New FDA Face Mask Guidance to Support Response Efforts to the COVID-19 Pandemic

On March 26, 2020, the Food and Drug Administration (FDA) provided new guidance to support response efforts to the COVID-19 pandemic: Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency.

This new FDA guidance is immediate and should be instructive for optometry offices attempting to acquire additional face masks, to reuse and sterilize face masks or use non-medical N95 masks to fulfill Personal Protective Equipment (PPE) requirements for health care providers examining patients in a medical setting of an optometry office during this COVID-19 pandemic. Additionally, it will provide useful information on face masks that you can provide patients and the general public.

Highlights include:

1. Informed descriptions of the various types of face masks:
   a. **Face Mask** – A mask that covers the user’s nose and mouth and may or may not meet fluid barrier or filtration efficiency levels.
   b. **Surgical Mask** – A mask that covers the user’s nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests.
   c. **Filtering Facepiece Respirator** – A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.
   d. **N95 Respirator** – A disposable half-mask FFR that covers the user’s airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level and when used in a healthcare setting is a Class II device, regulated by FDA.
   e. **NIOSH Approved N95 Respirator** – An N95 respirator, approved by the National Institute for Occupational Safety and Health (NIOSH) that meets an approved filtration efficiency level.
   f. **Surgical N95 Respirator** – A disposable FFR used in a healthcare setting that is worn by health care professionals (HCPs) during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at a predetermined N95 filtration efficiency level. A surgical N95 respirator is a Class II device, regulated by FDA.

2. Optometry offices should note that face masks originally intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease are
regulated by the FDA. Other face masks and filtering facepiece respirators marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications, are not regulated by the FDA.

3. In general, FDA recommends that health care providers, like doctors of optometry, follow current Centers for Disease Control and Prevention (CDC) guidance regarding PPE that should be used during the COVID-19 outbreak. To ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, for the duration of the public health emergency FDA does not intend to object to the distribution and use of face masks (not including respirators) that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face mask does not create an undue risk in light of the public health emergency: prior submission of a premarket notification is not required.

4. Optometry offices should also note that there are FDA PPE requirements for personnel reprocessing respirators, as follows:
   a. FDA is responsible for the oversight of reprocessed single use medical devices and generally requires the submission of a 510(k) from entities performing these activities. To facilitate the safe reuse and conservation of PPE for the duration of the public health emergency, FDA is working with manufacturers on the reprocessing of otherwise disposable N95 particulate filtering facepiece respirators (and other FFRs) to facilitate marketing authorization through an emergency use authorization (EUA) for reprocessed devices. The FDA will assess the description of the process and validate bioburden reduction/disinfection and approve protocols and acceptance criteria for scale-up of the process. Optometry offices should thus beware of purchasing reprocessed face masks without an FDA label saying the process used was approved. For example:
      i. The FDA will also evaluate mask materials compatibility with methods of reprocessing. For example, cellulose-based materials are incompatible with hydrogen peroxide as hydrogen peroxide will degrade cellulose.
      ii. The FDA will evaluate evidence to demonstrate that repeated exposure to reprocessing cycles does not interfere with the filtration ability or breathability of the masks.
      iii. The FDA will evaluate evidence to demonstrate that repeated exposure to the reprocessing cycle steps does not decrease the ability of the mask to form a tight fit to the wearer’s face. This includes evidence to demonstrate that the reprocessing cycle steps do not compromise the integrity of the elastic bands to maintain an appropriate fit to the wearer.

5. Wherever possible, optometry offices should continue to use FDA-cleared face masks and NIOSH-approved and/or FDA-cleared N95 respirators or better. In response to the COVID-19 pandemic, FDA has also issued EUAs that authorize certain N95 FFRs, including NIOSH-approved disposable FFRs and imported non-NIOSH-approved disposable FFRs, for use in healthcare settings by healthcare personnel and are intended to help increase availability of these devices to front-line personnel during the public health emergency. i ii

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i https://www.fda.gov/media/135763/download
ii https://www.fda.gov/media/136403/download