Product Responsibility Best Practices

SUBJECT
FDA Emergency Use Authorization

LAST UPDATE
January 2021

APPLIES TO
- Suppliers
- Distributors

FOCUS ON
Emergency FDA Guidance

QUICK LINKS
- PPAI Corporate Responsibility: ppai.org/corporate-responsibility/
- Consumer Product Safety Commission: www.cpsc.gov

Intended for intermediate compliance programs

Italic grey text indicates a hyperlink listed in the Online Resources section of this document.

The Food and Drug Administration (FDA) has employed regulatory flexibility to alleviate medical product shortages and augment the availability of medical products that are necessary for mitigating the impact of COVID-19. The FDA has two methods available to implement this policy. One option employed by the FDA is the Immediately-in-Effect (IIE) guidance, and the other option is the Emergency Use Authorization (EUA).

Immediately-In-Effect Guidance

The *FDA's IIE guidance* outlines the intended use of face masks for source control. According to the FDA, source control is described as preventing the transmission of infection through a person's respiratory secretions which are produced when speaking, coughing, or sneezing. Considering the public health emergency, and provided that a face mask does not create an undue risk, the FDA does not object to a mask's distribution and use intended for a medical purpose, even if the mask does not comply with specific regulations outlined in the guidance document. The normally applicable regulation includes a registration requirement, a quality system requirement, protocols for corrections and removals, and a unique device requirement. This guidance applies whether the mask is being used by medical personnel or the general public.

There are solutions available for determining whether a mask creates an undue risk. The product must be labeled as a face mask, not a surgical mask or respirator. The product must also include a list of body contacting materials, and not include any *drugs* or biologics. The product's label should include recommendations for further reducing the risk of use, for example not using the mask in a surgical setting. Another recommendation for minimizing risk associated with use of the product includes not using the mask if there could be exposure to hazardous fluids. It is also important to ensure the product does not have any additional antimicrobial or anti-viral claims made within its labelling.

Emergency Use Authorization

The FDA has also issued *Emergency Use Authorizations* regarding facemasks in pursuit of its policy related to COVID-19. FDA policies regarding facemasks include clarification that, in accordance with the federal *Food, Drug, and Cosmetic Act*, the masks comprise medical devices only when they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases. This is an important distinction; unlike respirators and surgical masks, face masks are not considered *Personal Protective Equipment (PPE)*.

Under the EUA, face masks are also intended to help stop the spread of COVID-19 by providing source control. Conditions for authorization include labeling requirements of the product and waivers of certain FDA requirements, including quality system regulation and the Unique Device Identifier (UDI). This is an "umbrella" EUA, which means the manufacturer does not need to take any further action and does not need to submit a request to the FDA for inclusion under the EUA. However, it is important to note that adverse event reporting and record keeping are still required.

When working under an EUA, the Department of Health and Human Services (HHS) provides liability coverage under the *Public Readiness and Emergency Preparedness (PREP) Act*. The PREP Act authorizes the HHS Secretary to make a declaration that provides immunity from potential liability, except for cases of intentional misconduct, regarding claims related to loss caused by using covered countermeasures associated with the public health emergency.

When the public health emergency is officially terminated for products that are either in use or in warehouses, the FDA will issue policies that outline the transition process. It is important to keep in mind that face masks are products that are exempt from the *premarket notification requirements* implemented under the Federal Food, Drug, and Cosmetic Act. That means

premarket submissions are not necessary with some face masks, however the other regulations that are waived during the public health emergency would be in effect. Some examples of those requirements include registration and listing, quality systems, and reports of corrections and removals. It will be important for companies to maintain compliance with those requirements if they intend to maintain products in the market, after the EUAs expire.

Online Resources:

FDA Regulated Face Masks: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-including-surgical-masks-and-respirators-covid-19

FDA Enforcement Policy: https://www.fda.gov/media/136449/download

N95 Respirators, Surgical Masks, and Face Masks: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks

Importing Medical Devices During the COVID-19 Pandemic: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/importing-medical-devices-during-covid-19-pandemic

Surgical Masks - Premarket Notification [510(k)] Submissions: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions

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