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The FDA Revokes EUAs for Decontamination Systems and Non-NIOSH-Approved Respirators (i.e., KN95 Respirators)

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Since early last year, the United States Food and Drug Administration (FDA) issued several Emergency Use Authorizations (EUAs) for personal protective equipment (PPE) products to address concerns about their availability during the COVID-19 public health emergency. Since that time, there has been an increase in the domestic supply of respirators approved by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH)[1] such that the FDA believes the use of crisis capacity strategies by health care facilities is no longer required. The FDA's view is consistent with updated CDC recommendations and the Occupational Safety and Health Administration's (OSHA) recently issued Emergency Temporary Standard to protect healthcare workers from occupational exposure to COVID-19.

In response to these developments, the FDA has revoked EUAs for (i) decontamination and bioburden reduction systems; and (ii) non-NIOSH-approved disposable respirators, which includes KN95 respirators previously authorized and published in Appendix A and other respirators previously authorized and published in Exhibit 1. The EUAs revoked by the FDA include the following:

- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China
- Decontamination and Bioburden Reduction System EUAs for Personal Protective Equipment[2]

Accordingly, health care personnel are no longer authorized to use in health care settings the devices authorized under those EUAs. Health care personnel may, however, continue to use in health care settings NIOSH-approved respirators—which include N95 respirators—under the EUA for NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings

During Response to the COVID-19 Public Health Emergency or any FDA-cleared respirators.

For current inventories of non-NIOSH-approved respirators, the FDA recommends health care personnel and facilities consider redistributing those respirators to:

- → Non-health care settings for non-medical use (i.e., 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 (i.e., 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

Practically speaking, non-FDA-cleared, non-NIOSH-approved respirators, such as KN95 respirators, should no longer be used for medical purposes. Further, due to the plentiful supply of NIOSH-approved N95 respirators, health care personnel should stop reusing decontaminated NIOSH-approved N95 respirators and transition back to single-use for single-patient interactions, as appropriate.

If you have any questions, you can reach out to Hamilton Barber at hbarber@nexsenpruet.com.

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[1] "From January 2020 through May 2021, NIOSH has approved over 875 respirator models or configurations with some of these manufactured by approximately 20 new, domestic NIOSH approval holders." *Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities*, U.S. Food & Drug Admin. (June 30, 2021), https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators.

[2] The FDA has also 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