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INTERNATIONAL BUSINESS ALERT

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Importing masks and respirators from overseas during COVID-19 under FDA's relaxed rules

The U.S. generally classifies face masks into three categories: (1) face masks and N95 respirators not intended for a medical purpose; (2) face masks intended for a medical purpose, but not to provide a liquid barrier protection; or (3) surgical masks intended to provide a liquid barrier protection.

In normal circumstances, the Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH) have responsibilities for evaluating and regulating respiratory protective devices for health care workers. Respirators that are used in workplaces in the United States must be approved by NIOSH and meet standards and test results specified by regulation. (42 CFR Part 84). In addition, the FDA regulates face masks when they meet the definition of a device under Section 201(h) of the Federal Food, Drug and Cosmetic Act (FDCA). A face mask is a device subject to the FDCA and FDA regulations when it is intended for a medical purpose, or otherwise "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." The products that are subject to regulation include masks used by the general public in public health emergencies, as well as more robust masks like surgical masks with and without antimicrobial/antiviral agents, surgical respirators and N95 respirators. Face masks intended for a medical purpose, but not to provide liquid barrier protection, as well as surgical masks intended to provide liquid barrier protection, are generally subject to the FDA 510(K) premarket notification, registration and listing, quality system regulation, report of corrections and removals, and unique device identification requirements.

Information about COVID-19 and its impact on local, state and federal levels is changing rapidly. This article may not reflect updates to news, executive orders, legislation and regulations made after its publication date. Visit our COVID-19 resource page to find the most current information.

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With the continued COVID-19 pandemic, face masks and N95 respirators remain a precious commodity for the general public and healthcare professionals. With the high demand and shortage of supply in the domestic market, companies are looking overseas to satisfy their domestic face mask and respirator needs. However, face masks and N95 respirators imported from other countries are unlikely to have received NIOSH approval and/or FDA clearance, unless the masks were imported to the U.S. prior to the COVID-19 pandemic. To help expand the availability of general use face masks for the general public and respirators for health care professionals during this pandemic, the FDA has issued multiple Emergency Use Authorizations and enforcement policies to significantly relax its rules and enforcement actions during the COVID-19 pandemic. The regulation of these medical devices during the COVID-19 pandemic is uncharted territory, and understanding how various FDA Emergency Use Authorizations fit together with enforcement policies has become particularly important.

FDA's relaxed rule applicable to disposable Filtering Facepiece Respirators

On March 24, 2020, the FDA issued an Emergency Use Authorization (reissued on March 28, 2020) along with the Non-NOISH Approved Respirator EUA FAQ for importing non-NIOSH Approved Disposable Filtering Facepiece Respirators (such as N95 Respirators), allowing certain respirators be imported into the U.S. "for use in healthcare settings by [healthcare professionals] as recommended by the Centers for Disease Control and Prevention (CDC) to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak" with reduced FDA information submission requirements. Specifically, disposable Filtering Facepiece Respirators that have been designed, evaluated and validated to meet a given performance standard and have corresponding acceptable product classifications from Australia, Brazil, Europe, Japan, Korea, and Mexico, who have similar standards to NIOSH, have specifically been authorized. In addition, disposable Filtering Facepiece Respirators which have a marketing authorization in one of the following regulatory jurisdictions have been specifically authorized:

- European CE Mark
- Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion
- Health Canada License
- Japan Pharmaceuticals and Medical Device (PMDA)/Ministry of Health Labour and Welfare (MHLW)

The March 24 EUA included an Exhibit 1 (last updated on April 14) which list authorized manufacturers with respirator models for use in the healthcare settings during the COVID-19 pandemic under the March 24 EUA. In order to be added to Exhibit 1 as an authorized manufacturer

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under the March 24 EUA, manufacturers and/or importers must send a request to FDA of their intent to import non-NIOSH approved disposable respirators that are eligible for authorization, along with certain required documents. Companies importing respirators from Australia, Brazil, Europe, Japan, Korea, and Mexico for use in the healthcare setting should check if the manufacturer is listed on Exhibit 1, and if not, submit a request, along with required materials, to the FDA to be included on Exhibit 1, prior to the import.

Notably, under the initial March 24 EUA, respirators manufactured in China to the KN95 air filtering standard (the Chinese equivalent of the U.S. government's N95 standard) are not included within the EUA list. However, to ease the demand to import from China, the FDA also published FAQs on Shortages of Surgical Masks and Gowns (FAQ) on April 3, 2020 (last updated on April 9, 2020), authorizing respirators manufactured in China to the KN95 air filtering standard to be imported and used in the U.S. during the COVID-19 pandemic. The FDA also issued a separate EUA "Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China" on April 3, 2020, which makes KN95 respirators eligible for authorization "for use in healthcare settings by [healthcare professionals] as recommended by CDC to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak" if certain criteria are met, including evidence demonstrating that the respirator meets certain standards. Following the issuance of the FAQ and April 3 EUA, the CDC updated its Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies website, which previously only listed respirators from Australia, Brazil, Europe, Japan, Korea and Mexico as authorized alternatives to N95 respirators, to include KN/KP95 and KN/KP100 respirators manufactured in China.

