

FDA Non-NIOSH Approved Respirators

On May 7, 2020, in [a letter](#) to health care providers, the U.S. Food and Drug Administration [reissued the Emergency Use Authorization \(EUA\) for Non-NIOSH approved Disposable Filtering Facepiece Respirators \(FFRs\) Manufactured in China](#). Based on a review of performance testing, the updated EUA revised the eligibility criterion for authorization of respirators from recognized independent test laboratories submitted to the FDA by manufacturers and/or importers.

According to the letter, test reporting reviewed by the agency indicated that a number of previously authorized, non-NIOSH approved FFRs, “failed to demonstrate a minimum particulate filtration efficiency of N95 percent” and did not meet their labeled performance standard. As result, respirators previously authorized under the previous EUA were removed from the authorized list ([Appendix A](#)) and are no longer authorized to be marketed, or distributed, in the United States as “respirators.” Additionally, the FDA advised that respirators that no longer appear in the appendix “may not be reliably decontaminated in any decontamination system authorized for use during the COVID-19 pandemic.”

Non-NIOSH approved respirators that meet eligibility criteria, outlined in the May 7, 2020 EUA for Non-NIOSH approved FFRs Manufactured in China remain authorized and continue to be listed in [Appendix A](#) in addition to those manufactured in other countries listed in [Exhibit 1](#) (Imported, Non-NIOSH Approved Disposable Respirators [Emergency Use Authorization for Respirators Manufactured in Other Countries](#)). To determine whether Non-NIOSH approved respirators manufactured in China have been tested and to review the results, please refer to the [NIOSH Assessment webpage](#) listing of International Assessment Results- Not NIOSH-Approved.

Although masks removed from Appendix A can no longer be marketed or distributed in the United States as respirators, they may be “re-labeled as face masks and authorized if certain criteria are met.” Specific guidance regarding general use face masks during COVID-19 can be found in the FDAs [Face Mask Emergency Use Authorization](#) and the [revised FDA Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency Guidance Document](#)).

For complete details and additional considerations outlined by the FDA to health care facilities, please see the May 7, 2020 letter to Healthcare Providers, [Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection](#) and the FDAs [Frequently Asked Questions \(FAQs\) about Non-NIOSH-Approved Filtering Facepiece Respirators](#).

Links to Appendix A above include the “current” list of Non-NIOSH approved respirators

More information is available on the [FDA pulling approvals on dozens on mask makers in China](#).