March 28, 2020

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

Dear Mr. Rose:

This letter is in response to your request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the Battelle Decontamination System at the Battelle Memorial Institute, for use in decontaminating compatible N95 or N95-equivalent[1] respirators ("compatible N95 respirators")[2] for reuse by healthcare personnel (HCP)[3] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic resulting from the Coronavirus Disease 2019 (COVID-19)[4] pandemic.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[5] 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

[1] For purposes of this EUA, "N95-equivalent respirators" refers to 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.

[2] For purposes of this EUA, "compatible N95 respirators" means any N95 or N95-equivalent respirator that does not contain cellulose-based materials. Respirators containing cellulose-based materials are incompatible with the Battelle Decontamination System.

[3] 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.

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

[5] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 4, 2020) (accessible at https://www.fda.gov/media/135010/download).

authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[6]

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 for decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms during the COVID-19 pandemic 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 Battelle Decontamination System may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic by decontaminating, for a maximum of 20 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, and that the known and potential benefits of the Battelle Decontamination System, when used to decontaminate compatible N95 respirators for reuse by HCP to prevent exposure to pathogenic airborne particulates during FFR shortages during the COVID-19 pandemic, outweigh the known and potential risks; 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 reuse by HCP during FFR shortages during the COVID-19 pandemic.[7,8]

## II. Scope of Authorization

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[6] 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*, March 24, 2020.

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

[8] 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.

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 at the Battelle Memorial Institute, 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 20 decontamination cycles per respirator, for reuse by HCP to prevent exposure to pathogenic airborne particulates during the COVID-19 pandemic.

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 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 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 Battelle Decontamination System may be effective at preventing HCP exposure to pathogenic airborne particulates during FFR shortages during the COVID-19 pandemic by decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the Battelle Decontamination System, when used to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The Battelle Memorial Institute must provide the following information pertaining to the emergency use of the authorized product before the decontamination process begins (i.e., before a healthcare facility begins preparing and collecting compatible N95s for decontamination), which are authorized to be made available to HCP and healthcare facilities:

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System ("Instructions for Healthcare Personnel");
- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System ("Instructions for Healthcare Facilities"); and
- Labeling and instructions for use developed by Battelle Memorial Institute ("Battelle") that include the Fact Sheet, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities set forth in this section (Section II).

In addition, compatible N95 respirators decontaminated by the authorized product must be accompanied by the following labeling, developed by the Battelle Memorial Institute, upon return to the healthcare facility:

- Fact Sheet for Healthcare Personnel: Battelle Decontamination System for Compatible N95 Respirators ("Fact Sheet").

The Fact Sheet, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, and Instructions for Use are referred to as "authorized labeling."

The Battelle authorized labeling must be provided to HCP and healthcare facilities as directed in Section II, and shall include the specified information as follows:

> 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. N95 respirators containing cellulose-based materials are **not** compatible with decontamination by the Battelle Decontamination System.
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> Each decontamination cycle in the Battelle Decontamination System consists of 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 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 not reused or decontaminated.
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> Instructions for Healthcare Personnel are sent to all healthcare facilities requesting decontamination of compatible N95 respirators and the facility should make these instructions available to HCP to prepare their own individual, compatible N95 respirator for decontamination. Using a permanent marker, the compatible N95 respirator is labeled by the HCP (following the procedure established by the healthcare facility) with a unique three-digit site code and a two-digit location identifier. The unique three-digit site code corresponds to the return delivery address for each respirator following decontamination.
>
> Instructions for Healthcare Facilities are sent to all healthcare facilities requesting decontamination of compatible N95 respirators. The facility should create a collection station for compatible N95 respirators to be sent to Battelle for decontamination. Collection stations should contain bags ("primary collection bag") to collect compatible N95 respirators prepared according to the Instructions for Healthcare Personnel. The healthcare facility shall close the primary collection bag. The primary collection bag is then placed into a secondary collection bag, and the facility will appropriately close and decontaminate (using alcohol or other suitable decontaminant) the secondary collection bag. The bags are then placed into rigid, closed boxes clearly labeled with biohazard symbols, taped securely shut, and labeled outside with the three-digit site code and two-digit location identifier. According to the healthcare facility's agreement with Battelle, the facility should complete the chain of custody form provided by Battelle for each shipment, and send to the designated Battelle location. Upon return of the decontaminated compatible N95 respirators from Battelle to the healthcare facility, the healthcare facility should inspect each compatible N95 respirator for visible damage or

soiling, as well as confirm the N95 respirator contains a green sticker and numerical indicator of the decontamination cycle. Any problems should be immediately reported to Battelle.

