

October 15, 2020

To: Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators manufactured in China;
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 authorized the emergency use of certain FFRs under section 564 of the Act (21 U.S.C. §360bbb-3). On May 7, 2020, in response to concerns about substandard FFRs under the April 3, 2020 letter, FDA revised and reissued the EUA pursuant to section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3) to limit the Scope of Authorization based on the information available at that time.² FDA subsequently determined that further revisions to the Scope of Authorization in accordance with section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3) were necessary and appropriate to address continued questions and concerns about substandard products. As such, FDA accordingly revised and reissued the EUA on June 6, 2020.³ In each of these reissuances, the intended use

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 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 third 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.

³ The June 6, 2020 letter included five main revisions to the May 7, 2020 letter. First, FDA revised the second

of the authorized products remained for use in healthcare settings by healthcare personnel (HCP)⁴ when used in accordance with 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. Based on this review and considering previous revisions and all available information, FDA has concluded that the criteria for issuance under section 564(c) of the Act are met with respect to the respirator models listed in [Appendix A](#) as of the date of this reissuance. In doing so, FDA has determined that the eligibility criteria under the previous versions of this EUA are no longer appropriate. As such, and as outlined in Section II of this letter, those criteria are being removed and thus no additional respirator models will be added to Appendix A under those criteria.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met with respect to the respirator models listed in Appendix A of this letter, I am authorizing the emergency use of the respirators listed in Appendix A, 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.

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 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 from the authorization decontaminated respirators. 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.

⁴ 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).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the respirator models listed in Appendix A of this reissued letter of authorization 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 and other information available to FDA, it is reasonable to believe that the respirator models listed in Appendix A 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 these respirator models for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread during the COVID-19 emergency.^{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 respirator models in Appendix A of this reissued letter of authorization 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.

Authorized Respirators

Respirator models authorized by this EUA are imported, non-NIOSH-approved FFR models manufactured in China that are listed in Appendix A of this letter and meet at least a 95% filtration efficiency level. FDA has determined based on the available information that these respirator models may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 emergency. All authorized respirator models listed in Appendix A were listed in Appendix A 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). FDA will provide the manufacturer advance notice of such revocation as required

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

⁶ 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.

by section 564(g) and (h) of the Act. A respirator model that has been removed from Appendix A will be included in a list of respirator models whose authorization has been revoked that is 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 respirator models listed in [Appendix A](#) of this letter 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 respirator models listed in Appendix A of this reissued letter of authorization 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 respirator models, 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 respirator models listed in Appendix A of this reissued letter of authorization 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 respirator models are authorized to be used in healthcare settings by HCP under the terms and conditions of this EUA.

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 must 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 their page.
- B. Manufacturers of authorized respirators must include in the product’s packaging, 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, and the manufacturer’s website address (URL) that meets Condition A.
- C. Manufacturers of authorized respirators must comply with the labeling requirements under 21 CFR Part 801 Subpart A (general labeling provisions) and 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.
- D. Manufacturers of authorized respirators must 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 an authorized respirator model also receives the information required under Condition B.
- E. Manufacturers of authorized respirators must have a process in place for reporting adverse events of which they become aware and send such reports to FDA.
- F. Manufacturers 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.
- G. If requested by FDA, manufacturers and 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.
- H. The manufacturers and 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 designed by FDA that indicates one or more of 30 sampled respirators has

a filtration efficiency of less than 95%.

Conditions Related to Printed Materials, Advertising and Promotion

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