FAQs on Shortages of Surgical Masks and Gowns

Q1. Is there a shortage of gowns? Surgical masks?

The FDA is aware that as the COVID-19 outbreak continues to expand globally, the supply chain for these devices will continue to be stressed if demand exceeds available supplies. We have received information from healthcare organizations that some distributors may have placed certain types of personal protective equipment (PPE) on allocation, basing the quantity available to the healthcare organization on previous usage, not projected use. Increased use may exceed the available supply of PPE, resulting in shortages at some healthcare organizations.

The FDA recommends conservation strategies for use by healthcare organizations and personnel—categorized for a range of clinical needs and supply levels—intended to assist healthcare organizations in determining conservation procedures during this time period. The FDA's recommendations are intended to augment, and not intended to replace, specific controls and procedures developed by health care 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.

Q2. Can respirators approved under standards used in other countries, such as KN95, be used in the US during the COVID-19 pandemic?

Yes. The FDA is working diligently to mitigate any potential shortages in the supply chain and taking action to assure health care personnel on the front lines have sufficient supplies of respiratory protective devices. The FDA concluded, based on the totality of scientific evidence available, that certain imported respirators that are not NIOSH-approved are appropriate to protect the public health or safety.

On March 24, 2020, the FDA issued an Emergency Use Authorization (EUA) for importing non-NIOSH-approved N95 respirators. Under this EUA, among other criteria, the FDA accepts marketing authorization from Australia, Brazil, Europe, Japan, Korea and Mexico who have similar standards to NIOSH. The FDA did not list KN95 respirators made per China's standards in this EUA because of concerns about fraudulent products listed as KN95s. On April 3, 2020, in response to continued respirator shortages, the FDA issued a new EUA for non-NIOSH-approved N95 respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic.

The FDA also issued guidance to provide a policy to help expand the availability of general use face masks for the general public and respirators for health care professionals during this pandemic. The guidance applies to KN95 respirators as well. It explains that for the duration of the pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA, including KN95 respirators, if they are on the Centers for Disease Control and Prevention (CDC) list of respirator alternatives during the COVID-19 pandemic. Although not required, if a KN95 respirator does not have an EUA, importers may want to take appropriate steps to verify authenticity of these products.

The FDA is ready and available to engage with importers to minimize disruptions during the importing process. The FDA established a special email inbox, COVID19FDAIMPORTINQUIRIES@fda.hhs.gov, for industry representatives to quickly communicate with the agency and address questions or concerns.

Q3. How can manufacturers of personal protective equipment (PPE) who may be considering increasing availability of these products to the US market engage with the FDA?

The FDA recognizes that the need by healthcare providers and personnel for personal protective equipment (PPE) such as surgical masks and surgical and isolation gowns, may outpace the supply during the Coronavirus Disease 2019 (COVID-19) outbreak.

The FDA is collaborating with manufacturers of personal protective equipment (PPE) to help facilitate mitigation strategies related to the COVID-19 outbreak. The FDA's door is open, and we are available to collaborate with stakeholders.

To help alleviate supply pressures, the FDA may consider expedited review of manufacturing site changes or premarket submissions—manufacturers of PPE (particularly surgical masks and surgical or isolation gowns) may contact FDA regarding plans to increase availability of these products to the U.S. market.

For reference, the applicable product codes discussed in these FAQs are:

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

FDA is interested in hearing from manufacturers who may be able to help mitigate potential shortages of the above product codes by increasing U.S. availability of such devices. These manufacturers may email FDA at deviceshortages@fda.hhs.gov, which is closely monitored and has proven to be a valuable resource thus far in helping FDA mitigate potential supply chain disruptions.

To facilitate a rapid response to your email, please see an example of information that FDA would find helpful to have initially below:

Subject of the email: "Product Codes XXX, Shortage Mitigation Options for FDA Engagement," where XXX represents the product code(s).

Body of the email:

- Describe the affected product or products which may include the brand name, model number, 510(k) number, etc.
- Describe the proposed mitigation approach.
- Identify what you are interested in discussing with FDA, such as:
    - Expedited review of a premarket submission, or
    - Expedited review of a manufacturing site change if you are a class III device manufacturer, or
    - Information about importing certain products.

Q4. Which gowns are FDA-cleared? Which surgical masks are FDA-cleared?

To identify FDA-cleared products, search the 510(k) Premarket Notification database using the product codes for gowns (FYA, FYB, FYC) and surgical masks (FXX, OUK, OXZ).

Q5. Do gowns and surgical mask provide protection from coronavirus?

Gowns and surgical masks are intended to provide broad barrier protection. Please see current guidelines from the Centers for Disease Control and Prevention (CDC) on recommended use of PPE during the COVID-19 outbreak. At this time, FDA has not cleared, approved, or authorized any gowns or surgical masks for specific protection or prevention against the virus that causes COVID-19.

Q6. Can we use expired gowns and surgical masks? Do they offer the protection needed?

These products were designed to serve as protective barriers and thus FDA believes they may still offer some protection even when they are used beyond the manufacturer's designated shelf life or expiration date. The user should visibly inspect the product prior to use and if there are concerns (such as degraded materials or visible tears) the product should be discarded. As a conventional capacity strategy, expired products may be used for training and demonstration purposes where barrier protection is not needed.

Q7. Can reusable cloth gowns be used in a shortage?

FDA cleared or approved reusable cloth gowns can be used. Adequate laundering can reduce the level of pathogen contamination to a negligible level and lower the overall risk of disease. The gown should be used at the barrier protection level indicated in the labeling. Coated or laminated fabrics should be checked to ensure they retain resistance to liquid and microbial penetration following decontamination, cleaning and/or sterilization.

Q8. How can I know in advance that manufacturers will have a shortage of masks and gowns so I can prepare?

If you are a part of a group purchasing organization (GPO), you may want to contact the GPO staff to determine what communication they receive from their suppliers; otherwise, you can contact manufacturers directly. Medical device manufacturers are not required to notify the FDA when they become aware of a circumstance that could lead to a device shortage or meaningful disruption in the supply of that device in the United States.

Q9. My health care organization already has a plan for protection against COVID-19, which includes other types of protective equipment (such as Powered Air Purifying Respirators (PAPRS) or Controlled Air Purifying Respirators (CAPRS)) and other strategies. Are we required to follow the FDA's recommendations listed in the letter to health care providers?

The letter to health care providers is intended to aid in the management of gowns and surgical masks. The FDA's recommendations in the letter should supplement a health care organization's policy.

Q10. How do I know what the manufacturer-designated shelf life is?

The manufacturer-designated shelf life may be found in the product labeling and if not, you can contact the manufacturer directly.