HEALTH CARE

FDA TAKES STEPS TO ADDRESS CRITICAL SHORTAGE OF PERSONAL PROTECTIVE EQUIPMENT

by Billee Lightvoet Ward

"Unprecedented" may be the most commonly-used adjective in the English language at the moment, but it accurately describes the circumstances faced by our nation and others as COVID-19 continues to spread throughout our populations. As our healthcare providers face this situation head-on, they do so under increasingly dire circumstances in which the protective equipment so critical to their jobs is largely unavailable. This is not news to anyone – it has received widespread media attention and has engaged many individual and corporate citizens eager to do their part to address the problem. The issue has not gone unnoticed at any governmental level, and the U.S. Food and Drug Administration (FDA); the agency responsible for public health in relation to the safety and effectiveness of drugs and medical devices, among other products; has taken recent action.

On March 24, 2020, Dr. Stephen Hahn, Commissioner of the FDA, issued a statement that, to increase U.S. supplies to support the U.S. response to COVID-19, the agency provided instructions to manufacturers importing personal protective equipment and other devices. In the statement, Commissioner Hahn notes:

> *"One of FDA's priorities in combating the COVID-19 pandemic is facilitating access to critical personal protective equipment (PPE) and devices. We are engaging with importers and others involved in the import trade community during this pandemic to facilitate the entry of needed products, including PPE, into the U.S. These instructions to importers clarify the types of PPE that can be imported without engaging with FDA. They also include information about the type of information importers can submit to facilitate their entries. We have adjusted our import screening to further expedite imports of legitimate products and are continually monitoring our import systems to prevent and mitigate any potential issues."*

Commissioner Hahn recognizes in the statement that "many companies are stepping up across America to help with manufacturing critical and life-saving medical supplies to strengthen the U.S. response." To facilitate communication with industry representatives, the FDA created an email inbox at COVID19FDAIMPORTINQUIRIES@fda.hhs.gov to specifically address questions or concerns in relation to importation of such products.

The FDA's instructions address three categories of personal protective equipment and other devices, and instructions relating to the importation of each.

- First, in relation to general purpose personal protective equipment (masks, respirators, gloves, etc.) intended for general purpose or industrial use (not for the prevention of disease or illness), the instructions note that such products are not regulated by the FDA and entry information should be transmitted to U.S. Customs and Border Protection, not the FDA.
- Second, in relation to products authorized for emergency use pursuant to the FDA's Emergency Use Authorization (EUA), the FDA provides instructions on submitting the necessary entry information to the FDA, and notes that it has reduced the information required. Further, the instructions provide direction on requesting an EUA, and note that certain diagnostic tests, masks and respirators are currently approved by an EUA.
- Finally, the FDA addresses products regulated by the FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance. In issuing such enforcement discretion policies, the FDA exercises its "enforcement discretion" to decline to enforce certain medical device requirements in defined circumstances.

To date, specific to products related to COVID-19, the FDA has issued enforcement discretion policies relating to non-invasive remote monitoring devices, and vaccines and accessories and other respiratory devices. These enforcement policies, "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency" and "Enforcement Policy for Vaccines and Accessories and Other Respiratory Devices During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency", were issued on March 20, 2020 and March 22, 2020, respectively.

The relaxation of certain FDA requirements as outlined in the importation instructions and enforcement policies referenced above is not intended to remain in effect long-term, but rather, reflects temporary measures taken by the agency to address specific issues in relation to the COVID-19 public health emergency.

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