CLIENT ALERT

FDA Reissues EUA for Non-NIOSH Approved Respirators Manufactured in China

May.08.2020

At the outset of the COVID-19 pandemic, the U.S. Food and Drug Administration (FDA) barred the importation of various personal protective equipment (PPE) from abroad – particularly from China. However, in response to PPE shortages caused by the crisis, FDA changed course. As noted in a previous alert, on April 3, 2020, the Agency issued an Emergency Use Authorization (EUA) permitting the importation of non-NIOSH approved filtering face-piece respirators (respirators) manufactured in China, including KN95 masks. The April 3 EUA allowed dozens of manufacturers of masks made in China to begin importing and distributing their products as respirators within the U.S. However, on May 7, 2020, the FDA yet again changed course and revised the April 3, 2020 EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China to revoke authorization for over 50 Chinese manufacturers to market non-NIOSH approved face masks as respirators under the EUA.

FDA issued a letter explaining that the Agency's decision to stop importation of non-NIOSH approved face masks from China occurred because it was "concerned that certain filtering facepiece respirators (respirators) from China may not provide consistent and adequate respiratory protection to health care personnel exposed to COVID-19." This concern stemmed from recent filtration performance testing conducted by NIOSH which revealed a number of these respirators did not demonstrate a minimum particulate efficiency of 95 percent.

In the updated EUA, the Agency revised one of the eligibility criteria that had formerly allowed for the authorization of respirators based on review of test reports from recognized independent test laboratories submitted to the FDA by the manufacturer or importer. FDA has now removed from Appendix A all respirators that had been authorized under that criterion, regardless of whether they passed or failed NIOSH testing.

Products labeled as "respirators" must meet the applicable FDA requirements or receive an EUA to be imported and distributed in the U.S. Therefore, respirators that were removed from Appendix A of the EUA and that did not meet their labeled performance standard are no longer eligible and are no longer authorized to be marketed or distributed in the U.S. as respirators. FDA noted that these products may instead be re-labeled as face masks and authorized under a separate face mask EUA, so long as criteria under that EUA are met.

The FDA removed over 50 face mask manufacturers from Appendix A, leaving only around 14 authorized firms. The Agency stated that it is increasing surveillance of face masks imported from China and will subject shipments to random testing.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

John Fuson
Partner – Washington, D.C.
Phone: +1 202.624.2910
Email: jfuson@crowell.com

Chalana N. Damron
Counsel – Washington, D.C.
Phone: +1 202.624.2566
Email: cdamron@crowell.com

Mariam Sarwar
Associate – Los Angeles
Phone: +1 213.443.5570
Email: msarwar@crowell.com