Battelle agrees to the following procedures pertaining to the authorized product:

Battelle shall enter into agreements with healthcare facilities requesting decontamination of compatible N95 respirators, and provide such healthcare facilities with the authorized labeling and chain of custody documentation for completion by the healthcare facility to send to Battelle. Upon receipt of the compatible N95 respirators and chain of custody documentation by Battelle, the box of compatible N95 respirators is barcoded and logged into the Battelle Decontamination System tracking database and chain of custody. The used compatible N95 respirator is loaded into the Battelle Decontamination System and undergoes a decontamination cycle. Upon completion of each decontamination cycle, each compatible N95 respirator is removed from the decontamination system and labeled with a green sticker to indicate successful decontamination. Each compatible N95 respirator is also labeled numerically (1, 2, 3, etc.) with a permanent marker to indicate the number of decontamination cycles completed, up to a maximum of 20 cycles. After all decontaminated compatible N95 respirators are labeled, they are boxed and returned to provider with a chain of custody form and the Fact Sheet.

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 of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the authorized Battelle Decontamination System is authorized to be used at Battelle Memorial Institute for decontaminating compatible N95 respirators that are authorized to be used by HCP in healthcare settings under the terms and conditions of this EUA. Changes to the process, procedures, or labeling for the authorized product may require an EUA amendment subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery Devices/OPEQ/CDRH and OCET/OCS/OC.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

**III. Waiver of Certain FDA Requirements**

I am waiving the following requirements for the Battelle Decontamination System during the duration of this EUA:

- applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the authorized Battelle Contamination System used in accordance with this EUA; and
- labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements (see Subpart B of 21 CFR Part 801), except that the

Battelle Decontamination System must comply with the authorized labeling requirements specified in this EUA (Section II).

**IV. Conditions of Authorization**

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

Battelle Memorial Institute

A) The Battelle Decontamination System shall only be used at the Battelle Memorial Institute ("Battelle") and shall not be distributed to third parties.
B) 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.
C) Battelle will make available to customers the authorized labeling for the Battelle Decontamination System through posting on the Battelle website and will send the appropriate authorized labeling to each healthcare facility when it returns each shipment of the decontaminated respirators, consistent with Section II of this letter.
D) Battelle is authorized to decontaminate up to 10,000 compatible N95 respirators per day, consistent with the data provided to FDA. Battelle shall provide FDA weekly reports, including data according to a testing plan for scale-up reviewed by FDA, regarding the decontamination of compatible N95 respirators, including any reductions in decontamination ability. Battelle shall provide FDA, in advance of additional scale-up to increase the number of compatible N95 respirators decontaminated per day, a plan and supportive data, which Such requests will be made in consultation with, and require concurrence of, the Division of Infection Control and Plastic and Reconstructive Surgery Devices/OPEQ/CDRH .
E) All descriptive printed matter relating to the use of the Battelle Decontamination System shall be consistent with the authorized labeling. No descriptive printed matter relating to the use of the Battelle Decontamination System may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.
F) Battelle will have a process in place for reporting adverse events about the authorized product and the decontaminated respirators of which they become aware and send such reports to FDA, and will establish a process to collect information from healthcare facility customers regarding degradation of decontaminated N95 respirators and reports of infection or potential infection of users of the decontaminated N95 respirators and send such reports weekly to FDA.
G) 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.
H) Battelle will maintain records of the chain of custody of the N95 respirators sent to Battelle for decontamination through use of a barcode system and tracking database.
I) Battelle will track and maintain records of the number of times a N95 respirator is reprocessed up to a maximum of 20 decontamination cycles per N95 respirator. Battelle will maintain records of all decontamination cycles.

J) 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.

K) Battelle will maintain records and provide reports to FDA of the routine monitoring and testing of its personnel consistent with the monitoring and schedule set forth below:

- Battelle personnel are to be enrolled in the Battelle SARS-CoV-2 Fever Monitoring Program.
- Battelle personnel will undergo routine testing for SARS-CoV-2 (subject to availability of diagnostic tests).
- Battelle will keep records and provide weekly reports to FDA during the decontamination system scale-up process (i.e., data on chemical indicators and biological indicators), and weekly reports to FDA for a minimum of two weeks post-implementation of the full scale-up of the decontamination process to monitor the safe use of the Battelle Decontamination System by Battelle personnel.
- After the decontamination scale-up process is established and operational, Battelle will provide bi-weekly reports and promptly notify FDA of adverse events relating to infections and exposures of Battelle personnel to SARS-CoV-2.

Healthcare Facilities

L) Healthcare facilities using respirators that have undergone decontamination using the Battelle Decontamination System ("the decontaminated respirators") should make available to HCP who are or may be using the decontaminated respirators the authorized Fact Sheet for Healthcare Personnel that is required to be provided by Battelle.

M) Healthcare facilities using the decontaminated respirators should monitor HCP who use such respirators for the signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to Battelle, so that Battelle can provide a weekly report to FDA consistent with Section IV.F of this EUA. Reports of adverse health indications should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

N) Healthcare Facilities using the decontaminated respirators must inspect the decontaminated respirators upon receipt from Battelle. Any discoloration or other signs of degradation with a decontaminated respirator should promptly be reported to Battelle, and the healthcare facility should dispose of such respirator.

## V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of the Battelle Decontamination System during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Denise M. Hinton -S3

Digitally signed by Denise M. Hinton -S3
Date: 2020.03.28 23:28:54 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures