January 21, 2021

Mr. Jeff Rose
Battelle Memorial Institute
505 King Ave.
Columbus, OH 43201

Dear Mr. Rose:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 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.[2]

On March 28, 2020, based on your[3] request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ (hereafter referred to as "your product" or "the Battelle Decontamination System") at the Battelle Memorial Institute (hereafter "Battelle") for use in decontaminating compatible N95 respirators[4] for multiple-user[5] reuse by healthcare personnel (HCP)[6] to prevent exposure to pathogenic biological airborne particulates when there are

[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).
[2] 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).
[3] For ease of reference, this letter will use the term "you" and related terms to refer to Battelle Memorial Institute ("Battelle").
[4] In the March 28 and 29, 2020 letters, "compatible N95 respirators" were defined as any N95 or N95-equivalent respirators that do not contain cellulose-based materials. The March 28 and 29, 2020 letters also defined "N95-equivalent respirators" as respirators identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
[5] Multiple-user reuse means that healthcare personnel may receive a different respirator following decontamination than the one they had previously used. In the March 28 and 29, 2020 letters, this was not explicitly stated as "multiple-user" reuse. FDA has revised this to be clearer in the letter and notes that this clarifying edit does not change the Scope of Authorization.
[6] For the 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

insufficient supplies of filtering facepiece respirators (FFRs) resulting from the COVID-19 pandemic.

On March 29, 2020, in response to your request to operate the Battelle Decontamination System at multiple locations, FDA reissued the March 28, 2020 letter in its entirety to clarify the authorized use of the Battelle Decontamination System is operated by the Battelle Memorial Institute.

On June 6, 2020, FDA reissued the March 29, 2020 letter in order to revise the Scope of Authorization to additionally allow Battelle to distribute decontaminated, compatible N95 respirators[7] to a different healthcare facility, in addition to the previously authorized distribution to the healthcare facility from which the compatible N95 respirators were collected and to address public health and safety concerns regarding certain respirators by adding respirators that have exhalation valves to the description of incompatible respirators.

On January 21, 2021, in response to public health and safety concerns regarding the decontamination of certain respirators, FDA is again reissuing the June 6, 2020 letter in order to revise the authorization of the Battelle Decontamination System to include the following aspects:

1. Limitation of the respirator features that are considered to be compatible N95 respirators[8] in which this decontamination system is authorized to decontaminate.
2. Limitation of the maximum number of decontamination cycles to four (4) cycles per compatible N95 respirator with the option to increase the maximum cycles with the submission of, and subject to review and concurrence with, real-world evidence (RWE) for more than 4 cycles.
3. Incorporation of a post-authorization study to collect RWE to verify that compatible N95 respirators are capable of adequate reuse after 4 decontamination cycles.
4. Incorporation of a Condition of Authorization that requires healthcare facilities to ensure that HCP receive the same model of decontaminated compatible N95 respirator for which

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).

[7] In the June 6, 2020 EUA, "compatible N95 respirators" were defined as non-cellulose containing respirators that do not have an exhalation valve that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[8] For purposes of this revised EUA, "compatible N95 respirators" are any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-bill design, and that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at https://www.fda.gov/emergency-preparedness-and-response/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization. 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.

> they have been fit tested. If such model of respirator is unavailable, then healthcare facilities must provide HCP with fit testing prior to using an alternative model of decontaminated compatible N95 respirator.[9]

Your product is no longer authorized to decontaminate compatible N95 respirators with antimicrobial/antiviral agents or a duck-bill design. Additionally, your product is no longer authorized to decontaminate compatible N95 respirators up to 20 cycles and is now authorized to perform such decontamination for a maximum of 4 times per respirator. A Condition of Authorization (Section IV.R) has been added in which you must conduct a post-authorization study to verify that compatible N95 respirators are adequate for reuse following 4 decontamination cycles. The maximum number of cycles can be increased following submission and review of RWE for greater than 4 decontamination cycles (see Section IV.S). These revisions are reflected in the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and authorized labeling. Having concluded that revising the June 6, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act, FDA is reissuing the June 6, 2020 letter in its entirety with the revisions incorporated.

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 characterizing the effect of vaporous hydrogen peroxide (VHP) on compatible N95 respirators contaminated with viruses and the most difficult to inactivate bacterial spores; the effect of VHP on multiple types of viruses and the most difficult to inactivate bacterial spores; filtration efficiency and breathability testing following multiple decontamination cycles; historical biological indicator inactivation data for your product; testing regarding hydrogen peroxide residuals after decontamination; and fit testing for decontaminated, compatible N95 respirators.

