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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

Background

- 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

Recommendations

- **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.

Recommendations (cont.)

- **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).

FDA Actions

- **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
  - Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the Coronavirus Disease (2019) Public Health Emergency

FDA Actions (cont.)

- 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 No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities: https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators
  FDA FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic
- https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic
- FDA Considerations for Selecting Respirators for Your Health Care Facility https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/considerations-selecting-respirators-your-health-care-facility

- CDC Strategies for Optimizing the Supply of N95 Respirators: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html
  CDC Personal Protective Equipment (PPE) Burn Rate Calculator: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html

- OSHA Occupational Exposure to COVID-19 Emergency Temporary Standard: https://www.federalregister.gov/documents/2021/06/21/2021-12428/occupational-exposure-to-covid-19-emergency-temporary-standard
- 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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