrelated to COVID-19, they should contact CDER’s Division of Drug Information (DDI) at 855-543-3784, 301-796-3400, or druginfo@fda.hhs.gov. Also, FDA’s [Drug Shortage web page](#) has information related to current shortages.

Clinical Trials: Sponsors who have questions regarding the conduct of clinical trials impacted by COVID-19 should contact clinicaltrialconduct-COVID19@fda.hhs.gov.

Animal Drugs and Animal Food: If a constituent has questions or concerns related to COVID-19 and its impact on products regulated by FDA’s Center for Veterinary Medicine, they may contact AskCVM@fda.hhs.gov, and their inquiry will be routed to the appropriate subject matter expert for response. A [list of known animal drug shortages](#) is kept by FDA’s Center for Veterinary Medicine.

Inspections: If your state has questions regarding the postponement of inspections under an agreement or contract with the FDA, they should contact OPFeedback@fda.hhs.gov or reach out to their specific project manager. In the meantime, we encourage states currently under contract to please submit their invoices to ensure payment for work completed. We will process their invoices as quickly as possible.