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 Battelle Decontamination System, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Battelle 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;

[9] Other minor corrections and clarifications have also been made during the review and edit process for reissuance of the January 21, 2021 letter.

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Battelle Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCPs 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 Battelle Decontamination System for decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic.[10,11]

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 the Battelle Decontamination System operated by Battelle, 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 four (4) decontamination cycles per respirator, for multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Battelle is authorized to provide decontaminated, compatible N95 respirators to either the healthcare facility from which the respirators were collected ("Closed System"), or to a different healthcare facility ("Open System"), based on an agreement with the specific healthcare facility(ies). In a Closed System, the healthcare facility collects compatible N95 respirators for decontamination by Battelle, and Battelle returns the decontaminated, compatible N95 respirators to the same healthcare facility. In an Open System, the healthcare facility collects compatible N95 respirators for decontamination by Battelle, and Battelle returns the decontaminated, compatible N95 respirators to a different healthcare facility in need of decontaminated, compatible N95 respirators.

The Battelle Decontamination System is not authorized for use in decontaminating incompatible N95 respirators. N95 respirators containing cellulose-based materials, respirators that have exhalation valves, antimicrobial agents, and duck-billed design are not compatible with the Battelle Decontamination System. This system is also not authorized to decontaminate respirators authorized by the non-NIOSH-approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.

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

[11] 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.

Authorized Battelle Decontamination System

The Battelle Decontamination System is a self-contained decontamination device that uses vapor phase hydrogen peroxide (VPHP) for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

Upon receipt of the compatible N95 respirators and chain of custody documentation by Battelle, the box of compatible N95 respirators is barcoded with a unique healthcare facility site code and logged into the Battelle Decontamination System tracking database and chain of custody. Battelle is authorized to decontaminate up to 10,000 compatible N95 respirators per chamber load, consistent with the data provided to FDA.

The used, compatible N95 respirator is loaded into the Battelle Decontamination System and undergoes a decontamination cycle that meets the following critical parameters: injecting VPHP into the decontamination chamber until achieving a saturated atmosphere indicated by micro condensation; maintaining the VPHP exposure for a 150-minute dwell time; and allowing the VPHP to off gas to a level of 1 ppm prior to post decontamination processing. A minimum of five calibrated chemical indicators are dispersed throughout the system to indicate a successful decontamination cycle. This decontamination system enables multiple-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled or damaged must be discarded and not reused or decontaminated.

Upon completion of each decontamination cycle, each compatible N95 respirator is removed from the decontamination system. Each compatible N95 respirator is labeled numerically (1, 2, 3, etc.) with a permanent marker to indicate the number of decontamination cycles completed, up to a maximum of 4 cycles. After all decontaminated, compatible N95 respirators are labeled, they are boxed, and the box is barcoded with a unique recipient healthcare facility site code and returned to a healthcare facility with a chain of custody form, which indicates successful decontamination.

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 HCP and healthcare facilities, as relevant for an Open System or Closed System:

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System for Return to the Same Healthcare Facility;

- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System for Return to the Same Healthcare Facility;

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System for Reuse by Other Healthcare Facilities; and

- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System for Reuse by Other Healthcare Facilities.

In addition, following decontamination, compatible N95 respirators decontaminated by the Battelle Decontamination System must be accompanied by the following labeling, developed by Battelle, upon shipment of respirators to the healthcare facility:

- Fact Sheet for Healthcare Personnel: Battelle Decontamination System for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, both of the Instructions for Healthcare Personnel, and both of the Instructions for Healthcare Facilities are collectively referred to as "authorized labeling." The above described product, when accompanied with the described 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 Battelle 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 Battelle 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 Battelle 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 Battelle 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 Battelle 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:

Battelle Memorial Institute ("Battelle")

A. The Battelle Decontamination System shall only be operated by Battelle and shall not be distributed to third parties.

B. Battelle 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.

C. Battelle must provide to all healthcare facilities the authorized labeling, as relevant to the Open or Closed System, before the decontamination process begins.

D. Battelle must notify all healthcare facilities about the conditions of this authorization applicable to healthcare facilities before the decontamination process begins.

E. Battelle may request changes to this EUA for the Battelle Decontamination System[12], 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.

[12] 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.

F. Battelle may request and be allowed to add compatible N95 respirator models under Condition E. To support such a request, Battelle must provide to FDA validation data to support new respirator models.

