Publications

Despite New Regulatory Flexibilities, Risks Persist for Companies Transitioning to Production, Sale, and Importation of Face Masks and Respirators

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Jolie N. Havens

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As widespread shortages of face masks and N95 respirators needed to help fight the COVID-19 pandemic persist, manufacturers, brokers, and other companies across the nation are looking to retool their operations for the production and sale of these crucial items.

The federal Food and Drug Administration (FDA), which regulates face masks and respirators as medical devices when they are intended for the prevention of disease (including stopping the spread of COVID-19), has taken significant steps to facilitate this effort; however, while certain ordinarily applicable requirements have been relaxed or suspended, the specific language in a product's labeling and related contractual terms could dramatically expand a company's risk of regulatory enforcement and breach-of-contract or consumer protection claims. For this reason, a thorough review of a product's labeling (including any specifications sheet and user manual) and related contractual terms is incredibly important.

For example, even where a product may otherwise be lawfully marketed in the United States, mischaracterizing the level of FDA review to which it has been subjected, even inadvertently, may render it "misbranded" and illegal to distribute under the Food, Drug and Cosmetic Act (FD&C Act). Additionally, using certain terms of art (e.g., "surgical" or "liquid") may trigger additional regulatory requirements, potentially undermining a company's ability to rely on available enforcement guidance.

Further, for companies importing face masks and respirators from overseas, additional regulatory considerations arise. For example, it is important to ensure that the manufacturer's information about the product is reliable and accurate. Our team has already seen clients receiving inaccurate product descriptions and mischaracterized regulatory documentation. Incorporating such information into a company's own advertising and agreements could potentially give rise to significant liability, including liability for false advertising or other misrepresentation.

If your company is considering transitioning into the production, sale, and/or importation of face masks or respirators and you have questions about applicable FDA requirements and limiting your related business risk, please contact Jolie Havens, Mairi Mull, Nita Garg, or your regular Vorys attorney.

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VORYS COVID-19 TASK FORCE

Vorys attorneys and professionals are counseling our clients in the myriad issues related to the coronavirus (COVID-19) outbreak. We have also established a comprehensive COVID-19 Task Force, which includes attorneys with deep experience in the niche disciplines that we have been and expect to continue receiving questions regarding coronavirus. Learn more and see the latest updates from the task force at vorys.com/coronavirus.