January 15, 2021

Ms. Nancy Havill
Manager, Infection Prevention Ambulatory Services
Yale New Haven Health System
20 York Street
New Haven, CT 06504

Dear Ms. Havill:

This letter is in response to your[1] request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of your product[2] for use in decontaminating compatible N95 respirators[3] for multiple-user reuse[4] by healthcare personnel (HCP)[5] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of filtering facepiece respirators (FFRs) resulting from the Coronavirus Disease 2019 (COVID-19) pandemic.

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 COVID-19.[6] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020,

REVOKED

[1] For ease of reference, this letter will use the term "you" and related terms to refer to the Yale New Haven Health System.
[2] For ease of reference, this letter will use the term "your product" to refer to the Yale New Haven Health FFR Decontamination System.
[3] For purposes of this EUA, "compatible N95 respirators" are limited to 3M's respirator models 1860 and 1870 only. Please see FDA's website for further information on N95 respirators, available at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks.
[4] Multiple-user reuse means that healthcare personnel may receive a different respirator following decontamination than the one they had previously used.
[5] For purposes of this EUA, HCP 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 HCP 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).
[6] 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).

that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[7]

Your product has not been previously cleared or approved by FDA for any indication. In addition, there are no FDA approved or cleared devices for decontaminating compatible N95 respirators, which are needed for use by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. In evaluating this EUA, FDA reviewed the totality of scientific evidence available, which includes: scientific literature and other information related to decontamination and the use and reuse of FFRs; information related to compatible N95 respirator fit testing; and performance data for decontamination of compatible N95 respirators, such as material compatibility, residual analysis of hydrogen peroxide post-decontamination, sporicidal testing, filtration efficiency, breathability, and worst-case scenario challenges.

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 Yale New Haven Health FFR Decontamination System, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

REVOKED

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Yale New Haven Health FFR Decontamination System, as described in the Scope of Authorization (Section II) of this letter, 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 Yale New Haven Health FFR Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Yale New Haven Health FFR Decontamination System for decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and

[7] U.S. Department of Health and Human Services, *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 17335 (March 27, 2020).

other pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic.[8,9]

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 the Yale New Haven Health FFR Decontamination System, for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of three (3) decontamination cycles per respirator, for multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

The Yale New Haven Health System is authorized, pursuant to the Conditions of Authorization (Section IV) of this letter, to collect and distribute decontaminated, compatible respirators to healthcare facilities within the Yale New Haven Health System, as well as to the following community partners: New Haven Fire Department, Branford Fire Department, West Shore Fire Department, and The Connecticut Hospice (hereafter referred to as "community partners").

Authorized Yale New Haven Health FFR Decontamination System

The Yale New Haven Health FFR Decontamination System is housed within a dedicated decontamination facility including 1 negative pressure room, 2 sealed decontamination rooms, and 1 clean room. The Yale New Haven Health FFR Decontamination System utilizes a Bioquell Clarus C Hydrogen Peroxide Vapor Generator in a 49 cubic meter room to decontaminate a maximum capacity of 2,700 compatible N95 respirators per decontamination cycle. The decontamination process involves conditioning the chamber to a temperature range between 22-24ºC and a humidity level of 29-64%, injecting vaporized hydrogen peroxide (VHP) at a rate of 10 grams per minute into a controlled, airtight chamber and allowing that concentrated VHP (14 g/m^3) to dwell for a period of 30 minutes to ensure penetration into the filtration material of the compatible N95 respirators. The chamber is then aerated to reduce the VHP for 300 minutes or until the VHP reaches a concentration level of 1.0 parts per million (ppm) or lower.

At least four (4) biological indicators and one (1) chemical indicator must be used in each run to confirm that decontamination cycles have been effectively conducted. For the first two weeks, the loads of decontaminated, compatible N95 respirators are released based on the results of the biological indicators to demonstrate process control (i.e., no growth on the biological indicator after one-week incubation). After successful demonstration of the two-week process control using biological indicators, the decontaminated, compatible N95 respirators may be released based on the results of either the biological indicators or per parametric release

REVOKED

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

[9] There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of N95 respirators, HCP may need to treat patients without personal protective equipment (PPE) or use a bandana or other less effective masks unless single-use N95 respirators can be decontaminated for reuse. Providing a method for decontaminating compatible N95 respirators reduces stress on the supply chain and helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with FFRs is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

criteria using the result of the chemical indicator. However, biological indicators must continue to be used in each decontamination cycle and the results of the biological indicators must be recorded and monitored weekly to continue to monitor process control. Exposure conditions (time, temperature, and pressure) and critical process parameters (room volume, injection rate, dwell time, and aeration) must always be monitored.

