



March 24, 2021

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

Dear Stakeholder:

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).¹ Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.²

On March 24, 2020, in response to this public health emergency and concerns about filtering facepiece respirator (FFR) or respirator availability, FDA authorized the emergency use of certain FFRs under section 564 of the Act for use in healthcare settings by healthcare personnel (HCP)³ when used in accordance with the Centers for Disease Control and Prevention (CDC) recommendations to prevent HCP exposure to pathogenic biological airborne particulates

¹ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

² U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 13907 (March 10, 2020).

³ For purposes of this EUA, 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).

during FFR shortages resulting from the COVID-19 outbreak. On March 28, 2020, to further address availability concerns with disposable FFRs, FDA determined it was necessary to reissue the March 24, 2020 letter in order to amend the Scope of Authorization (Section II) to additionally authorize the use of authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system.⁴ FDA reissued the March 24, 2020 letter on March 28, 2020 in its entirety with the revisions.⁵ FDA subsequently determined that further revisions to the Scope of Authorization in accordance with section 564(g)(2)(C) of the Act were necessary and appropriate to address the safety of these products. As such, FDA accordingly reissued the EUA on June 6, 2020.⁶ In each of these reissuances, the intended use of the authorized products remained for use in healthcare settings by HCP when used in accordance with the CDC recommendations to prevent HCP exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

Since June 6, 2020, FDA has continued to periodically review the circumstances and the appropriateness of authorizing the emergency use of FFRs under this EUA as required by section 564(g)(1) of the Act. In determining that further revisions are required, FDA reviewed the totality of scientific evidence available, which includes manufacturing data, imports data accessed from the FDA Imports database, and information compiled from requests for addition of respirator models to Exhibit 1 of the EUA. FDA also engaged with healthcare organizations to obtain HCP insights regarding the use and availability of respirators, including those manufactured outside the U.S. These organizations indicated that non-NIOSH-approved respirators manufactured outside the U.S. are not in high demand and that their members preferred NIOSH-approved respirators. Based on this review, and considering previous revisions and all available information, FDA determined that the eligibility criteria under the previous versions of this EUA are no longer appropriate. As such, and pursuant to section 564(g)(2)(C) of the Act, and as outlined in Section II of this letter, FDA determined it was necessary to reissue the June 6, 2020 letter to remove the eligibility criteria, so that no additional respirators will be added to [Exhibit 1](#) under those criteria in order to protect the public health or safety. Additionally, FDA also determined it was necessary to add Medical Device Reporting per 21 CFR 803 as a Condition of Authorization for Manufacturers and

⁴ For purposes of this emergency use authorization (EUA), an “authorized decontamination system” means any decontamination system that has been issued an EUA. Authorized decontamination systems can be found on FDA’s Emergency Use Authorization webpage, available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

⁵ The March 28, 2020 revision to the March 24, 2020 letter revised the Scope of Authorization to include authorized respirators listed in Exhibit 1, and authorized respirators listed in Exhibit 1 that are decontaminated using an authorized decontamination system.

⁶ The June 6, 2020 letter included five main revisions to the March 28, 2020 letter. First, FDA revised criterion 2 to only authorize disposable FFRs that conform to Personal Protective Equipment (PPE) Directive 89/686/EEC (for those placed into distribution before April 21, 2019) or that conform to PPE Regulation (European Union (EU)) 2016/425 (for those placed into distribution after April 21, 2019), as evidenced by a CE mark. Second, FDA added a third criterion that authorizes disposable FFRs that are manufactured by entities that hold one or more NIOSH approvals for FFRs, that have been verified by FDA, and that are produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country. Third, FDA revised the Scope of Authorization such that decontaminated respirators with exhalation valves are no longer in the scope of products authorized by the EUA. Fourth, FDA added Conditions of Authorization to require samples for testing when requested by FDA and prevent distribution that fail testing. Fifth, FDA added Conditions of Authorization regarding printed materials, advertising, and promotion under section 564(e)(4) of the Act.

