

June 6, 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 public health emergency and 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 to support 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 Emergency Use Authorization (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

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

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

On May 7, 2020, in response to questions and concerns that were received by FDA after issuance of the April 3, 2020 letter, FDA reissued the letter to revise the Scope of Authorization to address concerns about sub-standard products 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)).³

On June 6, 2020, in response to continued questions and concerns and having concluded that revising this letter is again 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 May 7, 2020 letter to revise the Scope of Authorization (Section II) and Conditions of Authorization (Section IV).⁴

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 HCP 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.

healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

³ The May 7, 2020 letter made four main revisions to the April 3, 2020 letter. First, FDA revised what was originally the third criterion in the April 3, 2020 letter of authorization, removing from the list of authorized respirators in Appendix A all the respirators that were originally authorized under the original second criterion. Second, the Chinese National Medical Products Administration (NMPA) registration certification by an appropriate provincial or municipal regulatory authority, authenticated and verified by FDA, was added to the second criterion. Third, the EUA was revised so that only manufacturers could request to be added to Appendix A, excluding importers from requesting FFRs to be added to Appendix A. Fourth, FDA described the process for removing respirators from Appendix A if FDA has reason to believe that the respirator is no longer eligible for authorization.

⁴ This letter makes five main revisions to the May 7, 2020 letter. First, FDA revised the second eligibility criterion to limit the jurisdictions to only certain CE mark (European Economic Area certification mark) FFRs in addition to respirators that have an NMPA certification (which was included in the May 7, 2020 revision). Second, FDA has revised the third criterion such that a respirator model that is sampled by FDA and tested by NIOSH, and that has results according to NIOSH that indicates one or more of the 30 sampled respirators has a filtration efficiency of less than 95% is no longer authorized. Third, FDA revised the Scope of Authorization to remove decontaminated respirators from the Scope of Authorization. As such, authorized respirators that are decontaminated are no longer authorized under this EUA. They may, however, be authorized under an individual decontamination system EUA. Please refer to the individual decontamination system EUAs for this information, which are available at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>. Fourth, FDA added Conditions of Authorization to require samples for testing when requested by FDA and prevent distribution of shipments that fail testing. Fifth, FDA added Conditions of Authorization regarding printed materials, advertising, and promotion under section 564(e)(4) of the Act.

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 HCP 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 wearer exposure to pathogenic biological airborne particulates during FFR shortages, and that the known and potential benefits of the authorized respirators, when used for such use, 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.^{5,6}

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 that are authorized because they meet the below criteria for eligibility, for use in healthcare settings by HCP pursuant to [CDC's recommendations](#) to prevent HCP 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 is authorized under this EUA if it meets any of the criteria below.

1. The respirator is manufactured by an entity that holds one or more NIOSH approvals, that have been verified by FDA, for FFRs, and that are produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country.
2. The respirator:

⁵ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

⁶ 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.

- a. Has a registration certification, reflecting regulatory authorization, under the jurisdiction of the Chinese National Medical Products Administration (NMPA) and that is given by an appropriate provincial or municipal authority,⁷ and that has been authenticated and verified by FDA, or
 - b. Conforms to Personal Protective Equipment (PPE) Directive 89/686/EEC (for those placed into distribution before April 21, 2019) or that conforms to PPE Regulation (European Union (EU)) 2016/425 (for those placed into distribution after April 21, 2019), as evidenced by a CE mark,⁸ and the CE mark has been authenticated and verified by FDA.
3. The respirator 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 the May 7, 2020 letter, and has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent.⁹ A respirator authorized under this EUA because it meets the criterion in the previous sentence is no longer authorized if it has been sampled by FDA, tested by NIOSH via a modified version of STP TEB-APR-STP-0059, and has results according to NIOSH that indicates one or more of the 30 sampled respirators has a filtration efficiency of less than 95%.¹⁰

A respirator that meets 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

⁷ Registration certification must be for a medical protective mask. Short term emergency registration certifications, (e.g., 3-5 month authorizations) are not eligible for authorization under this EUA.

⁸ There was a transition period for the EU regulation. Between April 21, 2018 and April 21, 2019 conformance to either PPE Directive 89/686 or PPE Regulation (EU) 2016/425 is acceptable. Short term type certificates are not eligible for authorization under this EUA.

⁹ FDA will generally sample respirators from already imported lots of respirators under this criterion.

¹⁰ Under this criterion, FDA will sample and send 30 respirators from a shipment of the same model to NIOSH for testing using a modified version of STP TEB-APR-STP-0059. 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. More information about this modified version of testing is available on NIOSH’s website at https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NonNIOSH_Filtration_TestPlan.pdf. If an FDA-sampled respirator model fails to meet the expected filtration efficiency performance per NIOSH testing, the respirator model will no longer be authorized under this EUA. FDA defines “failure” as any result from NIOSH that indicates one or more of the 30 sampled respirators has a filtration efficiency of less than 95%. FDA will post a list of these models on its [EUA website](#).

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 labeling¹¹ for the authorized respirator you want added to Appendix A
- 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:

- The manufacturer contact information (name, address, contact person, phone number, and email), model number, and a copy of the product labeling¹² for the authorized respirator you want added to Appendix A
- Either a:
 - i. marketing authorization document/certificate from NMPA, or
 - ii. CE mark as evidenced by the following from a competent notified body for PPE:
 1. EU type examination certificate and evidence of production monitoring and/or control or of quality assurance of the production system
or
 2. European Commission (EC) type examination certificate and evidence of production monitoring and/or control or of quality assurance of the production system
- 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 on May 7th (i.e., June 21st), please provide:

¹¹ 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.

¹² 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 labeling¹³ for the respirator you want added to Appendix A
- 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.

As with any EUA, authorized products are subject to surveillance and monitoring.

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 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 consistent 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 consistent 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 and Importers 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. If requested by FDA, manufacturers and importers of authorized respirators will submit new lots for testing by NIOSH or by another entity designated by FDA.
- I. The manufacturers and importers of authorized respirators must not distribute any lot or shipment that fails testing.

Conditions Related to Printed Materials, Advertising and Promotion

- J. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product, shall be consistent with the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- K. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product, may represent or suggest that the authorized product is NIOSH-approved.

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