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

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 U.S. Food and Drug Administration (FDA).

Optometry offices should note that on May 7, 2020, the FDA rescinded a substantial portion of their April 3, 2020, FDA Emergency Use Authorization (EAU) in a letter to healthcare providers to protect the public health or safety of providers and patients from KN95 masks imported from China (details below).

Optometry offices should also note that on June 6, 2020, the FDA, being responsible for the oversight of reprocessed single use medical devices, removed decontaminated respirators from the scope of authorized products (details below).

The National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) reported that 60% of the KN95 products received and tested achieved filtration efficiency below the stated 95%. FDA responded by revising the April 3, 2020 EUA for clarity and to address concerns about sub-standard products, which includes revising the third criterion for eligibility and adding a process for removal from Appendix A. Most products submitted for evaluation to NPPTL are no longer on the approved FDA EUA Appendix A list.

Timeline of Face Mask Guidance to Support Response Efforts to the COVID-19 Pandemic

- On February 29, 2020, Centers for Disease Control and Prevention (CDC) published guidance Strategies for Optimizing the Supply of N95 Respirators. This guidance provided Crisis Alternate Strategies that included the option: “Use of respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators.”
- On March 2, 2020, the FDA issued an Emergency Use Authorization (EAU) for release of all disposable filtering N95 facepiece respirators from the Strategic National Stockpile to be distributed to HCPs.
- On March 4, 2020, it was reported that U.S. medical workers will need 3.5 billion face masks and that the country only has 1% of that number.
- On March 26, 2020, the FDA provided new guidance: Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. This new FDA guidance allowed reuse and sterilization of face masks and the use of non-medical N95 masks to fulfill PPE requirements for health care providers examining patients in a medical setting.
- On April 3, 2020, in response to the evolving public health emergency and continued concerns about filtering facepiece respirator (FFR or respirator) availability, FDA concluded based on the totality of scientific evidence available at that time that certain product classifications for
imported disposable FFRs that are manufactured in China and not approved by the CDC’s NIOSH and for which data exists that supports the respirators’ authenticity, were appropriate to protect the public.

- The April 3, 2020, EUA further authorized respirators listed in Appendix A as authorized for use in healthcare settings by healthcare personnel (HCP) when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

While the supply of respirators dramatically increased, there were growing concerns of product safety.

- On May 7, 2020, in response to questions and concerns that have been received by FDA since issuance of the April 3, 2020 letter and having concluded that revising the April 3, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA reissued the April 3, 2020 letter with certain revisions: Factors to Consider when Planning to Purchase Respirators from Another Country, Including KN95 Respirators from China.iii

- On June 6, 2020 the FDA further revised the Scope of Authorization of this EUA, among other changes, further revised the third eligibility criterion, revised the second eligibility criterion, and removed decontaminated respirators from the scope of authorized products such that authorized respirators listed in Appendix A will no longer be authorized if they are decontaminated. Further explanation of the revisions can be found in the Frequently Asked Questions (FAQs) about Non-NIOSH-Approved Filtering Facepiece Respirators.


- Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA FAQs.

- Appendix A: Authorized Respirators, Non-NIOSH Respirators Manufactured in China (updated June 24, 2020).

- Respirator Models No Longer Authorized (updated June 24, 2020).

Optometrists should be cautious when purchasing face masks and should consider the following to protect themselves, their staff and their patients:

1. Make sure product is on the FDA EUA Appendix A.iv Wherever possible, optometry offices should continue to use FDA-cleared face masks and NIOSH approved and/or FDA-cleared N95 respirators or better.

2. Assess the risk associated with the intended use.

3. Verify that the chosen product is certified to meet the necessary level of protection.

4. Fit test to ensure that the product configuration fits the operational individual.

5. Safely operate following best practices.
Descriptions of various types of face masks include:

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.

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i https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSH.html
ii https://www.fda.gov/media/136664/download
iii Factors to Consider when Planning to Purchase Respirators from Another Country, Including KN95 Respirators from China, May 7, 2020 NIOSH webinar: https://www.cdc.gov/niosh/npptl/webinars/Webinar-Factors-To-Consider.html
iv https://www.fda.gov/media/136663/download