



March 2, 2020

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

Dear Dr. Redfield:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of, (1) all disposable filtering facepiece respirators (FFRs) 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)³ 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

¹ For ease of reference, this letter refers to "(1) all disposable filtering facepiece respirators (FFRs) 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, and (2) FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life," as "respirators eligible for authorization under this EUA." "Authorized respirators" refers to those respirators eligible for authorization under this EUA that have been included in this EUA after FDA makes a determination that all criteria for issuance have been met. Authorized respirators will be added to this letter of authorization as Appendix B.

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, 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 On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). The new names are used throughout this document.

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.⁴

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am providing a list of respirators eligible for authorization under this EUA (Appendix A) and authorizing the emergency use of these respirators, contingent upon submission of a request from CDC, the manufacturer, or strategic stockpiler to FDA, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter. Authorized respirators will be added to this letter of authorization as Appendix B for use in healthcare settings by HCP to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak. 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 Appendix B for use in healthcare settings by HCP to prevent wearer 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 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, outweigh the known and potential risks of such product; 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 FFR shortages to prevent disease spread.^{5,6}

⁴ 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.

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

⁶ As the COVID-19 outbreak continues to expand globally, the supply chain for respiratory protective devices (RPDs), such as disposable FFRs (e.g., N95s), that are both NIOSH-approved and meet FDA regulatory requirements has been substantially stressed, with shortages already being observed in United States healthcare institutions, with demand exceeding available supply. This shortage situation has led CDC to make recommendations to healthcare facilities for use of N95 standard respirators that do not meet FDA regulatory requirements, but these too appear to be in a shortage situation with demand exceeding supply. Under the

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 authorized respirators listed in Appendix B for use in healthcare settings by HCP to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

The Authorized Respirators

A list of respirators eligible for authorization under this EUA is provided in Appendix A. FDA will add a respirator from Appendix A to the list of authorized respirators in Appendix B upon submission of request from CDC, the manufacturer, or strategic stockpiler to FDA, as described in the Scope of Authorization Section of this letter (Section II) and pursuant to the Conditions of Authorization in this EUA.

For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: [Strategies for Optimizing the Supply of N95 Respirators](#).

CDC or the Office of the Assistant Secretary for Preparedness and Response (ASPR)/HHS may request the authorization of additional respirators that were NIOSH-approved that have been held beyond their manufacturer-intended shelf life or expiration date (e.g., N95s in federal Strategic National Stockpile),⁷ which may be authorized by FDA in consultation with, and with concurrence of, the Office of Strategic Partnerships and Technology Innovation (OST)/Center for Devices and Radiological Health (CDRH), Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).

Manufacturers may request the authorization of additional respirators, upon submission of an attestation from the manufacturer to FDA with a copy to CDC (CVSDBadmin@cdc.gov) specifying the NIOSH-approval number, model number, and place of manufacture. Such requests will be made by the manufacturer in consultation with, and require concurrence of,

circumstances of this emergency, nationwide shortages are expected and the CDC and FDA are taking steps to address the observed and anticipated shortages prior to a potential wide-spread outbreak in the United States. These disposable respirators are an integral part of routine patient care. Providing HCP who are on the forefront of the COVID-19 response with RPDs 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. In conclusion, there are not sufficient quantities of RPDs available that comply with FDA's regulatory authority to meet the needs of the United States healthcare system.

⁷ On the date of issuance of this EUA, FFRs were not authorized for use beyond their manufacturer-intended shelf life or expiration date under this EUA. However, FDA is aware of operational needs for the use of such product during the COVID-19 outbreak given reported and estimated supply challenges, especially if the outbreak were to become more severe. CDC may request authorization under this EUA of FFRs that have been held beyond their manufacturer-intended shelf life or expiration date (e.g., in federal strategic stockpiles) at a later time. If FDA authorizes use of such product based on a review of the scientific data, communication about such authorization will be posted on FDA's EUA website at the time of amendment of this EUA (e.g., through a memorandum). <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

OST/CDRH, Division of Infection Control and Plastic Reconstructive Surgery/CDRH and OCET/OCS/OC.