This decontamination system enables the reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and must not be reused or decontaminated.

The above described product is authorized to be accompanied with the following product-specific information (that will be made available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) pertaining to emergency use, and is required to be made available to staff responsible for decontamination procedures at the Yale New Haven Health System, and HCP, healthcare facilities, and community partners, respectively:

- Instructions for Decontamination Personnel at Yale New Haven Health System: Emergency Decontamination of Compatible N95 Respirators Using the Yale New Haven Health FFR Decontamination System; and

- Instructions for Healthcare Personnel, Healthcare Facilities, and Community Partners: Emergency Decontamination of Compatible N95 Respirators Using the Yale New Haven Health FFR Decontamination System.

In addition, following decontamination, compatible N95 respirators decontaminated by the Yale New Haven Health FFR Decontamination System must be accompanied by the following labeling, developed by Yale New Haven Health System, upon return of the respirators to HCP:

- Fact Sheet for Healthcare Personnel: Yale New Haven Health Decontamination System for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, Healthcare Facilities, and Community Partners, and Instructions for Decontamination Personnel are collectively referred to as "authorized labeling." The above described product, when accompanied with the authorized labeling is authorized to be distributed to and administered under this EUA, despite the fact that it does 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 Yale New Haven Health FFR Decontamination System, when used and labeled consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such 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 Yale New Haven Health FFR

REVOKED

Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic, when used consistently with the Scope of Authorization (Section II) of this letter, 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 of this letter, and concludes that the Yale New Haven Health FFR Decontamination System (as described in the Scope of Authorization (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the Yale New Haven Health FFR Decontamination System 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 and conditions 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 Yale New Haven Health FFR Decontamination System is authorized for emergency use, as described in the Scope of Authorization (Section II).

III. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practices otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under section 520(f)(1) of the Act. FDA grants that waiver, including the quality system requirements under 21 CFR Part 820.

IV. Conditions of Authorization

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

Yale New Haven Health System ("Yale")

A. Yale must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions), as well as those described in Section II of this letter, the Scope of Authorization.

B. Yale must provide to all Yale New Haven Health System healthcare facilities and community partners the authorized labeling before the decontamination process begins.

REVOKED

C. Yale must notify all Yale New Haven Health System healthcare facilities and community partners about the conditions of this authorization applicable to healthcare facilities and community partners before the decontamination process begins.

D. Yale may request changes to this EUA for the Yale New Haven Health FFR Decontamination System[10], including changes to the authorized labeling. Any request for changes to this EUA must be submitted to the Division of Infection Control and Plastic and Reconstructive Surgery (DHT4B)/Office of Health Technology 4: Office of Surgical and Infection Control Devices (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Such changes require appropriate authorization from FDA prior to implementation.

E. Yale may add compatible N95 respirator models upon request and subject to review and concurrence of DHT4B/OHT4/OPEQ/CDRH prior to implementation. To support such a request, Yale must provide to FDA validation data to support new respirator models.

F. Yale may increase the maximum capacity of 2,700 compatible N95 respirators per decontamination cycle upon request and subject to review and concurrence of DHT4B/OHT4/OPEQ/CDRH prior to implementation. To support such a request, Yale must provide FDA validation data to support the increased decontamination capacity.

G. Use of the Yale New Haven Health FFR Decontamination System on other types of personal protective equipment is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.

