The Bottom Line

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FDA ENDS EMERGENCY USE AUTHORIZATIONS FOR PPE

Summary

The U.S. Food and Drug Administration (FDA) is revoking the Emergency Use Authorizations (EUAs) for non-NIOSH-approved disposable respirators (revocation effective July 6, 2021) and the EUAs for decontamination and bioburden reduction systems (revocation effective June 30, 2021).

Background

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. In order to process an import of these products, the Customs entry must include registration numbers for all the parties involved and the products being imported. During the COVID crisis, the FDA had issued an Emergency Use Authorization (EUA) to facilitate the import of masks, which made the reporting of the registration information optional. This EUA allowed for the import of NIOSH-approved (National Institute for Occupational Safety & Health) masks as medical devices and covered non-NIOSH approved masks validated to meet specific performance standards or have a marketing authorization from certain countries. The EUA also allowed for the importation of decontamination systems which would allow for the reuse of personal protective equipment during times of scarcity.

Current Status

The FDA has announced the revocation of EUAs for imported, non-NIOSH-approved respirators as well as decontamination and bioburden reduction systems because of an increase in domestically manufactured NIOSH-approved N95s available throughout the country. As access to domestic supply of disposable respirators continues to significantly improve, health care organizations should transition away from crisis capacity conservation strategies that were implemented at the onset of the pandemic. Since the beginning of the pandemic, NIOSH has approved more than 875 respirator models or configurations, with some of these manufactured by approximately 20 new, domestic NIOSH-approval holders. In addition, as of today, there are more than 6,400 total respirator models or configurations on the NIOSH-certified equipment list which have met the NIOSH-approved EUA criteria and thus are FDA-authorized. These include:

- more than 600 filtering facepiece respirator (FFR) models (of which there are over 530 N95 FFR models),
- more than 5,500 elastomeric respirator configurations, including new elastomeric respirators without an exhalation valve, and
- more than 360 powered air purifying respirator configurations.

Impact

As these Emergency Use Authorizations are revoked, the procedures for the importation of these products reverts to pre-pandemic rules. Non-NIOSH-approved respirators are no longer approved for use in medical settings and cannot be sold as such. The FDA recommends health care personnel transition from extended use of disposable respirators to single-use for single-patient interactions as appropriate.

It is anticipated that as the burden on health care infrastructure decreases, other EUA's currently still in operation will also be revoked. These include infusion pumps, in-vitro diagnostic kits and protective barrier enclosures. Anyone sourcing personal protective equipment from outside the U.S. should be aware of FDA requirements for those products and ensure that they meet current or pre-pandemic standards.

RESOURCES

FDA Revokes Emergency Use Authorizations for Certain Respirators and Decontamination Systems as Access to N95s Increases Nationwide (FDA)

FDA Recommends Transition from Use of Non-NIOSH-Approved and Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities (FDA)

Personal Protective Equipment EUAs (FDA)

FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators—Letter to health Care Personnel and Facilities (FDA)