



May 7, 2020

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.

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). 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.¹

On April 3, 2020, in response to this evolving public health emergency and continued concerns about filtering facepiece respirator (FFR or respirator) availability, FDA concluded based on the totality of scientific evidence available at that time that certain product classifications for imported disposable FFRs that are manufactured in China and not approved by the Center for Disease Control and Prevention's National Institute of Occupational Safety and Health (NIOSH) and for which data exists that supports the respirators' authenticity, were appropriate to protect the public health or safety under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under the original April 3, 2020 EUA, authorized respirators listed in Appendix A were authorized for use in healthcare settings by healthcare personnel (HCP)² when used in accordance with CDC recommendations to prevent wearer exposure to

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 4, 2020). U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal, Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 13907, (March 10, 2020).

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).

pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

On May 7, 2020, in response to questions and concerns that have been received by FDA since issuance of the April 3, 2020 letter and having concluded that revising the April 3, 2020 EUA 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 April 3, 2020 letter with certain revisions.³ Specifically, FDA has revised the April 3, 2020 EUA for clarity and to address concerns about sub-standard products, which includes revising the third criterion for eligibility and adding a process for removal from Appendix A.

This EUA does not affect the previous March 28, 2020, EUA for Non-NIOSH-Approved Imported FFRs (originally issued on March 24, 2020), which authorizes, in part, the emergency use of certain imported disposable FFRs that are not NIOSH-approved and excluded those manufactured in China, to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak, pursuant to Section 564 of the Act. FDA is re-issuing this EUA with certain revisions to authorize disposable respirators manufactured in China that meet certain criteria, including criteria concerning additional validation and review by FDA to confirm the respirator's authenticity.

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 pandemic.

For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: [Strategies for Optimizing the Supply of N95 Respirators](#). 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 as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP to prevent wearer

³ There are four main revisions to the April 3, 2020 letter. First, what was originally the third criterion in the April 3, 2020 letter of authorization has been revised and as a result, all respirators that were authorized under the test report eligibility criterion have been removed from the list of authorized respirators in Appendix A and are therefore no longer authorized unless the respirator is authorized under one of the criteria as outlined in the Scope of Authorization (Section II) of this re-issued letter. Second, the Chinese National Medical Products Administration (NMPA) registration certification by an appropriate provincial or municipal regulatory authority that is authenticated and verified by FDA has been added to the second criterion. Third, the EUA is being revised so that only manufacturers can request to be added to Appendix A. Importers will no longer be allowed to submit a request to add an FFR to Appendix A. Fourth, FDA has amended the Scope of Authorization (Section II) to describe a process FDA will use in removing respirators from Appendix A if FDA has reason to believe that the respirator is no longer eligible for authorization.

exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak meets 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 and other information available to FDA, it is reasonable to believe that the authorized respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages, and that the 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 authorized respirators for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.^{4,5}

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 use of the authorized respirators listed in Appendix A, and includes authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system,⁶ for use in healthcare settings by HCP as recommended by CDC to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

Respirators Eligible for Authorization under this EUA

A disposable non-NIOSH-approved respirator manufactured in China that meets one of the following criteria is eligible for authorization under this EUA:

1. It is manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA; or
2. It has a regulatory authorization under a jurisdiction, including the Chinese National

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

⁵ 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.

⁶ For purposes of this 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>.

Medical Products Administration (NMPA) registration certification by an appropriate provincial or municipal regulatory authority, that can be authenticated and verified by FDA; or

3. It was previously listed in Appendix A under the April 3, 2020 letter of authorization as an authorized respirator because it demonstrated acceptable performance to applicable standards as documented by test reports, has had particulate filtration efficiency assessed by NIOSH using a modified version of NIOSH’s Standard Test Procedure (STP) TEB-APR-STP-0059 within 45 calendar days of the date of issuance of this EUA, and has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent.⁷

A respirator that meets any of the eligibility criteria outlined above is authorized and will be added to Appendix A as an authorized respirator once FDA confirms the eligibility criteria are met. FDA may ask a manufacturer that is requesting addition to Appendix A for any additional information FDA needs to confirm the respirator is eligible under one of the criteria outlined above. Once FDA receives the requisite information, FDA will notify the manufacturer of the inclusion of its authorized respirator(s) in Appendix A under this EUA by replying to the manufacturer’s email. This process is further outlined below.