Strategic stockpilers may request authorization of additional respirators that were NIOSH-approved that have been held beyond their manufacturer-intended shelf life or expiration date (e.g. N95s in state or local strategic stockpiles) for authorized use under this EUA without manufacturer's attestation. The strategic stockpile will submit a request to FDA from the manager of the stockpile, with a copy of the request to CDC (CVSDBadmin@cdc.gov) and specifying the manufacturer, model number, and the product expiry date. Such requests will be made by the strategic stockpiler in consultation with, and require concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

The above described authorized respirators listed in Appendix B, when labeled consistently with the labeling approved by NIOSH, are authorized to be distributed to and used by HCP 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 listed in Appendix B, when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

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 listed in Appendix B 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 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 described in Appendix B are authorized to be used by HCPs under 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 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 listed in Appendix B 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.⁸
- 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 FFRs, please see: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>.”
- D. CDC will provide FDA any updates to their complete listing of all NIOSH-approved FFR manufacturers, contact information for each manufacturer, and model numbers.
- E. CDC or ASPR/HHS may request the authorization of respirators that were NIOSH-approved that have been held beyond their manufacturer-intended shelf life or expiration date (e.g., N95s in federal Strategic National Stockpile) for authorized use under this EUA without manufacturer’s attestation. Such requests will be made by CDC or ASPR/HHS in consultation with, and require concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.
- F. CDC is authorized to issue additional recommendations and instructions related to the emergency use of the authorized respirators listed in Appendix B as described in this letter of authorization, to the extent that additional recommendations and instructions are

⁸ 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.

necessary to meet healthcare needs during the COVID-19 outbreak when they are reasonably consistent with the authorized emergency use of the product.

- G. 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, Pursuant to Attestation From the Manufacturer

- H. Manufacturers of authorized respirators listed in Appendix B will have a process in place for reporting adverse events of which they become aware to FDA [per mandatory reporting requirements under 21 CFR Part 803](#).
- I. Manufacturers may request the addition of any authorized respirators, upon submission of an attestation from the manufacturer to FDA with a copy to CDC (CVSDBAdmin@cdc.gov) specifying the NIOSH-approval number, model number, and place of manufacture. Such requests will be made by the manufacturer in consultation with, and require concurrence of, OST/CDRH, Division of Infection Control and Plastic Reconstructive Surgery/CDRH and OCET/OCS/OC.
- J. Adverse events of which the manufacturer becomes aware will be reported to FDA.
- K. All descriptive printed matter relating to the use of the authorized respirators listed in Appendix B 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 and the applicable requirements set forth in the Act and FDA regulations.
- L. No descriptive printed matter relating to the use of the authorized respirators listed in Appendix B may represent or suggest that this product is safe or effective for the prevention of COVID-19.
- M. Manufacturers of authorized respirators listed in Appendix B 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.

Strategic Stockpilers

- N. To the extent feasible given the emergency circumstances, strategic stockpilers will maintain reports of adverse events they receive from healthcare personnel and facilities to which the authorized respirators were distributed.
- O. Adverse events of which the strategic stockpiler becomes aware will be reported to FDA via [Medwatch Forms for FDA Safety Reporting](#).

- P. Strategic stockpilers may request the addition of authorized respirators that were NIOSH-approved that have been held beyond their manufacturer-intended shelf life or expiration date (e.g. N95s in state or local strategic stockpiles) for authorized use under this EUA without manufacturer's attestation. The strategic stockpile will submit a request to FDA from the manager of the stockpile, with a copy of the request to CDC (CVSDBAdmin@cdc.gov) and specifying the manufacturer, model number, and the product expiry date. Such requests will be made by the strategic stockpiler in consultation with, and require concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.
- Q. 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.

The emergency use of the authorized respirators listed in Appendix B 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