Importers to report adverse events to FDA along with a process to collect adverse event information from healthcare facility customers. FDA has concluded that the criteria for issuance of an EUA under section 564(c) of the Act are met with respect to the respirators currently listed in [Exhibit 1](#)⁷ as of the date of this reissuance.

Having concluded that revising the June 6, 2020 letter is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the June 6, 2020, letter in its entirety⁸ with the revisions⁹ incorporated to authorize the emergency use of authorized respirators in [Exhibit 1](#), authorized respirators in [Exhibit 1](#) that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system, and to remove the eligibility criteria so that no additional respirators will be added to [Exhibit 1](#).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of the authorized respirators, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter for use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: [Strategies for Optimizing the Supply of N95 Respirators](#).¹⁰ This EUA does not permit use of authorized respirators by the general public.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized respirators listed in [Exhibit 1](#) meet the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized respirators listed in [Exhibit 1](#) may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages, and that the

⁷ Exhibit 1: Authorized Imported, Non-NIOSH Disposable Filtering Facepiece Respirators (FFR) is available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#exhibit1>.

⁸ This letter reissued on March 24, 2021, is being reissued in its entirety, and was originally issued on March 24, 2020, and reissued on March 28, 2020, and June 6, 2020.

⁹ The March 24, 2021, revisions to the June 6, 2020, letter removes the eligibility criteria so that no additional respirator models will be added to Exhibit 1 and revises the conditions of authorization to include Medical Device Reporting per 21 CFR 803 for both Manufacturers and Importers to report to FDA adverse events related to the authorized respirators and a process to collect adverse event information from healthcare facility customers.

¹⁰ Available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>.

known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during COVID-19, outweigh the known and potential risks of such products; and

3. There is no adequate, approved, and available alternative to the emergency use of the certain respirators for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.^{11,12}

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the respirators listed in [Exhibit 1](#) and authorized respirators in [Exhibit 1](#) that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system for use in healthcare settings by HCP in accordance with [CDC's recommendations](#)¹³ to prevent HCP exposure to pathogenic biological airborne particulates during respirator shortages resulting from the COVID-19 outbreak.

The Authorized Respirators

Respirators authorized by this EUA are imported, non-NIOSH-approved (i.e., not approved by National Institute for Occupational Safety and Health (NIOSH)) FFRs that are currently listed in [Exhibit 1](#) and meet at least a 95% filtration efficiency level. FDA has determined based on the available information that these respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 emergency. All authorized respirators listed in [Exhibit 1](#) were listed in Exhibit 1 at the time of this reissuance.

As with any authorization, authorized products are subject to surveillance and monitoring. FDA may revoke the authorization for a respirator authorized under this letter in accordance with section 564(g)(2) of the Act. FDA will provide the manufacturer advance notice of such revocation as required by section 564(g) and (h) of the Act. A respirator that has been removed from Exhibit 1 will be included in a list maintained on FDA's EUA webpage.

The above described authorized respirators listed in [Exhibit 1](#) and authorized respirators listed in [Exhibit 1](#) that have been decontaminated using an authorized decontamination system are authorized to be distributed to and used in healthcare settings by HCP when used in accordance with CDC's recommendations under this EUA, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

¹¹ No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

¹² Though supply is increasing as manufacturers increase capacity and NIOSH approves more FFR models, there are not sufficient quantities of FFRs that are both NIOSH-approved and meet FDA regulatory requirements to meet the needs of the U.S. healthcare system. These disposable respirators are an integral part of routine patient care. Providing HCP who are on the forefront of the COVID-19 response with FFRs consistent with the CDC's guidance and recommendations is necessary in order to reduce the risk of illness in HCPs and increase their willingness to provide care to affected patients or those suspected of having COVID-19.

¹³ CDC's recommendations for Strategies for Optimizing the Supply of N95 Respirators, available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized respirators when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized respirators may be effective at preventing HCP exposure to certain particulates to prevent disease spread, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized respirators, when used in healthcare settings to prevent HCP exposure to certain particulates to prevent disease spread (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized respirators under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under section 564(b)(1) of the Act, the authorized respirators are authorized to be used in healthcare settings by HCP under the terms and conditions of this EUA.

