

March 28, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

On March 2, 2020, based on a request by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) issued a letter authorizing emergency use of, (1) all disposable filtering facepiece respirators (FFRs or respirators) approved by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR Part 84, as non-powered air-purifying particulate FFRs,¹ and (2) FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, for use in healthcare settings by healthcare personnel (HCP)² to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On March 27, 2020, in response to questions and concerns that have been received by CDC and FDA since issuance of the March 2, 2020 letter, and requests to expand the scope to cover all particulate-filtering air purifying respirators (APRs), of which FFRs are a subset, and having concluded that revising the March 2, 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 reissued the March 2, 2020 letter in its entirety with the amendments³ incorporated.

¹ To address the shortage caused by COVID-19, FDA issued the March 2, 2020 EUA, which permitted "authorized respirators" for distribution to healthcare personnel for use in healthcare settings, including respirators that were not devices prior to that use (e.g., they had been for industrial use). For more information, please see FDA's March 11, 2020 letter clarifying this aspect of the March 2, 2020 Letter of Authorization to CDC, available on FDA's website at <https://www.fda.gov/media/136023/download>.

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 The amendments to the March 2, 2020 letter revise: (1) the scope of the EUA; (2) the process by which manufacturers are added to the list of authorized respirators; (3) the process by which eligible respirators held

On March 28, 2020, to further address the shortage of disposable FFRs, FDA determined it was necessary to reissue the March 27, 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 FDA-authorized decontamination system.⁴ Having concluded that revising the 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 March 27, 2020 letter in its entirety⁵ with the amendment⁶ incorporated to authorize the emergency use of:

- (1) Non-powered air-purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH in accordance with 42 CFR Part 84 and listed on the [NIOSH Certified Equipment list \(CEL\) for non-powered air purifying respirators with particulate protection](#);
- (2) Other powered air purifying respirators (PAPRs) approved by NIOSH, in accordance with 42 CFR Part 84, and that are listed on the [NIOSH CEL for PAPRs with particulate protection](#);
- (3) FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles⁷ (referred to within this letter as "expired FFRs"); and,
- (4) Any authorized respirator under (1) or (3) above that has been decontaminated pursuant to the terms and conditions of an authorized decontamination system,

for use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), 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 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

beyond their shelf life are added to the list of authorized respirators, and; (4) add conditions of authorization for importers of authorized respirators.

⁴ For purposes of this EUA, an "authorized decontamination system" means any decontamination system for which FDA has 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 This letter issued on March 28, 2020, is being issued in its entirety, and was originally issued on March 2, 2020, and reissued on March 27, 2020.

⁶ The March 28, 2020, amendment to the March 27, 2020 letter revises the scope of authorized respirators to include any authorized respirators under (1) or (3) that are decontaminated using an authorized decontamination system.

⁷ For purposes of this authorization, strategic stockpiles refer to stockpiles of authorized respirators held by public health agencies that have legal responsibility and authority for responding to a public health emergencies, based on political or geographical boundaries (e.g., city, county, tribal, territorial, State, or Federal), or functional range or sphere of authority (e.g., law enforcement, public health, military health) to prescribe, administer, deliver, distribute, hold, or dispense a medical product during an emergency situation.

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.⁸

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 these 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 respirator shortages resulting from the COVID-19 outbreak. Respirators may be added to this EUA as provided for under Section II. 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 exposure to pathogenic biological airborne particulates during respirator 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 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 respirator shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during respirator shortages, 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 respirators described for preventing HCP exposure to such particulates during respirator shortages to prevent disease spread.^{9,10}

⁸ 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. March 2, 2020.

⁹ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

¹⁰ 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 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.

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:

- (1) Non-powered air-purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH in accordance with 42 CFR Part 84 and listed on the [NIOSH Certified Equipment list \(CEL\) for non-powered air purifying respirators with particulate protection](#);
- (2) Other powered air purifying respirators (PAPRs) approved by NIOSH, in accordance with 42 CFR Part 84, and that are listed on the [NIOSH CEL for PAPRs with particulate protection](#);
- (3) FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles; and,
- (4) Any authorized respirator under (1) or (3) above that has been decontaminated pursuant to the terms and conditions of an authorized decontamination system,

for use in healthcare settings by HCPs as recommended by CDC to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the COVID-19 outbreak.

The Authorized Respirators

As described in this section (Scope of Authorization (section II)) and pursuant to the Conditions of Authorization (section IV) of this letter, I am authorizing use of the following respirators:

- (1) Non-powered air-purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators approved by NIOSH in accordance with 42 CFR Part 84 and listed on the [NIOSH CEL for non-powered air purifying respirators with particulate protection](#);¹¹
- (2) Other powered air purifying respirators (PAPRs) approved by NIOSH, in accordance with 42 CFR Part 84, listed on the [NIOSH CEL for PAPRs with particulate protection](#);
- (3) Expired FFRs (i.e., FFRs that were NIOSH-approved but have since passed the

¹¹ In the March 2, 2020, request for an EUA, CDC provided FDA with a list of NIOSH-approved respirators (listed as Appendix A with the original March 2, 2020 EUA). All respirators from Appendix A referenced in the March 2, 2020 Letter of Authorization that meet the criteria for issuance under section 564 of the Act and are also listed in the [NIOSH CEL for non-powered air purifying respirators with particulate protection](#) are automatically authorized for use under this reissued EUA. FDA notes, that respirators that are legally marketed under 21 CFR 878.4040 (surgical apparel) or 21 CFR 880.6260 (filtering facepiece respirator for use by the general public in public health medical emergencies) do not require an emergency use authorization (EUA). They are, however, authorized respirators when decontaminated pursuant to the terms and conditions of an authorized decontamination system.

