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INTERNATIONAL BUSINESS ALERT

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FDA updates its Emergency Use Authorization for KN95 respirators from China

On May 7, 2020, the U.S. Food and Drug Administration (FDA) issued an updated Emergency Use Authorization (EUA) with an updated Appendix A listing Chinese manufacturers with EUAs to import KN95 respirators from China. Details regarding the previous issued April 3, 2020 EUA may be found in this Porter Wright Law Alert. The FDA also issued a FAQ on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic explaining why the FDA updated the April 3 EUA for KN95 respirators from China. This May 7 EUA may impact companies' eligibility to continue to import KN95 respirators from China for use in healthcare settings by healthcare personnel. Thus, it is important for companies to understand those changes, and analyze whether and how their contracts might be impacted.

The May 7 EUA contains four major revisions:

1. It has revised the second and third authorization criteria set forth in the April 3 EUA.
2. The second criterion now allows Chinese National Medical Products Administration (NMPA) registration certification by an appropriate provincial or municipal regulatory authority that is authenticated and verified by the FDA.
3. Importers will no longer be allowed to submit a request for respirators made by foreign manufacturers to be added to Appendix A – only manufacturers can submit such requests.

4. The FDA has amended the Scope of Authorization (Section II of the EUA) to describe the process the FDA will use in removing respirators from Appendix A if the FDA has reason to believe that the respirator is no longer eligible for authorization.

Compared with the the much vaguer criterion under April 3 EUA, a KN95 respirator manufactured in China may be imported under the updated May 7 EUA, if:

- It is manufactured by an entity that holds one or more National Institute for Occupational Safety and Health (NIOSH) approvals for other models of filtering face piece respirators produced in accordance with the applicable standards of authorization in other countries that can be verified by the FDA; or
- It has a regulatory authorization under a jurisdiction, including the Chinese NMPA registration certification by an appropriate provincial or municipal regulatory authority, that can be authenticated and verified by the FDA; or
- It was previously listed in Appendix A under the April 3, 2020 letter of authorization as an authorized respirator because it demonstrated acceptable performance to applicable standards as documented by test reports, has had particulate filtration efficiency assessed by NIOSH using a modified version of NIOSH's Standard Test Procedure (STP) TEBAPR-STP-0059 within 45 calendar days of the date of issuance of this EUA, and has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent.

This May 7 EUA and Appendix A have reduced the number of Chinese manufacturers with EUAs for KN95 respirators from approximately 80 to 14. The FAQ explained that "new information has come to light that questions the performance of some of the respirators authorized under the original April 3, 2020 EUA and included in Appendix A." However, the 60 manufacturers originally authorized under the April 3 Appendix A were removed from the newly-issued May 7 Appendix A because the FDA revised the third eligibility criterion in the April 3 EUA, and as a result, all respirators that were authorized under the test report eligibility criterion have been removed. In other words, the removal of Chinese manufacturers listed on the April 3 Appendix A does not mean that the FDA has found the KN95 respirators manufactured by those manufacturers to be below the FDA standard; it only means that those Chinese manufacturers will need to be reauthorized under the new eligibility criterion as stated in the May 7 EUA.

For companies that have already entered into or plan to enter into a purchase agreement with Chinese manufacturers to import KN95 respirators from China for use in healthcare settings by healthcare personnel, this May 7 EUA may have a significant impact on contract performance. As approximately 60 originally-authorized Chinese manufacturers will now need to be reauthorized by the FDA under the new criteria, those manufacturers may not be able to meet shipping

schedules set forth in their contracts. In addition, it is possible that those manufacturers will not be reauthorized and will not ship at all. Impacted companies should understand this change, carefully review their purchase agreements, and analyze whether or how the change of the manufacturer's EUA would impact import and contract performance. Those companies may need to renegotiate purchase agreements, including any payment or shipment terms.

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