FDA NEWS RELEASE

FDA Reissues Emergency Use Authorization for Certain Non-NIOSH-Approved Filtering Face-Piece Respirators Manufactured in China

For Immediate Release:

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Today, the U.S. Food and Drug Administration (FDA) reissued the Emergency Use Authorization (/media/136664/download) (EUA) for certain filtering face-piece respirators (FFRs) that are manufactured in China and are not approved by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH).

Under the June 6, 2020 version of this EUA, a respirator was authorized if it met any of three predetermined eligibility criteria. Effective immediately, the reissued EUA no longer includes the three eligibility criteria, meaning the FDA will no longer review requests nor add to the list of authorized respirators–known as Appendix A—of this EUA based on those criteria.

The FDA recognizes there is still a shortage of FFRs, and to provide additional capacity as needed, the agency is continuing the emergency use authorization of respirator models that are already included in Appendix A (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#nonniosh) of this reissued EUA.

"Since the beginning of the COVID-19 public health emergency, we have taken appropriate actions to support the personal protective equipment needs of our health care personnel by issuing EUAs. As part of our continuing work to meet the demands of this public health emergency, we undertook and completed a shortage assessment and concluded that reissuing this EUA was appropriate to reflect the current U.S. demand for these products," said Suzanne Schwartz, M.D. M.B.A., Director of the FDA's Office of Strategic Partnerships and Technology Innovation in the Center for Devices and Radiological Health.

To further inform the EUAs, the FDA completed a respirator shortage assessment to understand current product availability for both NIOSH-approved N95s and KN95 respirators and use practices for each. The assessment shows that the KN95 respirator models authorized by this EUA meet the demand for these respirators. As part of this assessment, the agency heard directly from health care personnel that the KN95 design has limited adoption in health care

settings; from distributors that imported, non-NIOSH-approved product from China is sitting in warehouses unused; and from manufacturers that NIOSH-approved N95 production is increasing. Additionally, CDC/NIOSH continues to issue more N95 approvals.

The FDA is reissuing this EUA to authorize only those respirators the FDA had already authorized and that are presently listed in Appendix A. As outlined in the reissued EUA, FDA has removed the previous eligibility criteria and, therefore, no additional respirator models will be added to Appendix A under those criteria. As such, the FDA is no longer reviewing requests submitted based on the June 6, 2020 EUA's criteria.

As a result of this EUA's reissuance, FDA expects that staff and agency resources that were devoted to reviewing those submissions can instead focus on other critical needs during the COVID-19 public health emergency, including continuing to work with CDC/NIOSH to help facilitate the availability of respiratory protection that meets the applicable standards and demands of health care personnel. The FDA is committed to refining our policies and approaches as appropriate to further facilitate the development and availability of these devices for health care personnel.

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.

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Related Information

- FDA: Personal Protective Equipment EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-

euas)

- CDC/NIOSH: N95 and Other Respirators (https://www.cdc.gov/coronavirus/2019-ncov/hcp/n95-other-respirators.html)

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