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INTERNATIONAL BUSINESS ALERT

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FDA futher updates its Emergency Use Authorization for KN95 respirators from China

On June 6, 2020, the U.S. Food and Drug Administration (FDA) issued an updated Emergency Use Authorization (EUA) on Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) Manufactured in China. The following day, the FDA issued an updated Appendix A listing Chinese manufacturers with EUAs to import KN95 respirators from China. Details regarding the previous issued April 3, 2020 and May 7, 2020 EUAs may both be found in this Porter Wright Law Alert. The June 6 EUA may further 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 June 6 EUA contains five major revisions related to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of the May 7 EUA.

1. While the May 7 EUA permits the importation of KN95 respirators manufactured in China if the respirators have regulatory authorization under specified jurisdictions, including the Chinese National Medical Products Administration (NMPA) certification (which was included in the May 7, 2020 revision), the June 6 EUA has revised the second eligibility criterion to permit the importation of KN95 respirators manufactured in China only if they contain a certain CE mark (European Economic Area certification mark) or have a NMPA certification.

2. The FDA has revised the third criterion such that a respirator model that is sampled by the FDA and tested by the Centers for Disease

Control and Prevention's National Institute of Occupational Safety and Health (NIOSH), and that has results that, according to NIOSH, indicate one or more of the 30 sampled respirators has a filtration efficiency of less than 95% is no longer authorized.

3. The FDA revised the Scope of Authorization to remove decontaminated respirators from the Scope of Authorization. As such, authorized respirators that are decontaminated are no longer authorized under this June 6 EUA. They may, however, be authorized under an individual decontamination system EUA according to the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised).

4. The FDA added Conditions of Authorization to require samples for testing when requested by the FDA and prevent distribution of shipments that fail testing.

5. The FDA added Conditions of Authorization regarding printed materials, advertising, and promotion under section 564(e)(4) of the Act.

A KN95 respirator manufactured in China may be imported under the updated June 6 EUA, if:

1. The respirator is manufactured by an entity that holds one or more NIOSH approvals, that have been verified by the FDA, for FFRs, and that is produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country;

2. The respirator:

   a. Has a registration certification for a medical protective mask (not for short- term emergency registration certifications), issued by an appropriate Chinese provincial or municipal authority in accordance with the regulatory authorization under the NMPA, and that has been authenticated and verified by the FDA, or

   b. Conforms to Personal Protective Equipment (PPE) Directive 89/686/EEC (for those placed into distribution before April 21, 2019) or that conforms to PPE Regulation (European Union (EU)) 2016/425 (for those placed into distribution after April 21, 2019), as evidenced by a CE mark, and the CE mark has been authenticated and verified by the FDA; or

3. The respirator 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) TEB-APR-STP-0059 within 45 calendar days of the date of issuance of the May 7 EUA, and has

> results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent. A respirator authorized under this EUA because it meets the criterion in the previous sentence is no longer authorized if it has been sampled by the FDA, tested by NIOSH via a modified version of STP TEB-APR-STP-0059, and has results according to NIOSH that indicate one or more of the 30 sampled respirators has a filtration efficiency of less than 95%.

According to the June 6 EUA and Assessment of Filter Penetration Performance for Non-NIOSH Approved Respirators – the National Personal Protective Technology Laboratory (NPPTL) Assessment to Support the COVID-19 Response, the FDA will sample and send 30 respirators from a shipment of the same model to NIOSH for testing using a modified version of STP TEB-APR-STP-0059. The FDA will generally sample from lots that have been imported and are either at a port of entry or at a storage facility/warehouse in the United States. If an FDA-sampled respirator model fails to meet the expected filtration efficiency performance per NIOSH testing, the respirator model will no longer be authorized under this EUA. As noted above, the FDA defines "failure" as any result from NIOSH that indicates one or more of the 30 sampled respirators has a filtration efficiency of less than 95%. On June 7, 2020, the Appendix A was updated, listing 31 Chinese manufacturers as authorized KN95 respirator manufacturers under the June 6 EUA. However, it is possible that the Appendix A may continue being updated as the FDA continues its sampled respirator model testing discussed above.

Take away

The frequent change of EUA standards may present some practical challenges 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. Impacted companies should understand this change and carefully monitor Appendix A and NPPTL Assessment updates to make sure that the products purchased remain authorized to be marketed and sold to healthcare professionals under the EUA.

Companies that have already entered into or plan to enter into a purchase agreement with Chinese manufacturers to import KN95 respirators from China should recognize the possibility that certain Chinese manufacturers may no longer be authorized under the EUA. The value of respirators that may still be imported for the general public, but not for healthcare use, may decrease. Manufacturers may not meet the shipping schedule set forth in their contract, or if the manufactured KN95 respirator is not reauthorized, may not ship at all. Importing companies should carefully review their purchase agreements, analyze whether or how the change of the manufacturer's EUA would impact import and contract performance, and renegotiate purchase agreements, including any payment or shipment terms. Those companies should additionally collaborate with the Chinese manufacturers to reapply for the EUA under the newly-issued criteria, in

order to mitigate damages. However, those companies should also prepare for disputes under the purchase agreements should efforts to renegotiate fail.

Companies planning to enter into a purchase agreement with Chinese manufacturers to import KN95 respirators from China for use in healthcare settings by healthcare personnel should understand the rapidly changing circumstances and negotiate terms in the agreement to address those possibilities. Some examples are terms regarding (a) the quality of the goods, including whether the products must be authorized by an FDA EUA at the time of the contract or at the time of the delivery, (b) whether the removal by the FDA of a certain respirators or manufacturer from the Appendix A constitute force majeure or act of God, (c) the remedies of the parties in such circumstances, and the dispute resolution mechanism.

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