G. Battelle may request and be allowed to increase the maximum capacity of 10,000 compatible N95 respirators per chamber load under Condition E. To support such a request, Battelle must provide FDA validation data to support the increased decontamination capacity.

H. Use of the Battelle 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.

I. Battelle 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 Battelle becomes aware related to the Battelle Decontamination System and compatible N95 respirators that have undergone decontamination using the Battelle 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 Battelle 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 Battelle. 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.

J. Battelle will have a process in place to collect information on the performance of the Battelle Decontamination System, including, but not limited to, 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. The information collected, and reported, if warranted in accordance with 21 CFR Part 803, shall also include if the healthcare facility is participating in the "Open System" or "Closed System."

K. Battelle will maintain records of the chain of custody of the compatible N95 respirators sent to Battelle from all healthcare facilities for decontamination through use of a barcode system and tracking database. Battelle will provide the chain of custody form upon shipment of decontaminated, compatible N95 respirators to the healthcare facility.

L. Battelle must inspect the compatible N95 respirators upon receipt from the healthcare facilities for visible evidence of soil or damage. If there is any discoloration, any signs of soiling, or other signs of degradation, the compatible N95 respirator must not be decontaminated, and Battelle shall discard the respirator.

M. Battelle will track the number of times a compatible N95 respirator is decontaminated, up to a maximum of 4 decontamination cycles per compatible N95 respirator. Battelle will maintain records of all decontamination cycles.

N. Battelle is authorized to decontaminate up to 10,000 compatible N95 respirators per chamber load, consistent with the data provided to FDA.

O. Battelle shall provide FDA, in advance of establishing satellite facilities where Battelle will perform decontamination using the Battelle Decontamination System, confirmation that all chambers, critical parameters, logistics, processes, containment systems, and labeling are identical and in place at all satellite facilities. After implementation, at the current and all satellite facilities, if Battelle demonstrates any reduction in decontamination ability for a given site, Battelle shall immediately notify FDA.

P. Battelle 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.

Q. Battelle 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.

R. Battelle 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 four (4) cycles of decontamination. The authorized maximum number of four (4) 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 1500 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[13] compatible N95 respirators (minimum of 5 male and 5 female subjects) following 4 decontamination cycles.

[13] Samples must be collected for testing after the 4th decontamination cycle (which is after the 5th use, to confirm through real-world use data that respirators can withstand 4 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

   c. Test Design: OSHA guidelines OSHA 1910.134 Appendix A Fit Testing Protocol[14]

2. Filtration Efficiency (**Required**)
   a. Acceptance Criteria: ≥ 95%
   b. Sampling: Minimum of 10 representative[13] compatible N95 respirators following 4 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[15]
3. Indelible Markings (**Required**)
   a. Acceptance Criteria: Markings must be clearly legible.
   b. Sampling: Minimum of 10 representative[13] compatible N95 respirators from Fit Testing following 4 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, Battelle may request and be allowed to increase the maximum number of decontamination cycles per compatible N95 under Condition E. To support such a request, Battelle must provide to FDA information regarding filtration efficiency and respirator fit testing based on RWE, including, but not limited to, evidence collected in the study design and methods adopted in accordance with Condition R.

Healthcare Facilities

T. Healthcare facilities shall make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Fact Sheet for Healthcare Personnel. Healthcare facilities shall make available to HCP the Instructions for Healthcare Personnel that is required to be provided by Battelle, as relevant to the Open or Closed System.

U. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the Battelle 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, and monitoring HCP handling contaminated, compatible N95 respirators. 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

type, model, materials, number of decontamination cycles, etc., must be kept for each sample tested.

[14] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA.

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

malfunctions of the authorized product used to decontaminate the compatible N95 respirators

V. Healthcare facilities using the decontaminated, compatible N95 respirators shall review the chain of custody form, which indicates successful decontamination of the compatible N95 respirators, and the authorized labeling. Healthcare facilities 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 Battelle, and the healthcare facility must discard the respirator. Any decontaminated, compatible N95 respirator that has exceeded 4 decontamination cycles shall be discarded.

W. Healthcare facilities 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 must provide HCP with fit testing[16] prior to using an alternative model of decontaminated, compatible N95 respirator.

Conditions Related to Printed Materials, Advertising and Promotion

X. 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.

Y. 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.

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

- the Battelle 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 Battelle 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

[16] 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.

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.

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,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures