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Transitioning from the Use of Non-NIOSH-Approved Respirators

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

June 8, 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 May 27, 2021, the FDA issued a letter to health care personnel and facilities recommending they **transition away from crisis capacity conservation strategies**, such as using **non-NIOSH-approved disposable respirators including non-NIOSH-approved imported respirators such as KN95s**.

- This recommendation is in follow-up to the April 9, 2021, letter in which the FDA recommended a transition away from decontamination or bioburden-reduction systems for cleaning and disinfecting disposable respirators, which were being reused by health care personnel

- Based on the **increased domestic supply of new 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, the FDA believes health care personnel and facilities can transition away from using non-NIOSH-approved respirators and from utilizing decontamination and bioburden reduction systems. These crisis capacity conservation strategies have been used to address respirator shortages during the COVID-19 outbreak.

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:
  - **Limit use of all non-NIOSH-approved respirators, including imported non-NIOSH-approved respirators**, to only when there are insufficient supplies of new NIOSH-approved filtering facepiece respirators (FFRs), or when any new respirators are unavailable.
  - **Limit decontamination of disposable respirators**. Decontaminated respirators and respirators that have undergone bioburden reduction should be used only when there are insufficient supplies of new FFRs or when any new respirators are unavailable.
  - **Transition away from a crisis capacity strategy for respirators**, such as use of non-NIOSH-approved respirators and decontamination of N95 and other FFRs.
  - **Increase inventory of available NIOSH-approved respirators**—including **N95s and other FFRs**, **elastomeric respirators**, including new elastomeric respirators without an exhalation valve that can be used in the operating room, and **powered air-purifying respirators (PAPRs)**. Even if health care personnel and facilities are unable to obtain the respirator model that they would prefer, the FDA recommends obtaining and using a new NIOSH-approved respirator before using a non-NIOSH-approved respirator or decontaminating or bioburden-reducing a preferred disposable respirator.

FDA Actions

- 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 Recommends Transition from Use of Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities: https://www.fda.gov/medical-devices/letters-health-care-providers/fda-recommends-transition-use-decontaminated-disposable-respirators-letter-health-care-personnel-and

- 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 Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace: https://www.osha.gov/coronavirus/safework

- OSHA enforcement memoranda that include time-limited discretions: https://www.osha.gov/coronavirus/standards#temp_enforcement_guidance

Questions?

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

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