



June 30, 2021

To: Manufacturers of Imported, Non-NIOSH Approved Filtering Facepiece Respirators;
Health Care Personnel;
Hospital Purchasing Departments and Distributors;
Importers and Commercial Wholesalers; and
Any Other Stakeholders

This letter is to revoke the Emergency Use Authorization (EUA) issued March 24, 2020 and revised and reissued on March 28, 2020, June 6, 2020, and March 24, 2021, for emergency use of imported non-National Institute for Occupational Safety and Health (NIOSH) approved respirators¹ in healthcare settings by healthcare personnel (HCP)², when used in accordance with Centers for Disease Control and Prevention (CDC) recommendations to prevent HCP exposure to pathogenic biological airborne particulates during filtering facepiece respirator (FFR) shortages resulting from the COVID-19 outbreak. The revocation is effective July 6, 2021.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act).

FDA has reviewed the totality of scientific evidence available, including data provided by device manufacturers, distributors, Group Purchasing Organizations (GPOs), FDA Imports database, healthcare organizations, and federal/state stockpiles. Based on the change in CDC recommendations, the increase in availability of NIOSH-approved respirators, the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS) requirements, and information provided by healthcare organizations and others,³ FDA has concluded that the

¹ [Umbrella EUA: Imported, Non-NIOSH Approved Disposable Filtering Facepiece Respirators](#).

² Healthcare personnel refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

³ Non-NIOSH approved FFRs were previously recommended by CDC as a crisis capacity strategy when there was a severe shortage of NIOSH-approved FFRs available for HCP. Available information now shows an increase in the current and projected U.S. supply of [NIOSH-approved respirators, including N95s](#). As such, on April 9 and May 27, 2021, CDC updated their recommendations to reflect that healthcare facilities should return to conventional capacity strategies and thus CDC no longer recommends the use of non-NIOSH-approved FFRs. On May 27, 2021, FDA also recommended that healthcare facilities and HCP “transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including imported respirators such as KN95s.” In addition, on June 21, 2021, OSHA issued an [Emergency Temporary Standard \(ETS\)](#) to adequately address the hazard of COVID-19 for HCP. The ETS requires, among other things, healthcare employers to provide NIOSH-approved or FDA-authorized respirators for healthcare workers potentially exposed to COVID-19.

known and potential benefits of these respirators, when used for such use, no longer outweigh the known and potential risks of continued use, and pursuant to section 564(g)(2)(B), the criteria under section 564(c) of the Act for issuance of the EUA are no longer met. In addition, based on the same information, revocation of the EUA is appropriate to protect the public health and safety pursuant to section 564(g)(2)(C) of the Act.

Accordingly, pursuant to section 564(g)(2)(B) and 564(g)(2)(C) of the Act, FDA revokes the EUA.

Effective on July 6, 2021, which is 15 days after the effective date of the OSHA ETS, and the date by which compliance by healthcare facilities is required, the devices listed in Exhibit 1 as covered by the March 24, 2021 EUA are not authorized by FDA for use as respirators in healthcare settings by HCP to prevent HCP exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak, and therefore cannot be legally introduced into interstate commerce with that intended use.

FDA encourages manufacturers and other stakeholders to inform their customers and HCP, as applicable, of this revocation. Manufacturers, HCP, hospital purchasing departments, distributors, importers, commercial wholesalers, states, and any other stakeholders who have questions about options to redistribute or recondition their supply of non-NIOSH-approved respirators that will not be authorized effective July 6, 2021, may reference the publicly posted frequently asked questions ([FAQ](#)) regarding this revocation letter or contact FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

_____/s/_____
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration