July 12, 2021

Rochelle P. Walensky, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Walensky:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of 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 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 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,[2] 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)[3] to prevent wearer exposure to pathogenic biological airborne

[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 7, 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] 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.

[3] 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

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 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, FDA reissued the March 2, 2020, letter in its entirety with the amendments[4] incorporated.

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.[5] Having concluded that revising the EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act, FDA reissued the March 27, 2020 letter in its entirety with the amendment[6] 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 stockpiles[7] (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,

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

[4] The amendments to the March 2, 2020 letter revised: (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 beyond their shelf life are added to the list of authorized respirators, and; (4) add conditions of authorization for importers of authorized respirators.

[5] In the March 28, 2020 letter, an "authorized decontamination system" meant any decontamination system for which FDA had issued an EUA.

[6] The March 28, 2020, amendment to the March 27, 2020 letter revised 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 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.

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.

FDA has continued to evaluate the circumstances and appropriateness of this EUA and based on the totality of scientific evidence available, has determined that it is necessary to reissue this EUA to no longer authorize decontaminated or expired FFRs. This determination is based in part on new information about increased availability of NIOSH-approved FFRs for HCP use and CDC's updated recommendations on returning to conventional capacity strategies. Of note, CDC no longer recommends that HCPs use decontaminated or non-NIOSH-approved FFRs, as well as respirators that are beyond the manufacturer-designated shelf life.[8] Based on this information, on April 9, 2021, May 27, 2021, and June 30, 2021, the FDA recommended that healthcare facilities transition away from crisis capacity conservation strategies (e.g., decontaminating disposable respirators, using non-NIOSH-approved respirators). Moreover, on June 30, 2021, the FDA revoked the remaining decontamination system and bioburden reduction EUAs.

In conjunction with these actions, the FDA determined it is necessary to reissue the March 28, 2020, letter in order to amend the Scope of Authorization (Section II) to remove FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life and to remove the emergency use authorization of decontaminated respirators from the scope of authorization. Therefore, this EUA now only authorizes the use of NIOSH-approved non-powered air-purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators, and other powered air purifying respirators (PAPRs), which can still be cleaned, disinfected, and reused per the manufacturer's instructions as set forth in the revised Scope of Authorization (Section II). Having concluded that revising the EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act, FDA is reissuing the March 28, 2020, letter in its entirety[9] with the above described revisions.

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

[8] See CDC Strategies for Optimizing the Supply of N95 Respirators, available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html.

[9] This letter issued on July 12, 2021, is being issued in its entirety, and was originally issued on March 2, 2020, and reissued on March 27, 2020 and March 28, 2020.

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.[10] Specifically, 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.[11]

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; and
(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;

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

[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[11] 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.

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 elastomerics 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;[12] and
(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;

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. Manufacturers and strategic stockpilers do **not** need to submit request to FDA to request authorization of additional NIOSH-approved respirators.

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 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 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 available to FDA, that it is reasonable to believe that the authorized respirators may be

[12] 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).

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.

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 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) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, the authorized respirators are authorized to be used in healthcare settings by HCPs under the terms and conditions of this EUA.

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.[13]

B. CDC will inform relevant stakeholders, such as manufacturers and HCPs, of this EUA, including the terms and conditions herein and any updates.

[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.

C. CDC will provide to FDA any updates related to the NIOSH-approved APRs manufacturers, contact information for each manufacturer, and model numbers.

D. 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.

E. CDC may request changes to this EUA. Any request for changes to this EUA should be submitted to the Office of Strategic Partnerships and Technology Innovation (OST)/Center for Devices and Radiological Health (CDRH) and Office of Health Technology 4 (OHT4)/Division of Infection Control and Plastic and Reconstructive Surgery/CDRH. Such changes require appropriate authorization from FDA prior to implementation.[14]

Manufacturers of Authorized Respirators

F. Manufacturers of authorized respirators must have a process in place and adequate Medical Device Reporting procedures, in accordance with 21 CFR 803, to report to FDA adverse events of which they become aware related to authorized respirators. Manufacturers must also establish a process to collect adverse event information from healthcare facility customers.

G. All descriptive printed matter, advertising, and promotional materials relating to the use of the authorized respirator under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the applicable requirements set forth in section 502(a) and (q)(1) and (r) of the Act, as applicable, and FDA implementing regulations.

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 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.

Strategic Stockpilers

J. 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

[14] The following types of revisions may be authorized without reissuing this letter: (1) non-substantive editorial corrections to this letter; (2) new types of authorized labeling, including new fact sheets; (3) new carton/container labels; (4) changes to manufacturing processes, including tests or other authorized components of manufacturing; (5) new conditions of authorization to require data collection or study; (6) new instruments, associated software, components or materials in the authorized product or modifications in the way that the device is used. All changes to the authorization require review and concurrence from OST/CDRH and OHT4/OPEQ/CDRH. For changes of the type listed in (5) or (6), review and concurrence also is required from the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

authorized respirators are distributed.

K. Any such adverse events that the strategic stockpiler becomes aware will be reported to FDA via Medwatch Forms for FDA Safety Reporting.

L. 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

M. All descriptive printed matter, advertising, and promotional materials relating to the use of the authorized respirator under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the applicable requirements set forth in section 502(a) and (q)(1) and (r) of the Act, as applicable, and FDA implementing regulations.

N. 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.

O. Importers of authorized respirators must 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.

P. Importers of authorized respirators must ensure that any records associated with this EUA are maintained until the end of this public health emergency.

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)(2) of the Act.

Sincerely,

Denise M. Hinton -S

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Date: 2021.07.12 10:43:17 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration