FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Reissues Emergency Use Authorizations Revising Which Types of Respirators Can Be Decontaminated for Reuse

For Immediate Release:

June 07, 2020

In response to public health and safety concerns about the appropriateness of decontaminating certain respirators, the agency is reissuing certain emergency use authorizations (EUAs) to specify which respirators are appropriate for decontamination. Based on the FDA's increased understanding of the performance and design of these respirators, the FDA has decided that certain respirators should not be decontaminated for reuse by health care personnel. For example, the FDA has learned from the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) testing (https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html) that authorized respirators manufactured in China may vary in their design and performance. As such, the FDA has determined that the available information does not support the decontamination of these respirators and has accordingly revised the relevant EUAs. In addition, the FDA is also revising relevant EUAs to no longer authorize decontamination or reuse of respirators that have exhalation valves.

"During this unprecedented global pandemic, the FDA continues to provide flexibility and adapt to the evolving needs of Americans based on data and science. We are committed to carefully evaluating available information and will continue to take action when there is a need to do so to protect the public health," said Anand Shah, M.D., FDA Deputy Commissioner for Medical and Scientific Affairs. "While we continue to support efforts to meet the urgent need for respirators, we are also doing everything in our authority to ensure health care personnel are adequately protected. As part of those efforts, we are announcing that we have revised and reissued a number of EUAs to amend which respirators are authorized to be decontaminated."

Among other things, the FDA has reissued the EUAs for:

- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (https://www.fda.gov/media/136664/download) by revising the Scope of Authorization such that authorized respirators listed in Appendix A will no longer be authorized if decontaminated.
- Multiple decontamination systems so that they 1) are no longer authorized to decontaminate respirators manufactured in China, where applicable (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe), and 2) only authorize decontamination of non-cellulose respirators that do not have an exhalation valve that are either authorized in the NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency (https://www.fda.gov/media/135763/download) EUA or that are authorized and identified in Exhibit 1 (https://www.fda.gov/media/136731/download) of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (https://www.fda.gov/media/136403/download) to be decontaminated.

According to CDC's recommendations, decontaminated respirators should only be used when new FDA-cleared N95 respirators, NIOSH-approved N95 respirators, or other FDA authorized respirators are not available. The decontamination systems are only authorized to decontaminate non-cellulose compatible N95 respirators. As such, health care personnel should not reuse a respirator that is incompatible with an authorized decontamination system but has nonetheless been decontaminated. Users of any respirator (whether or not decontaminated) should always assess for proper fit after placement. Respirators with poor fit, visible soiling, or damage should not be used.

The FDA continues to be vigilant and take prompt action on imported, non-NIOSH-approved respirators to ensure health care personnel receive adequate protection. For instance, the FDA is also reissuing the two EUAs covering imported respirators by tightening criteria in the Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (https://www.fda.gov/media/136664/download) as well as in the Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (https://www.fda.gov/media/136403/download) to not only include new

language related to decontamination as noted above, but also to revise the Scope of Authorization with respect to which jurisdictions are included in the criteria for eligibility in both EUAs, among other revisions.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Inquiries

Media:

Megan McSeveney (mailto:megan.mcseveney@fda.hhs.gov)

202-380-7748

Consumer:

888-INFO-FDA

Related Information

- Coronavirus Disease 2019 (COVID-19) (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)
- Emergency Use Authorization: Coronavirus (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)
- FAQs on Shortages of Surgical Masks and Gowns During the COVID-19 Pandemic (/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns-during-covid-19-pandemic)

- FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic (/medical-devices/emergency-situations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic)
- Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection - Letter to Health Care Providers (/medical-devices/letters-health-care-providers/certain-filtering-facepiece-respirators-china-may-not-provide-adequate-respiratory-protection-letter)

More Press Announcements (/news-events/newsroom/press-announcements)