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FDA's Policy in Response to Face Mask and Respirator Shortages Resulting from COVID-19

March 30, 2020

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In the confusion brought about by efforts to address the mass shortages of face masks and respirators for both public and health care professionals, FDA's recent guidance document, Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency is welcome. This guidance aims to expand the availability of general use face masks for the public and facepiece respirators for health care professionals during the COVID-19 public health emergency. Like the other recent FDA policies to address the shortages caused by the pandemic, this policy is effective only during the duration of the public health emergency.

The first part of the guidance identifies and defines the different categories of "face masks" subject to the policy, and the level of protection each type provides, from masks that are not intended to provide filtration or a fluid barrier, to those designed to protect against microorganisms, body fluids and particulate material. The different categories are:

- **Face Mask**: Covers the user's nose and mouth; may or may not meet fluid barrier or filtration efficiency levels
- **Surgical Mask**: Covers the user's nose and mouth, provides a physical barrier to fluids and particulate materials; meets certain fluid barrier protection standards and flammability tests
- **Filtering Facepiece Respirator (FFR)**: Covers the user's nose and mouth, disposable half face-piece non-powered; air-purifying; intended to help reduce exposure to pathogenic biological airborne particulates
- **N95 Respirator**: FFR that protects from particulate materials at an N95 filtration efficiency level; is an FDA-regulated Class II device in health care settings
- **NIOSH Approved N95 Respirator**: An N95 respirator; approved by NIOSH
- **Surgical N95 Respirator**: FFR used in a health care setting; worn by health care providers during procedures; protects the patient and HCP from microorganisms, body fluids and particulate material at an N95 efficiency level

The guidance draws a distinction between masks and respirators intended for medical use (e.g., intended to prevent or mitigate a disease or condition), which are FDA-regulated medical devices, and those that are not intended for medical use, which are not medical devices and therefore have not been reviewed and cleared by FDA (e.g., construction masks). Classification depends, in part, on how the products are labeled or otherwise intended to be used by health care professionals or in a health environment or whether they include a drug, biologic or anti-microbial/anti-viral agent.

FDA's policy towards masks and respirators that have not been FDA-cleared are summarized below. For full details, you should refer to the guidance document. FDA also does not intend to object to an individual's distribution of improvised personal protective equipment (PPE) where no alternative exists.

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Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection

For the duration of the public health emergency, FDA does not intend to object to, and will allow, the distribution of face masks (not respirators) for a medical purpose, without compliance with most of the medical device regulations, as long as they do not create a undue risk in light of the pandemic. FDA believes that an undue risk would not exist where:

- The labeling describes the product as a face mask (as opposed to an FFR) and lists the skin contacting material, which cannot include drugs or biologics.
- The labeling makes recommendations that reduce risk, such as recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level is high; and use in the presence of a high intensity heat source or flammable gas.
- The product is not intended for a use that would create undue risk (for instance, the labeling does not make infection prevention, antimicrobial or antiviral protection or particulate filtration claims).

Surgical Masks Intended to Provide Liquid Barrier Protection

For the duration of the public health emergency, FDA does not intend to object to, and will allow, the distribution of surgical masks without FDA 510(k) clearance if they do not create undue risk, which means that:

- The labeling describes the product as a surgical mask and lists the skin contacting materials, which cannot not include drugs or biologics.
- The mask meets the ASTM F1862 standard for fluid protection.
- The mask meets certain flammability requirements (unless the labeling recommendations against use in the presence of a high intensity heat source or flammable gas).
- The mask is not intended for a use that would create undue risk (for instance, the labeling does not make infection prevention, antimicrobial or antiviral protection or particulate filtration claims).

Emergency Use Authorizations (EUAs) for Masks and Respirators

FDA is looking to engage with manufacturers regarding possible EUAs for the following:

- Reprocessing single use N95 particulate filtering facepiece respirators (and other FFRs), which otherwise would require FDA-clearance

  The guidance details information that interested manufacturers should send to FDA, if available, such as:

  i. The process for disinfection/reprocessing controls
  ii. Validation of bioburden reduction
  iii. Supply chain safety measures for collecting, receiving and segregating soiled masks
  iv. Material compatibility, including effects of detergent and process on mask materials, level of detergent residues after reprocessing, and maximum number of reprocessing cycles with tracking method
  v. Filtration performance and maintenance of fit following each reprocessing cycle
  vi. Proposed labeling, that includes FDA recommendations

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- Non-FDA cleared N95 Filtering Facepiece Respirators, including NIOSH-approved disposable FFRs and imported non-NIOSH-approved disposable FFRs, which otherwise were not intended for medical use

  FDA already has issued device-specific EUAs on March 2 and March 24, which were updated last week, for certain of these FFRs for use in health care settings by health care personnel, but is seeking to add more. Thus, FDA is seeking to engage more manufactures, including those with products that are not FDA-cleared for marketing in the U.S. and those who have not previously manufactured masks or respirators, but that have the capability to do so. The guidance outlines information that manufacturers should send to FDA, if available, to expedite evaluation for masks that are not FDA-cleared, including:

  i. Contact information
  ii. Labeling
  iii. Regulatory status in other countries
  iv. Whether the products were manufactured in accordance with the US Quality Systems Regulations or ISO-13485
  v. A description of product testing, including testing standards met. Interested manufacturers that have not previously manufactured masks or respirators should contact FDA. Any EUA will be subject to FDA determined conditions, such as requirements to inform health care professionals and patients about the benefits and risks of using an EUA device and any alternatives, adverse event reporting and manufacture recordkeeping requirements.

3D-Printed Masks

FDA also addresses in a separate FAQs, 3D-printed PPE, including masks, and other accessories and components. The FAQ provides recommendations to health care providers if they use 3D-printed masks, highlights that 3D-printed PPE are unlikely to provide the same level of protection, filtration and infection control as conventional PPE, and cites three times the CDC recommendations for optimizing the supply of face masks. The FDA then goes on to provide recommendations to health care providers if they do use 3D-printed masks.

Both guidance and FAQs demonstrate FDA's ongoing flexibility as it continues to try to be helpful during the PPE shortage crisis.

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