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Coronavirus (COVID-19) Information from U.S. FDA’s
Intergovernmental Affairs Staff (IGA)
Updated: 4/17/2020

Your offices and your constituents may find FDA’s COVID-19 FAQ useful in addressing questions related to vaccines, biologics, human tissue products, drugs, medical devices and tests, and food products. We also have specific COVID-19 FAQs for Emergency Use Authorizations, Diagnostic Testing, Food Safety for Industry, Healthcare Professionals, and other specific audiences. These are updated as information becomes available. Below you will find specific information for the most common areas of concern.

RESOURCES FOR STATE/LOCAL/TRIBAL/TERRITORIAL STAKEHOLDER OFFICES

CONTACTING FDA
When reaching out to FDA on COVID-19, we strongly recommend that you direct your inquiries to the IGA Staff (IGA@fda.hhs.gov) on your email correspondence. This will ensure your inquiry is triaged and routed as quickly as possible to the person best equipped to assist you. Constituents reaching out directly should direct their inquiry to the appropriate office as noted below.

EMERGENCY USE AUTHORIZATION AND PRODUCT APPROVAL SUBMISSIONS:
FDA appreciates that you may be receiving many inquiries from medical product developers regarding the status of their submissions for an emergency use authorization (EUA) or approval of products intended to diagnose, treat, or prevent COVID-19. FDA recognizes the urgent nature of these submissions and is reviewing them as quickly as possible, although turnaround times can vary based on the information provided by the applicant. When questions arise or additional information is needed FDA works directly with the developer to keep the review moving. FDA prioritizes those submissions that, based on the information provided, may offer the most impact for the response.

Consistent with our legal and regulatory obligations, and to avoid even the appearance of impropriety during this critical period of product development, the agency is unable to provide status checks or updates on pending applications for anyone other than product sponsors. (In fact, unless a company has made its submission public, FDA cannot even confirm that it has been received, except to the sponsor.) Additionally, this preserves the time of the experts within the review divisions so they can complete reviews and engage with the sponsors more quickly. We thank you for your understanding and commitment to ensuring that FDA review remains the world’s gold standard and maintains the highest level of integrity.

Intergovernmental Affairs Staff
U.S. Food and Drug Administration
Office of Policy, Legislation, and International Affairs
Office of the Commissioner
10903 New Hampshire Avenue, Silver Spring, MD 20993
www.fda.gov
FDA CONTRACT 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.

RESOURCES FOR YOUR CONSTITUENTS
We know that in many cases your constituents are looking for specific COVID-19 information, and we want you to have resources available, especially as these issues are time-sensitive. Below is some information that may be helpful.

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.

IMPORTATION/SHIPMENTS
 Constituents who have a shipment of COVID-19 supplies held 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 FDA office for their shipment, based on where the product is entering the United States. To speed assistance, they should provide the CBP entry number (this 11-digit number can be obtained from their CBP Form 3461 Block #5, CBP Form 7501 block #1, or by contacting their Filer/U.S. Customs Broker), 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.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
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**

**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.

**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/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.

**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.