EUA revisions may be undertaken as needed with concurrence of, Office of Strategic Partnerships and Technology Innovation (OST)/Center for Devices and Radiological Health (CDRH), Division of Infection Control and Plastic and Reconstructive Surgery/Office of Health Technology 4 (OHT4)/CDRH, and Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).

III. Waiver of Certain FDA Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized respirators that are used in accordance with this EUA.

IV. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions on this authorization:

Manufacturers of Authorized Respirators

- A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized respirators that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. FDA will make this information available to the public on its EUA website at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe>. Manufacturers must notify FDA of any changes to the website.
- B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end-user facility (e.g., each hospital, etc.) that receives the authorized respirators. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.
- C. Manufacturers will have a process in place and adequate Medical Device Reporting procedures, in accordance with 21 CFR 803, to report to FDA adverse events of which they become aware related to authorized respirators. Manufacturers must also establish a process to collect adverse event information from healthcare facility customers.
- D. Manufacturers of authorized respirators will notify the importer (if applicable) of the terms and conditions of this EUA and ensure that the end-user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.
- E. Manufacturers of authorized respirators will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- F. Manufacturers of authorized respirators that are decontaminated by an authorized decontamination system are not responsible for any additional conditions that may apply to the manufacturer and/or operator of the decontamination system, unless they are the same manufacturer.
- G. If requested by FDA, manufacturers of authorized respirators must submit new lots for testing by NIOSH or by another entity designated by FDA. FDA will generally sample from lots that have been imported and are either at a port of entry or at a storage facility/warehouse in the United States.
- H. Manufacturers of authorized respirators must not distribute any lot or shipment that fails testing. FDA defines failure as any result from FDA, NIOSH, or another entity designated by FDA, that indicates one or more of 30 sampled respirators have a filtration efficiency of less than 95%.

Importers of Authorized Respirators

- I. Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end-user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.
- J. Importers of authorized respirators will have a process in place and adequate Medical Device Reporting procedures, in accordance with 21 CFR 803, to report to FDA adverse events of which they become aware related to authorized respirators. Importers must also establish a process to collect adverse event information from healthcare facility customers.
- K. Importers of authorized respirators must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.
- L. If requested by FDA, importers of authorized respirators must submit new lots for testing by NIOSH or by another entity designated by FDA. FDA will generally sample from lots that have been imported and are either at a port of entry or at a storage facility/warehouse in the United States.
- M. Importers of authorized respirators must not distribute any lot or shipment that fails testing. FDA defines failure as any result from FDA, NIOSH, or another entity designated by FDA, that indicates one or more of 30 sampled respirators have a filtration efficiency of less than 95%.
- N. Importers of authorized respirators whose authorized respirators are decontaminated by an authorized decontamination system are not responsible for any conditions that may apply to the manufacturer and/or operator of the decontamination system, unless the importer is the same as the manufacturer.

Manufacturers and/or Operators of Authorized Decontamination Systems

- O. Each manufacturer and/or operator of an authorized decontamination system that decontaminates authorized respirators must comply with all of the Conditions of Authorization and authorized labeling as set forth in the Letter of Authorization for the authorized decontamination system.

Conditions Related to Printed Materials, Advertising and Promotion

- P. All descriptive printed matter, advertising, and promotional materials relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, the authorized labeling, as well as the terms set forth in this EUA.
- Q. No descriptive printed matter, advertising, or promotional materials relating to the use of the authorized respirators may represent or suggest that the authorized respirators are NIOSH-

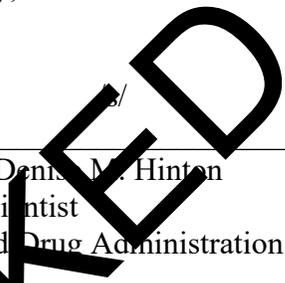
approved or FDA-cleared or approved, or that the authorized respirators are safe or effective for the prevention of COVID-19.

The emergency use of the authorized respirators as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,



RADM Denis M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

REVOKED