H. Yale will have a process in place and adequate Medical Device Reporting procedures, in accordance with 21 CFR Part 803, to report to FDA adverse events of which Yale becomes aware related to the Yale New Haven Health FFR Decontamination System and compatible N95 respirators that have undergone decontamination using the Yale New Haven Health FFR Decontamination System ("the decontaminated, compatible N95 respirators"). This includes, but is not limited to, reports concerning infection or potential infection of their personnel involved in the use of the Yale New Haven Health FFR Decontamination System based on routine fever monitoring and testing for SARS-CoV-2 (subject to availability of diagnostic tests) and users of the decontaminated, compatible N95 respirators. Records of routine fever monitoring and testing for SARS-CoV-2 shall be maintained by Yale. Other examples of reportable events that may be relevant to the authorized product include, but are not limited to: allergic reactions or eye, mouth, or nose irritation, evidence that a decontaminated, compatible N95 respirator is unable to perform its essential function, events related to residuals or user contact with residuals (if applicable), infection in decontaminated,

REVOKED

[10] 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. For changes of the type listed in (5) or (6), review and concurrence is required from the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

compatible N95 respirator wearers, or concerns with the process control or malfunctions of the authorized product used to decontaminate the compatible N95 respirators.

I. Yale will have a process in place to collect information on the performance of the Yale New Haven Health FFR Decontamination System, including information regarding degradation of decontaminated, compatible N95 respirators, and evaluate this information to determine if adverse event reporting in accordance with 21 CFR Part 803 is warranted.

J. Yale 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.

K. Yale is authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

L. Yale shall maintain documentation for use of the Yale New Haven Health FFR Decontamination System consistent with current healthcare facility protocols. This includes, but is not limited to, documentation of exposure conditions, including time, temperature, and pressure, as well as confirmation that the specified critical process parameters (room volume, injection rate, dwell time, and aeration) were met to achieve decontamination of compatible N95 respirators for each cycle. Yale shall maintain this documentation associated with this EUA until otherwise notified by FDA. Such documentation will be made available to FDA upon request.

M. The Yale New Haven Health FFR Decontamination System shall only be operated by the Yale New Haven Health System in the two decontamination rooms at 600 Derby Ave., West Haven, CT, and shall not be distributed to third parties.

N. Yale shall not distribute decontaminated, compatible N95 respirators to any other healthcare facility outside of the Yale New Haven Health System or community partners as described in the Scope of Authorization.

O. Yale is authorized to decontaminate up to 2,700 compatible N95 respirators per chamber load in the Yale New Haven Health FFR Decontamination System.

P. Prior to release of decontaminated, compatible N95 respirators, Yale must confirm that decontamination cycles have been effectively conducted using biological indicators and chemical indicators as follows:

1. Demonstrate process control for the first two-week period by using biological indicators to support release of decontaminated, compatible N95 respirators.
2. If no positive growth is observed for the biological indicators used through the two-week period, Yale may use parametric release criteria using chemical indicators to support release of decontaminated, compatible N95 respirators.

REVOKED

While the respirator load release criteria may change after the initial two-week period (which relies on data from the biological indicators), Yale must always use four (4) Bioquell biological indicators and one (1) Bioquell chemical indicator per decontamination load to confirm that decontamination cycles have been effectively conducted and to continue to monitor process control. Critical process parameters (room volume, injection rate, dwell time, and aeration) must always be monitored even when using Bioquell biological indicators and Bioquell chemical indicators.

Q. In the event of positive growth in a biological indicator or other data demonstrating incomplete decontamination, Yale must initiate a root cause analysis followed by a correction and removal of the affected respirators. Yale will report these activities to FDA in accordance with 21 CFR Part 803. After such correction and removal, the Yale must reinstate the respirator load release criteria per Condition P.

R. Yale must collect and submit to FDA real-world use data for FDA review to confirm the continued fit and performance of compatible N95 respirators authorized under this EUA after undergoing three (3) cycles of decontamination. The authorized maximum number of three (3) decontamination cycles per compatible N95 respirator (Scope of Authorization (Section II)) will be maintained or revised based on the real-world use data.

You must complete your study within 60 days of the date of this letter or before 1,500 compatible N95 respirators have been decontaminated using your system, whichever is later. You may seek an extension to complete your study where agreed upon by DHT4B/OHT4/OPEQ/CDRH. Your results must be submitted to DHT4B/OHT4/OPEQ/CDRH for review within 15 days of the study completion. Upon completion of FDA's review, you must publish the study results on your website.

