Importers Face Pitfalls as Demand for Medical Products Explodes During COVID-19 Pandemic

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Importers of medical equipment face pitfalls responding to the explosion in demand for their products as a result of the COVID-19 pandemic, according to Ben England of FDAImports.com, who spoke by phone interview March 25. The requirements of some emergency actions taken by FDA can be difficult or impossible to navigate, and the huge increase in demand for medical products, including protective equipment and ventilators, is a recipe for fraud, potentially creating unwelcome surprises for importers at the border, England said.

England and his consultancy are "swamped," he said, working overtime to match Chinese suppliers, which are again ramping up production as the worst of the pandemic subsides in their country, with importers in the U.S. "We started getting phone calls like crazy from all sorts of companies in China that want to export hand sanitizers, masks, ventilators, gloves, you name it. So we've been in a lot of deal-making, putting foreign suppliers together with U.S. importers who are in need of the products" so they can in turn be distributed to hospitals, clinics and the government.

For its part, FDA has been putting out emergency use authorizations (EUAs) and guidelines setting policies of enforcement discretion for equipment that is necessary to face COVID-19. That includes policies loosening requirements for ventilators and remote monitoring devices, and EUAs for N95 respirators for non-medical use and COVID-19 diagnostics (see 2003250028).

Some of those emergency actions need some tweaking to be truly effective, England said. For example, FDA's newest EUA for non-National Institute for Occupational Safety and Health (NIOSH)-approved N95 respirators still requires that the manufacturer meet labeling requirements and a mandate to post donning instructions on its website. But "every single walking human that works for these companies, if they don't have COVID, are on the floor making masks," England said. No one is available at these Chinese companies to create new webpages in English. So rather than comply, the masks will instead likely be sent to the European market. England says the policy needs to be changed to let importers satisfy the requirements on the manufacturer's behalf, and has suggested as much to FDA.

And FDA's enforcement discretion policy for ventilators, which allows products that are not ventilators to be modified for use as such, is not very useful in its present state because the manufacturer likely needs to have a 510k premarket submission with FDA, England said. Any

manufacturer with a 510k already on file has probably already brought their product in. Manufacturers that do not will likely ship them to England or Germany instead of getting one, he said.

England says he has already seen examples of fraud by unscrupulous actors trying to get around regulatory requirements for these products. He's aware of more than a dozen examples of companies being registered by third parties as device facilities and then listing the devices in an incorrect classification that does not require a 510k submission, including disposable surgical masks that are being listed as scavenging masks.

That's "going to create problems for the importer because the device listing is not going to match what the device really is," England said. The discrepancy will probably be caught when entry data is transmitted to CBP and the FDA, and the shipments "are probably going to be stopped, because there's no evidence that they are suitable for medical use," he said. While FDA is fine with imports of non-medical masks, which can be useful for the public, it does not allow them to be sold as medical masks, England said.

Many new importers and manufacturers face a learning curve in adapting to the new CBP and FDA regulatory requirements for medical products. But England said he is not seeing any issues with CBP's and FDA's ability to process the higher volumes amid the COVID-19 pandemic. "They're working overtime to oversee critical products getting to the U.S. market," while keeping their eyes peeled for fraud, England said.

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