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Respirator Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators

Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

July 13, 2021
Agenda

• Overview of FDA Letter to Health Care Personnel & Facilities
  – Background
  – NIOSH-Approved Respirators Authorized under Emergency Use Authorization (EUA)
  – Recommendations
  – FDA Actions

• Resources

• Questions
On June 30, 2021, the FDA announced it 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). For ORP

These actions are in follow-up to the May 27, 2021, letter in which the FDA recommended a transition away from non-NIOSH-approved disposable respirators as well as from reusing decontaminated or bioburden-reduced disposable respirators.

Based on the increased domestic supply of respirators approved by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH), and consistent with CDC's updated recommendations and in alignment with the Occupational Safety and Health Administration's (OSHA) recently published Emergency Temporary Standard (ETS) to protect health care workers, the FDA believes health care facilities should not use crisis capacity strategies any longer.
NIOSH-Approved Respirators Authorized under EUA

• During the COVID-19 public health emergency, **NIOSH-approved respirators, including N95 respirators, are authorized** on a continual basis under the FDA emergency use authorization (EUA) for NIOSH-Approved air purifying respirators (includes single-use respirators and those designed to be reusable)

• There are **over 6,400 total respirator models or configurations on the NIOSH certified equipment list**, which meet the NIOSH-Approved EUA criteria and thus are FDA-authorized, including:
  
  – **Over 600 filtering facepiece respirators (FFR) models** (of which there are over 530 N95 FFR models)
  – **Over 5,500 elastomeric respirator configurations**, including new elastomeric respirators without an exhalation valve
  – **Over 360 powered air-purifying respirators (PAPR) configurations**

* until the U.S. Department of Health and Human Services (HHS) Secretary’s declaration that circumstances exist justifying authorization is terminated or the EUA is revoked
• The FDA recommends that health care personnel and facilities:
  – Use only FDA-cleared or NIOSH-approved respirators, including N95s and other respirators under the Emergency Use Authorization (EUA) for NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency.
  – Transition from wearing disposable respirators for respiratory protection for an extended time to conventional capacity strategies that include wearing a disposable respirator for each patient contact, according to the CDC's strategies, as appropriate.
• The FDA recommends that health care personnel and facilities:
  – Consider redistributing current inventory of non-NIOSH-approved respirators, such as, to:
    • Non-health care settings for non-medical use (for example, construction)
    • Other countries in need (in accordance with the Federal Food, Drug, and Cosmetic Act export provisions)
    • While it is possible that non-NIOSH-approved respirators may be reconditioned for use as source control (see, for example as face masks in Import Alert 89-18), the FDA does not recommend that non-NIOSH-approved respirators undergo reconditioning at this time because there is currently sufficient supply of source control medical devices, among other things
  – Continue to increase inventory of available NIOSH-approved respirators, including:
    • N95s and other disposable filtering facepiece respirators (FFRs)
    • Elastomeric respirators, including new elastomeric respirators without an exhalation valve that can be used in an operating room
    • Powered air-purifying respirators (PAPRs).
On June 30, 2021, the FDA announced the revocation of the following EUAs:

- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (effective July 6, 2021)
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (effective July 6, 2021)
- Decontamination and Bioburden Reduction System EUAs for Personal Protective Equipment (effective June 30, 2021)

In addition, on June 30, 2021, the FDA has withdrawn two related decontamination and bioburden reduction guidance documents:

- Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff
The FDA will continue to monitor supply and demand to assess respirator availability as facilities systematically transition away from the most extreme measures of respirator conservation (that is, crisis capacity strategies) to contingency and conventional use.

Respirators, specifically surgical respirators, presently remain on the FDA’s device shortage list.

The FDA will continue to keep health care personnel and the public informed if new or additional information becomes available.
Resources


FDA FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic


• CDC Strategies for Optimizing the Supply of N95 Respirators: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html


• Overview of the OSHA Emergency Temporary Standard https://www.osha.gov/coronavirus/ets
Questions?

Email: CDRH-COVID19-SurgicalMasks@fda.hhs.gov

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Under Heading: Specialty Technical Topics and Sub-heading Personal Protective Equipment (PPE)

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