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IN LATEST RESPONSE TO COVID-19, UNITED STATES IMPOSES APPROVAL REQUIREMENT FOR EXPORT OF CERTAIN PROTECTIVE EQUIPMENT

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On Friday, April 10, 2020, the United States will join the list of countries requiring authorization for exports of certain medical and health-related equipment. Specifically, as of that date, authorization from the U.S. Department of Homeland Security, Federal Emergency Management Agency (FEMA) will be required for exports from the United States of the following personal protective equipment (PPE):

- N95 Filtering Facepiece Respirators;
- Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100);
- Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
- PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials; and
- PPE gloves, including exam gloves, surgical gloves, and other gloves intended for the same purposes.

These requirements take effect pursuant to a temporary final rule issued by FEMA and will be effective for a 120-day period (through August 8, 2020).

Under the rule, U.S. Customs and Border Protection (CBP) will temporarily detain any shipment of covered materials until FEMA can determine whether to: (1) return the items for use within the United States; (2) purchase the items on behalf of the United States; or (3) allow some or all of the items to be exported. The rule sets out six (6) factors that FEMA will consider when determining how to proceed with respect to each proposed shipment and states that FEMA will make its determination "within a reasonable timeframe after notification of an intended export." The rule does not, however, provide for a specific process by which exporters can submit information to

FEMA in support of the proposed export or additional clarity regarding what timeframes would be considered reasonable.

In addition, the final rule gives FEMA the ability to exempt from its review requirements shipments of PPE covered by the rule, provided that the shipment is made by or on behalf of U.S. manufacturers that have had continuous export agreements in place with non-U.S. customers since at least January 1, 2020, and at least 80 percent of the manufacturer's domestic production of such PPE, on a per item basis, was distributed in the United States in the preceding 12 months. We are awaiting further guidance as to how FEMA will implement this exemption; in the meantime FEMA has encouraged manufacturers to contact FEMA with specific information regarding their status under this exemption.

The final rule also provides that FEMA may designate additional materials for which an export authorization would be required. Such further designations would be announced via the *Federal Register*.

Those involved in the export of the PPE equipment covered by the rule should evaluate their current and upcoming orders and should take steps to address the need for approval from FEMA prior to such exports. Companies involved in exports of medical and health-related equipment generally may wish to consider taking preemptive steps in the event that their products become subject to the rule in the future.

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