FDA Develops Program to Expedite COVID-19 Drug Review

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In response to the public health threat of the COVID-19 pandemic, the U.S. Food and Drug Administration (FDA) has formed a special emergency program to expedite development of COVID-19 therapies – the Coronavirus Treatment Acceleration Program (CTAP). CTAP is coordinating with developers of new drugs and biologics as well as other public, academic, and private stakeholders to accelerate COVID-19 treatment development planning. CTAP is also responding to requests for investigational drug access around-the-clock and is working with industry and other regulators to transfer manufacturing to alternative sites to avoid supply disruptions.

CTAP is evaluating a variety of therapeutic areas, including antiviral drugs as well as host targets that may help reduce lung inflammation and improve lung function. FDA is also examining whether antibody-rich blood products taken from blood donated by people who have recovered from the virus could shorten the duration or lessen the severity of the illness. To supplement the data from traditional clinical studies and speed the process of evaluating the impact of potential therapies, FDA is also using real-world data from public and private sources in areas such as illness patterns and treatment outcomes.

As of April 3, there were ten therapeutic agents in active trials and another fifteen therapeutic agents in planning stages, with these numbers expected to change quickly. CTAP is expediting these development programs by:

- Triaging requests from researchers immediately;
- Providing interactive input on development plans on a prioritized basis;
- Providing rapid protocol review; and
- Expediting quality assessments

According to FDA, it has shifted its resources to implement CTAP by:

- Redeploying medical and regulatory staff to review teams dedicated to COVID-19 therapies;
- Bringing senior managers into the review of submissions;
- Shifting medical, operations, and policy staff to support the initiative;
- Streamlining and simplifying processes for receiving and responding to developer and scientific inquiries and requests for assistance; and
- Allocating additional resources to healthcare providers and researchers to help them submit emergency requests to use investigational products for patients with COVID-19 infections.

The FDA has been inundated with emergency use requests for diagnostic tests and expanded access requests for investigational drugs. The growing demands on FDA staff and resources to respond to the pandemic will almost assuredly impact the Agency's ability to meet user fee performance goals, including under the Prescription Drug User Fee Act (PDFUA), and attention has shifted increasingly to meeting first cycle review goals. The COVID-19 outbreak has affected FDA operations in other ways. For example, FDA announced earlier this month that it would postpone or scale back foreign and domestic establishment inspections due to safety concerns. Applicants are encouraged to call their FDA project managers handling current or pending submissions to discuss whether the PDUFA goal date for their application may not be met.

For sponsors, investigators and clinicians interested in communicating with the FDA and the CTAP teams, please see the contact

information below.

- **Drug Developers:** For therapeutics sponsors interested in submitting drug development proposals for review, see COVID-19 Therapeutics: General Information for Interested Stakeholders. Email COVID19-productdevelopment@fda.hhs.gov
- **Diagnostic Test Developers:** See FAQs on Diagnostic Testing for SARS-CoV-2. If you need additional information about completing the EUA template, would like to know how to submit your Pre-EUA/EUA submission to FDA, or wish to consider use of an alternative specimen type, please contact the Division of Microbiology Devices at (301) 348-1778 or email CDRH-EUA-Templates@fda.hhs.gov.
- **Vaccine and Biologic Developers:** Contact Manufacturers Assistance and Technical Training Branch (MATTB). Email industry.biologics@fda.hhs.gov or call 1-800-835-4709 for further information.

Foley Hoag has formed a firm-wide, multi-disciplinary task force dedicated to client matters related to the novel coronavirus (COVID-19). For more guidance on your COVID-19 issues, visit our Resource Page or contact your Foley Hoag attorney.

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