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CLIENT ALERT

Post COVID-19: FDA Regulatory Considerations for Face Mask and PPE Companies

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The U.S. Food and Drug Administration (FDA) regulates the distribution of face masks and personal protective equipment (PPE) intended for a medical purpose. Face masks and PPE marketed for general non-medical purposes (e.g. construction and other industrial applications) are not regulated by the FDA.

Due to the COVID-19 emergency, the FDA has taken a number of measures to expand the availability of face masks and PPE it regulates. Some of these measures include the issuance of Emergency Use Authorizations (EUA) and enforcement policies that waive certain FDA premarket authorization requirements. However, the authorities granted under the COVID-19 EUAs and enforcement policies are only valid during the COVID-19 emergency, meaning that manufacturers and distributors must cease distribution of unapproved products once the COVID-19 Declared Emergency has ended.

Companies distributing unapproved face masks and PPE during the COVID-19 emergency have several options to continue the distribution of products. Some companies manufacturing face masks and PPE under the recent FDA COVID-19 EUAs and enforcement policies may wish to transition current products to a non-medical purpose (e.g. outdoor sporting apparel) since face masks and PPE marketed for general non-medical purposes are not regulated by the FDA. Companies transitioning products to a non-medical purpose will need to take care to ensure product labeling and advertising clearly express that the product is intended to be used for non-medical purposes.

Other manufacturers producing unapproved face masks and PPE under FDA COVID-19 EUAs and enforcement policies may instead plan to continue to distribute face masks and PPE to the general public or healthcare providers with the intent that such products are to be used to combat future pandemic outbreaks or for other medical purposes. Manufacturers that fall within this category may have established reliable supply chains and manufacturing capabilities. These manufacturers will need to seek FDA approval, and will need to establish both the safety and effectiveness of the face masks or PPE for their intended use post COVID-19.

There are two primary avenues for manufacturers to receive FDA approval. A manufacturer may seek approval through the premarket approval (PMA) process, or the manufacturer may seek approval through FDA's 510(k) process, depending on the device class (most Class I devices are exempt from premarket notification). The 510(k) process is a premarket submission for Class II medical devices (e.g., N95 respirators) that is made to the FDA to demonstrate that the new device is "substantially equivalent" to an already legally marketed device. Depending on the risk posed by the device, face mask and PPE manufacturers may be able to use the 510(k) process and hence potentially enter the market more quickly than completing a PMA.

A 510(k) submission generally requires a demonstration that the new device is "substantially equivalent" to an existing legally marketed device, known as a "predicate device." To be "substantially equivalent," the new device must have the same intended use as the predicate device and the same technological characteristics—or different technological characteristics that do not raise different questions of safety and effectiveness than the predicate device. A demonstration of substantial equivalence is achieved through clinical or scientific data. The data is used to demonstrate that the new device is as safe and effective as a

legally marketed predicate device. Additionally, the predicate device should have the same classification product code as the new device. Manufacturers are encouraged to identify a predicate device prior to the 510(k) submission process to help facilitate the FDA's decision-making process.

To allow a seamless transition, manufacturers currently distributing face masks or PPE under a FDA COVID-19 EUA or enforcement discretion should start to plan their post COVID-19 transition prior to the expiration of the current emergency declaration. Manufacturers wishing to distribute unapproved devices should submit a 510(k) or other premarket submission to the FDA. To help alleviate supply pressures during the COVID-19 emergency, the FDA may consider expedited review of premarket submissions for manufacturers of face masks or PPE.

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