Moreover, because all NIOSH-approved FFRs that have been stockpiled in accordance with manufacturers' storage conditions are automatically authorized under this reissued EUA, FDA is no longer requiring strategic stockpilers to send FDA information about their stockpiled product so long as their product meets the terms and conditions of this EUA.

- manufacturers’ recommended shelf-life, are not damaged, and have been held in accordance with manufacturers’ storage conditions in strategic stockpiles). Expired FFRs that are damaged or in disrepair are not authorized for use under this EUA to protect HCPs in healthcare settings; and,
- (4) Any authorized respirator under (1) or (3) above that has been decontaminated pursuant to the terms and conditions of an authorized decontamination system.

Manufacturers of NIOSH-approved FFRs that are listed on the [NIOSH CEL for non-powered air purifying respirators with particulate protection](#) will be notified of the inclusion of their models as authorized respirators under this EUA through FDA’s posting and public announcement of this reissued EUA at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe>. At any time, manufacturers may withdraw some or all of their authorized model numbers from this EUA by notifying FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with a copy to CDC at RecordsRoom@cdc.gov. FDA will list on its website those models that have been withdrawn or are otherwise no longer authorized under this EUA. This represents a change from the original March 2, 2020 letter, which required manufacturers or strategic stockpilers to request authorization of additional respirators. Manufacturers and strategic stockpilers do **not** need to submit request to FDA to request authorization of additional NIOSH-approved respirators.

This same process applies to authorized expired FFRs (i.e., FFRs that were NIOSH-approved but have since passed the manufacturers’ recommended shelf-life and have been held in accordance with manufacturers’ storage conditions in strategic stockpiles as described in this letter). This also represents a change from the March 2, 2020 letter which required strategic stockpilers to send FDA certain information. Strategic stockpilers do **not** need to notify FDA so long as their product(s) meets the terms and Conditions of Authorization (Section IV) of this EUA.

Under the March 28, 2020 reissued letter, authorized respirators remain authorized if they have been decontaminated using an authorized decontamination system. Manufacturers who develop decontamination systems may request an EUA for such a decontamination system through FDA’s EUA process.¹²

The above described authorized respirators listed in [NIOSH CEL for non-powered air purifying respirators with particulate protection](#) and the [NIOSH CEL for PAPRs with particulate protection](#) when labeled consistently with the labeling approved by NIOSH, expired FFRs as described in this letter, and authorized respirators that have been decontaminated using an authorized decontamination system, 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.

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 within the

¹² Please see FDA guidance, “Emergency Use Authorization of Medical Products and Related Authorities,” for EUA process information, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities>.

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 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 HCPs under the terms and conditions of this EUA. EUA amendments may be requested by CDC in consultation with, and 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. This waiver does not waive any applicable NIOSH requirements.

IV. Conditions of Authorization

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

Centers for Disease Control and Prevention (CDC)

- A. [CDC will make available on its website](#) and through other appropriate means, to respirator manufacturers and HCPs, CDC's recommendations to HCPs regarding use

of NIOSH-approved APRs including expired FFRs.¹³

- B. CDC will inform relevant stakeholders, such as manufacturers and HCPs, of this EUA, including the terms and conditions herein and any updates.
- C. CDC will post on its website the following statement: “For information about the FDA-authorized emergency use of NIOSH-approved APRs, please see: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>.”
- D. CDC will provide to FDA any updates related to the NIOSH-approved APRs manufacturers, contact information for each manufacturer, and model numbers.
- E. CDC 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.

Manufacturers of Authorized Respirators

- F. 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.
- G. All descriptive printed matter relating to the use of the authorized respirators shall be consistent with labeling approved by NIOSH and/or applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.
- H. No descriptive printed matter relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.
- I. 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.
- J. 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.

Strategic Stockpilers

- K. To the extent feasible given the emergency circumstances, strategic stockpilers will maintain reports of adverse events they receive from HCPs and facilities to which the

¹³ CDC’s webpage: [Strategies for Optimizing the Supply of N95 Respirators](#). As of March 2, 2020, CDC also recommended on its [Frequently Asked Questions about Personal Protective Equipment Page](#) that if at all possible, respirators with exhalation valves should not be used in situations where a sterile field must be maintained (e.g., during an invasive procedure in an operating or procedure room) because the exhalation valve allows unfiltered exhaled air to escape into the sterile field.

authorized respirators are distributed.

- L. Any such adverse events that the strategic stockpiler becomes aware will be reported to FDA via [Medwatch Forms for FDA Safety Reporting](#).
- M. Strategic stockpilers will alert and instruct recipients of the expired authorized FFRs to check the integrity of the respirator prior to use; expired FFRs that are damaged or in disrepair are not authorized for use under this EUA to protect HCPs in healthcare settings.
- N. Strategic stockpilers 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.

Importers

- O. All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.
- P. No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.
- Q. 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.
- R. Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.

Manufacturers and/or Operators of Authorized Decontamination Systems

- S. 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.

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