At minimum, the study design must include the following testing with acceptance criteria and sampling:

1. Fit Testing (**Required**)
   a. Acceptance Criteria: ≥ 70% of the subjects pass
   b. Sampling: Minimum of 10 representative[11] compatible N95 respirators (minimum of 5 male and 5 female subjects) following 3 decontamination cycles.
   c. Test Design: OSHA guidelines OSHA 1910.134 Appendix A Fit Testing Protocol[12]
2. Filtration Efficiency (**Required**)
   a. Acceptance Criteria: ≥ 95%

REVOKED

[11] Samples must be collected for testing after the 3rd decontamination cycle (which is after the 4th use, to confirm through real-world use data that respirators can withstand 3 cycles of decontamination and reuse). Test samples must include a representative variation of respirators that you are receiving for decontamination. Justification must be provided for the sample chosen, including materials, design characteristics, sizes, etc. Records regarding sample type, model, materials, number of decontamination cycles, etc., must be kept for each sample tested.
[12] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA.

   b. Sampling: Minimum of 10 representative[10] compatible N95 respirators following 3 decontamination cycles.
   c. Test Design: CDC guidelines Assessment of Filter Penetration Performance and Fit for Decontaminated N95 Respirators, Section "Particulate Filter Efficiency Testing" on Page 5[13]

3. Indelible Markings (**Required**)
   a. Acceptance Criteria: Markings must be clearly legible.
   b. Sampling: Minimum of 10 representative[10] compatible N95 respirators from Fit Testing following 3 decontamination cycles.
   c. Test Design: Respirators must be visually inspected prior to Fit Testing. An agreement will be met between 2 people evaluating legibility with a form to complete with "yes" or "no" on legibility.

S. Following completion of Condition R, Yale may request and be allowed to increase the maximum number of decontamination cycles per compatible N95 respirator under Condition D. To support such a request, Yale must provide to FDA information regarding filtration efficiency and respirator fit testing based on real-world evidence, including, but not limited to, evidence collected in the study design and methods adopted in accordance with Condition R.

Yale New Haven Health System Healthcare Facilities and Community Partners ("Healthcare Facilities and Community Partners")

T. Healthcare facilities and community partners shall make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Fact Sheet for Healthcare Personnel and Instructions for Healthcare Personnel, Healthcare Facilities, and Community Partners that are required to be provided.

U. Healthcare facilities and community partners will have a process in place to report adverse events of which they become aware related to the Yale New Haven Health FFR Decontamination System and the decontaminated, compatible N95 respirators in accordance with 21 CFR Part 803. This includes, but is not limited to, monitoring HCP using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections. Other examples of reportable events that may be relevant to the authorized product include, but are not limited to: allergic reactions or eye, mouth, or nose irritation, evidence that a decontaminated, compatible N95 respirator is unable to perform its essential function, events related to residuals or user contact with residuals (if applicable), infection in decontaminated, compatible N95 respirator wearers, or concerns with the process control or malfunctions of the authorized product used to decontaminate the compatible N95 respirators.

V. Healthcare facilities and community partners must inspect the decontaminated, compatible N95 respirators. Any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator shall promptly be reported to Yale, and the healthcare facility or community partner must discard the respirator.

[13] https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved_Decon_TestPlan10.pdf.

REVOKED

W. Healthcare facilities and community partners must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of three (3) decontamination cycles per compatible N95 respirator. Any decontaminated, compatible N95 respirator that has exceeded three (3) decontamination cycles shall be discarded.

X. Healthcare facilities and community partners must ensure that HCP receive the same model of decontaminated, compatible N95 respirator for which they have been fit tested. If such respirator model is unavailable, then healthcare facilities and community partners must provide HCP with fit testing[14] prior to using an alternative model of decontaminated, compatible N95 respirator.

Conditions Related to Printed Materials, Advertising, and Promotion

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

Z. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that such products are safe or effective for the decontamination of compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.

AA. All descriptive printed matter, advertising, and promotional materials relating to the use of your product clearly and conspicuously shall state that:

- the Yale New Haven Health FFR Decontamination System has neither been cleared or approved by FDA, but has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;

- the emergency use of the Yale New Haven Health FFR Decontamination System is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

REVOKED

[14] Under OSHA regulations, fit test means "the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual" (29 CFR 1910.134(b)). In addition, "an employee using a tight-fitting facepiece respirator [must be] fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter" (29 CFR 1910.134(f)(2)). Fit test differs from a user performing a self-seal check in that the latter refers to an action conducted by the respirator user to determine if the respirator is properly seated to the face. In practice, fit testing serves as an additional safeguard to performing a self-seal check when the end user receives a respirator model for which they have not been previously fit tested.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

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