Authorized Respirators

In order to be added to Appendix A as an authorized respirator under this EUA, manufacturers must demonstrate that the disposable non-NIOSH-approved respirator(s) manufactured in China meets at least one of the criteria above by sending a request to FDA with the subject line “FFRS Made in China” to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with the information below:

A. For respirators meeting criterion #1 above, please provide:

- The manufacturer contact information (name, address, contact person, phone number, and email), model number and NIOSH approval numbers for your NIOSH approved respirator(s)
- The manufacturer name, address, model number, and a copy of the product labeling⁸ for the respirator you want authorized
- An estimate of the number of respirators you are planning to import during the public health emergency
- A list of authorized importer(s) including contact information (name, address, contact person, phone number, and email)

B. For respirators meeting criterion #2 above, please provide:

⁷ FDA will sample respirators from already imported lots of respirators under this criterion. If a manufacturer has not shipped respirators to the United States at the time this EUA is reissued, FDA will work with a manufacturer who is eligible for this criterion in order to sample respirators once they arrive at a US port of entry.

⁸ Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

- The manufacturer contact information (name, address, contact person, phone number, and email), model number, and a copy of the product labeling⁹ for the respirator you want authorized
- Marketing authorization document/certificate from another regulatory authority or conformity assessment body acting on their behalf (including the authorization number and the name of the conformity assessment body)
- Certificate of conformity to the applicable standards
- An estimate of the number of respirators you are planning to import during the public health emergency
- A list of authorized importer(s) including contact information (name, address, contact person, phone number, and email)

C. For respirators meeting criterion #3 above, within 45 calendar days of the reissuance of the EUA, please provide:

- The manufacturer contact information (name, address, contact person, phone number, and email), model number, and a copy of the product labeling¹⁰ for the respirator you want authorized
- Weblink which displays the results of your NIOSH test report
- A list of authorized importer(s) including contact information (name, address, contact person, phone number, and email)
- An estimate of the number of respirators you are planning to import during the public health emergency

The above-described authorized respirators listed in Appendix A, when labeled as described in this letter, are authorized to be distributed to and used in healthcare settings by HCPs 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.

Additionally, authorized respirators listed in Appendix A that have been decontaminated using an authorized decontamination system remain authorized under this EUA to be used in healthcare settings by HCP when used in accordance with the terms and conditions of the authorized decontamination system without the need for any action by the respirators' manufacturer, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

As with any EUA, authorized products are subject to surveillance and monitoring. Here, for example, respirators on Appendix A are subject to random sampling and NIOSH testing upon importation into the United States. Respirators not meeting the eligibility criteria are subject to removal from Appendix A as described below.

FDA may remove a product that has been added to Appendix A if FDA has reason to believe that the product no longer meets the Criteria for Issuance (Section I), or the Scope of Authorization (Section II). FDA will provide the manufacturer advance notice of such removal, and will be

⁹ Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

available to work with the manufacturer regarding the planned removal of the product(s) from Appendix A. A respirator that has been removed from Appendix A will be included in a list maintained on FDA's EUA webpage.

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 and other information 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 and other information available to FDA, including the information supporting the conclusions described in Section I above, and conclude 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the authorized respirators are authorized to be used in healthcare settings by HCP under the terms and conditions of this EUA. EUA amendments may be undertaken as needed with concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

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 models 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. The subject line of this email should read “URL for FFR Made in China.” 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 this page.
- 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 respirator model. This letter must include the authorized respirator’s manufacturer, model, intended use, manufacturer’s webpage (if applicable), etc.
- C. 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.
- D. Manufacturers of authorized respirators will have a process in place for reporting adverse events of which they become aware and send such reports to FDA.
- E. All descriptive printed material relating to the use of the authorized respirators in the United States shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.
- F. No descriptive printed matter relating to the use of the authorized respirators in the United States may represent or suggest that the product is safe or effective for the prevention of COVID-19.
- G. 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.
- H. 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.

Manufacturers and/or Operators of Authorized Decontamination Systems

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

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 the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures