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FDA Revises its Enforcement Policy for Respirators During the COVID-19 Public Health Emergency

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Over the past several months, the United States Food and Drug Administration (FDA) has issued several guidance documents and guidelines to regulate the importation and distribution of respirators for medical purposes during the Coronavirus Disease 2019 (COVID-19) public health emergency. On April 2, 2020, FDA issued Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) ("Enforcement Policy") in part to expand the availability of respirators for health care personnel when FDA-cleared or National Institute for Occupational Safety and Health (NIOSH)-approved respirators are unavailable. In that Enforcement Policy, among other things, FDA represented that for the duration of the COVID-19 public health emergency, FDA had no intention to object to the importation, distribution, and use of respirators listed by the Centers for Disease Control and Prevention (CDC) as alternatives to FDA-cleared or NIOSH-approved N95 respirators when FDA-cleared or NIOSH-approved N95 respirators are not available. The Enforcement Policy allowed for noncompliance with several otherwise applicable regulatory requirements when importing, distributing, or using such respirator alternatives. One such respirator alternative listed by CDC is the KN95 respirator manufactured in China to standards similar to NIOSH standards. Several companies in the United States have been importing and distributing such KN95 respirators pursuant to FDA's Enforcement Policy.

Last week, in response to concerns about the performance of some respirators based on CDC testing, FDA issued an updated Enforcement Policy that reverses its earlier position pertaining to importing, distributing, and using certain respirator alternatives to FDA-cleared and NIOSH-approved N95 respirators. Now, those companies that have been importing and distributing for medical purposes KN95 respirators—or other respirator alternatives listed by the CDC—that are not FDA-cleared, NIOSH-approved, or authorized under an Emergency Use Authorization (EUA) can no longer do so without objection by FDA for noncompliance with certain applicable regulatory requirements.

According to FDA, those certain respirator alternatives may be used as “face masks,” which covers the user’s nose and mouth, by the general public and health care personnel as source control when certain criteria are met under the EUA for face masks. Companies that choose to go this route must label and advertise the respirator in accordance with the EUA for face masks. Since FDA’s guidance and guidelines are frequently changing during this COVID-19 public health emergency, please reach out to one of our attorneys should you need more information or help.

If you have any questions, you can reach out to Hamilton Barber at hbarber@nexsenpruet.com.

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