U.S. REGULATORY UPDATE ON COVID-19

On January 31, 2020, a public health emergency was declared by the U.S. Department of Health and Human Services (HHS) due to the coronavirus (COVID-19) outbreak. The U.S. FDA continues to release regulatory updates to address these immediate needs.

EMERGENCY USE AUTHORIZATIONS (EUAs)

An emergency use authorization is an expedited pathway which allows interstate distribution of medical countermeasures during a public health crisis, such as the COVID-19 pandemic. The most current list of products authorized for emergency use is posted to FDA’s website. Briefly, FDA has targeted the following products for EUAs:

- In vitro diagnostic products for COVID-19 diagnostic testing
- Personal protective equipment (PPE) (such as disposable filtering facepiece respirators)
- Ventilators (including accessories and other devices that can modified for use as ventilators)

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. Some of these guidances cover the following topics:

- Development and use of diagnostic tests and corresponding regulatory requirements, including EUA requests
- Conduct of clinical studies during the COVID-19 pandemic, including various measures to protect the safety of study participants

5 https://www.fda.gov/media/136238/download
Postmarket adverse event reporting for drugs, biologics, medical devices, combination products and dietary supplements during the COVID-19 pandemic, considering the anticipated workforce reduction.

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-19 exposure for patients.

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 requests.

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 shortages.

Clarification on an interim enforcement policy for face masks and respirators during the COVID-19 pandemic.

FDA COMMUNICATIONS/DEVELOPMENTS

FDA issued a letter to health care providers with strategies to conserve personal protective equipment such as surgical masks (not including N95 respirators), gowns and surgical gloves. These letters contain FDA’s recommended actions based on current supply levels and health care organizational needs.

FDA provided information for investigators seeking to study convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of single-patient emergency INDs and is discussing the development of a master protocol that can be used to streamline this effort.

FDA approved the first IND for a Phase 1 vaccine trial, evaluating a novel vaccine mRNA-1273, developed by Moderna as well as others. In addition, several drug treatments are being evaluated in clinical studies, including a Phase III trial of Gilead’s remdesivir.

FDA is working with regulatory bodies around the world to find ways to prevent and treat COVID-19, including collaborations with EMA on vaccine development, including the type of preclinical studies and data needed to address the theoretical potential for a vaccine to enhance disease.
FDA issued a FAQ on 3D printing, given that 3D printing may be used to address PPE shortages during the COVID-19 crisis, such as those reported for surgical and N-95 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 used\textsuperscript{16}.

FDA announced a new program, the Coronavirus Treatment Acceleration Program (CTAP), to develop and bring COVID-19 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 (CDER) and the Center for Biologics Evaluation and Research (CBER) providing guidance and reviewing documentation. The program also includes a more interactive approach, whereby documentation such as for clinical studies can be reviewed more quickly and there is direct communication between researchers/developers and appropriate FDA staff\textsuperscript{17}.

WE ARE HERE TO HELP

Our team consists of highly educated regulatory and clinical trial consultants that can provide support to your organization, especially for COVID-19 related product developments that are 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.

For additional information, please contact us at healthsciences@nsf.org.
