The Bottom Line

MAY 2020 | VOL. 40

FDA ISSUES REVISED REGULATIONS REGARDING KN95 FACE MASKS

Summary

To facilitate the import of masks, the Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) which makes the reporting of the registration information optional. This allows for the import of NIOSH-approved masks as medical devices. The EUA also covers some non-NIOSH-approved masks that have been validated to meet specific performance standards. This policy has been amended and the wide approval for all non-NOSH masks has been revealed.

Background

Face masks can be designed for either medical or non-medical use. Masks designed to protect the wearer from particulates in a commercial, non-medical setting are required to meet standards set by the National Institute of Occupational Safety and Health (NIOSH). Manufacturers of masks that meet NIOSH standards are not required to register with the FDA, but the masks are required to be identified as "not intended for medical use."

Under normal circumstances, equipment designed to prevent the spread of disease in a medical environment, such as gloves, face masks, face shields, respirators, and hand sanitizer, are regulated by the Food and Drug Administration to ensure that they meet minimum safety requirements. The FDA requires registration for anyone (manufacturer, importer or distributor) introducing regulated medical devices into the United States market. The individual devices are inspected and assigned a device listing number. To process an import of these products, the Customs entry must include registration numbers for all the parties involved and the products being imported.

The EUA published in March authorized the importation of non-NIOSH masks that met performance standards published in Australia, Brazil, Europe, Japan, Korea, and Mexico and allowed for their use in a medical setting when FDA-approved masks were not available.

Current Status

The FDA has determined the EUA has succeeded in increasing the availability of face masks for health care personnel and the general public. The FDA will be continuing their enforcement discretion regarding the importation of masks and has advised that they will not object to the distribution of masks where:

- The products are accurately labeled as either medical or non-medical.
- The labeling includes recommendations for safe use.
- The labeling does not create an undue risk by claiming antimicrobial or antiviral protection.

Impact

There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks and respirators are regulated by the FDA when they are intended for a medical purpose, including for use by health care personnel. Face masks that are not intended for a medical purpose are not medical devices. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in a medical setting, FDA device marketing authorization is not required, and all the other requirements of the Federal Food, Drug & Cosmetic Act do not apply to manufacturers, importers, and distributors of these products.

To be imported as a device for use in a medical setting, masks must either be FDA-registered and approved, or imported under the conditions outlined in the EUA. KN95 masks and other textile masks can still be imported, but not for use in a medical setting unless they are authorized under the EUA.

RESOURCES:

Enforcement Policy for Face Masks and Respirators (FDA)
List of Authorized Non-NIOSH Respirators from China (FDA)