FDA Reverses Decision to Authorize Use of Chinese KN95 Respirators

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Citing poor quality, the U.S. Food and Drug Administration (FDA) has barred the importation of certain KN95 filtering facepiece respirators manufactured in China. On May 7, 2020, FDA revised and reissued the Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China Emergency Use Authorization (EUA) that provided eligibility criteria authorizing the importation of respirators from China that are not approved by the National Institute for Occupational Safety and Health (NIOSH) (i.e., not certified as meeting the N95 standard). In our prior blog posts, we detailed the temporary enforcement policy regarding the manufacture and distribution of face masks and respirators during the COVID-19 public health emergency to address shortages of personal protective equipment, including FDA’s previous position that KN95 respirators could be imported without verified test reports or separate authentication. However, in a Letter to Health Care Providers, the FDA is now expressing concerns over some of the respirators from certain Chinese manufacturers, citing filtration performance testing conducted by NIOSH as evidence that such respirators do not provide adequate respiratory
In its May 7, 2020, revisions to the EUA, FDA removed the eligibility criterion allowing importation of Chinese non-NIOSH-approved respirators based on a test report from an independent laboratory demonstrating that the respirators met an applicable filtration standard accepted by the Centers for Disease Control and Prevention. American regulators were not required to test the imported KN95 masks under the original EUA. The results from NIOSH’s recent testing of these imported respirators demonstrated that a number of them failed to establish a minimum particulate filtration efficiency of 95%, meaning the respirators did not work properly. Additionally, Chinese respirators authorized under the test report eligibility criterion, regardless of whether such respirators passed or failed the NIOSH testing, have been removed from Appendix A of the revised EUA. However, FDA added a new eligibility criterion permitting any respirator that was previously authorized under the test report criterion to be reauthorized if it demonstrates at least 95% filtration efficiency in NIOSH testing.

The FDA revisions do not affect the non-NIOSH-approved respirators meeting the other eligibility criteria in the original and reissued EUA, which remain authorized for use by FDA during the COVID-19 public health emergency.

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