The April 3 EUA included an Appendix A (last updated on April 24, 2020) listing all of the authorized manufacturers from China with respirator models for use in healthcare settings during the COVID-19 pandemic. In order to be added to Appendix A as an authorized respirator manufacturer under this updated EUA, manufacturers and/or importers must demonstrate that the disposable non-NIOSH-approved respirator manufactured in China meets at least one of the criteria listed in the April 3 EUA by sending a request, along with the required materials, to the FDA. Companies importing respirators from China for use in the healthcare setting should check if the manufacturer is listed on Appendix A, and if not, submit a request, along with the required materials, to the FDA to be included on Appendix A, prior to the import.

FDA's relaxed rule applicable to all face masks

Subsequent to the March 24 EUA that applies only to disposable Filtering Facepiece Respirators, the FDA further issued an Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) (superseding the previously issued March 24 enforcement policy), that is applicable to all face masks subject to

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FDA regulations. This Enforcement Policy has provided certain exemptions for FDA clearance requirements **as long as the product and labeling does not create any undue risk for users, and the product has met all special labeling requirements** under the March 24 EUA. The exemption available is established on a tiered, risk-based analysis of the level of risk a device category presented. The lower the risks presented by a device category, the greater the adjustment of regulatory requirements with respect to that category. Specifically, face masks and N95 respirators not intended for a medical purpose are exempt from all FDA authorization requirements; face masks intended for a medical purpose, but not to provide a liquid barrier protection and surgical masks intended to provide a liquid barrier protection are both exempted from the FDA 510(K) premarket notification, registration and listing, quality system regulation, report of corrections and removals, and unique device identification requirements.

The Enforcement Policy explained that for face masks intended for medical purposes, but not intended to provide liquid barrier protection, the FDA assumes that those face masks would not create undue risk if they satisfy the following requirements:

1. The product includes accurate labeling describing the product as a face mask (not labeled as a surgical mask);
2. The labeling includes a list of the material that makes contact with the body (the contacting materials may not include any drugs or biologics);
3. The labeling makes recommendations that would sufficiently reduce any risks of usage (recommendation against use in a surgical setting or against use in environments with increased exposure to fluids or high intensity heat sources); and
4. The product is not intended for any use that would create an undue risk in light of the public health emergency.

Under the Enforcement Policy, face masks intended for medical purpose with liquid barrier protection are not believed to create an undue risk if the devices meet the above 4 requirements and the following additional requirements:

1. The product meets fluid resistance testing consistent with ASTM F1962 (Standard Guide for Use of Maxi-Horizontal Directional Drilling for Placement of Polyethylene Pipe or Conduit Under Obstacles, Including River Crossings);
2. The mask meets Class I or Class II flammability requirements pursuant to Title 16 of Code of Federal Regulations Part 1610;
3. The product includes accurate labeling describing the product as a surgical mask;
4. The product includes a list of materials contacting the body, which do not include drugs or biologics within the materials; and

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5. The product is not intended for any use that would create an undue risk in light of the public health emergency.

In the Enforcement Policy, the FDA further addressed two key omissions from the March 24 EUA. Specifically, the FDA provided additional guidance on: (1) the importation of respirators not approved by NIOSH; and (2) the manufacture and distribution of face shields. The Enforcement Policy does not refer to any country-specific standard, but discusses generally the quality requirement needed to be met for both general public and health care use. The FDA has made it clear that it is suspending the enforcement for certain face masks, and for the duration of the COVID-19 pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available. The FDA generally would not object to the importation and use of respirators not covered in the March 24 EUA. The FDA further stated it does not intend to object to companies importing and distributing alternative respirators identified in CDC recommendations. As mentioned above, to date, CDC has approved the respirator standards in Australia, Brazil, China, Europe, Japan, Korea and Mexico.

Following the issuance of the Enforcement Policy, the FDA issued another EUA on April 18, 2020, authorizing the use of face masks for use by members of the general public, including healthcare professionals in healthcare settings as PPE, to cover their noses and mouths during the COVID-19 pandemic. Authorized face masks must meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);

2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection, and includes recommendations that would reduce the risk of such use; and

3. The product is not labeled in such a manner that would misrepresent the product's intended use.

The general FDA quality system requirements, labeling requirements, and unique device identification requirements are generally waived, except that face masks must satisfy the special labeling requirements and conditions related to advertising and promotion under this EUA. Manufacturers of face masks do not need to take any action, other than complying with the requirements set forth above to be authorized to be imported and used under this EUA.

Conclusion

The purpose of the FDA EUAs and the Enforcement Policy is to ease compliance requirements that manufacturers would typically have to meet before importation and distribution of face masks and respirators. With the above relaxed FDA rules, importation and use office masks and

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respirators from overseas will generally be permitted during the COVID-19 pandemic so long as the face masks and respirators meet the specific criteria identified by the FDA and do not create undue risks. Consistent with the FDA's relaxed rules, the U.S. Customs and Border Protection Cargo Systems Messaging Service have published CSMS #42124872 (Information for Filing Personal Protective Equipment and Medical Devices During COVID-19), outlining the reduced FDA information submission requirement for importation of personal protective equipment and medical devices under the above discussed EUAs and Enforcement Policy. It remains crucial for companies importing face masks and respirators to ensure that such products have been authorized under the EUAs, or, at minimum, take action to seek authorization under the EUAs prior to import. Additionally, it is important to remember that the FDA does not confirm the authenticity of any alternative respirators from overseas. Importers must therefore perform proper due diligence and take appropriate steps to verify the authenticity of the products prior to the import.

For more information please contact Yuanyou Yang or any member of Porter Wright's International Business & Trade Practice Group.

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