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Food, Drug & Device/FDA ADVISORY ■

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FDA Seeks Help to Solve Personal Protective Equipment Shortages

by Cathy Burgess and Ben Wolf

Acknowledging a potential shortage of personal protective equipment (PPE), the U.S. Food and Drug Administration (FDA) posted a frequently asked questions (FAQ) page and a Letter to Healthcare Providers on Surgical Mask and Gown Conservation Strategies on March 11. PPEs, which include protective clothing, gowns, gloves, face shields, goggles, face masks and respirators, or other equipment designed to protect the wearer from injury or the spread of infection or illness, may already be in shortage or may be in short supply because of demand from the coronavirus disease (COVID-19) outbreak. The FDA has provided information for health care providers through its letter to health care providers and FAQ, and it is also attempting to work with manufacturers to identify ways to expand the availability of PPEs.

Health Care Provider Information

The FDA makes clear that its recommendations to health care providers are meant to supplement, not replace, "specific controls and procedures developed by healthcare organizations, the Centers for Disease Control and Prevention (CDC), or CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) to aid in infection prevention and control." The FDA provides basic information and advice pertaining to:

- Identifying FDA-cleared products.
- Determining shelf-life of products.
- Recommended use of PPE during the COVID-19 outbreak.
- Strategies for using alternate products (e.g., reusable gowns or expired product) or reusing products as mitigation strategies.

The FDA is also soliciting information about potential shortages, which manufacturers are not required to report, from health care providers, patients, manufacturers, or others within the supply chain.

Manufacturer Engagement

Question 2 in the FAQ is devoted to engaging PPE manufacturers to increase PPE supply. The FDA invites industry to engage the FDA to explore expedited pathways to market for products, including manufacturing site changes or premarket submissions. The FDA is particularly interested in increasing the supply of surgical masks, surgical gowns, and isolation gowns, but is also willing to discuss:

- Surgical masks (FXX)
- Surgical masks with antimicrobial/antiviral agent (OUK)
- Pediatric/child facemasks (OXZ)
- Surgical gowns (FYA)
- Isolation gowns and surgical apparel accessories (FYC, LYU, OEA)
- Surgical suits (FXO)

(Product codes in parentheses)

The FDA requests that companies with proposed shortage mitigation strategies email the FDA at deviceshortages@fda.hhs.gov with the email subject line "Product Codes XXX, Shortage Mitigation Options for FDA Engagement," where XXX represents the product codes. The body of the email should:

- Describe the affected product or products, which may include the brand name, model number, 510(k) number, etc.
- Describe the proposed mitigation approach.
- Identify the shortage mitigation proposal, e.g.:
  - Expedited review of a premarket submission.
  - Expedited review of a manufacturing site change for Class III device manufacturers.
  - Information about importing certain products.

The FDA has taken similar actions to address diagnosis of COVID-19 by issuing an emergency use authorization (EUA) for a test developed by the CDC, working with the CDC to make its EUA-authorized test available for other labs to use, and extending a policy that permits laboratories certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments (CLIA) after the test has been validated but before the EUA request has been submitted. The FDA's testing policy also encourages early and iterative interactions with the FDA to expedite test development as much as can reasonably be expected.

A Note on the Regulation of Surgical Attire

The FDA regulates surgical gowns, including isolation gowns for high-risk situations (product codes FYA, FYC), and masks (product codes FXX, OUK, and OXZ) as Class II medical devices under 21 CFR 878.4040. Other surgical attire, including isolation gowns for low-risk situations (product code OEA), surgical apparel accessories (product code LYU), surgical suits (product code FXO), and numerous other surgical attire categories are regulated as Class I medical devices.

Manufacturers of Class I devices must register their establishments, list their devices, and pay an establishment registration fee. They are also required to manufacture their devices in a manner that complies with the FDA's Quality System Regulation (QSR). Most Class I devices, including surgical apparel, do not require premarket clearance before being introduced to the market.

Manufacturers of Class II medical devices must also register, list, and pay a fee. They are also required to manufacture their devices in compliance with the QSR. Class II devices generally require premarket clearance; however, the FDA has exempted certain Class II face masks (N95 respirators, product code MSH) from premarket authorization under the following conditions:

- The product is not intended for:
  - Prevention of specific diseases or infections.
  - Filtering surgical smoke or plumes.

  - Filtering specific amounts of viruses or bacteria.
  - Reducing the amount of and/or killing viruses (e.g., the coronavirus), bacteria, or fungi.
  - Affecting allergenicity.
- The product does not contain coating technologies unrelated to filtration (e.g., to reduce or kill microorganisms).
- The user-contacting components are demonstrated to be biocompatible.
- The flammability has been characterized and demonstrated to be appropriate for the intended environment of use.
- The mask has demonstrated the ability to resist penetration by fluids (e.g., blood and body fluids) consistent with the intended use of the device.
- The National Institute for Occupational Safety and Health (NIOSH) has approved the mask under its regulations.

Conclusion

We are encouraged that the FDA has taken a liberal approach to encouraging patient and provider safety in response to the COVID-19 outbreak.

Alston & Bird has formed a multidisciplinary task force to advise clients on the business and legal implications of the coronavirus (COVID-19). You can view all our work on the coronavirus across industries and subscribe to our future webinars and advisories.

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If you have any questions or would like additional information, please contact your Alston & Bird attorney or any of the following:

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