U.S. FOOD & DRUG ADMINISTRATION

January 21, 2021

Joseph R. Haywood
Assistant Vice President of Regulatory Affairs
o/b/o F. Claire Hankenson, DVM, MS, Director
Campus Animal Resources and University Veterinarian
Michigan State University Animal Care Program
4000 Collins, Suite 120
Lansing, MI 48910

Dear Mr. Haywood:

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 July 24, 2020, in response to your[3] request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of your product[4] for use in decontaminating compatible N95 respirators[5] for single-user reuse[6] by healthcare personnel (HCP)[7] 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 the Michigan State University Animal Care Program.
[4] For ease of reference, this letter will use the term "your product" or "MSU Decontamination System" to refer to the MSU System for Decontaminating Compatible N95 Respirators.
[5] In the July 24, 2020 letter, "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.
[6] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination.
[7] 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

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

On January 21, 2021, in response to public health and safety concerns regarding the decontamination of certain respirators, FDA is reissuing the July 24, 2020 letter in order to revise the authorization of the MSU 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. Incorporation of a post-authorization study to collect real-world evidence (RWE) to verify that compatible N95 respirators are capable of adequate reuse after 3 decontamination cycles.[9]

Your product is no longer authorized to decontaminate N95 respirators with antimicrobial agents or a duck-billed design. Additionally, a Condition of Authorization (Section IV.P) has been added in which you must conduct a post-authorization study to verify that compatible N95 respirators maintain adequate performance following 3 decontamination cycles. The maximum number of decontamination cycles can be increased following submission and review of RWE to support greater than 3 decontamination cycles (see Section IV.Q). These revisions are reflected in the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and authorized labeling. Having concluded that revising the July 24, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act, FDA is reissuing the July 24, 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 airborn 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 VHP on compatible N95 respirators contaminated with viruses, including filtration efficiency and breathability testing following multiple decontamination cycles; biological indicator inactivation data for your product; and fit testing for decontaminated N95 respirators.

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).

[8] For purposes of this EUA, "compatible N95 respirators" are defined as any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed 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.

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

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 MSU 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 MSU 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 MSU Decontamination System may be effective at decontaminating compatible N95 respirators for single-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 MSU Decontamination System for decontaminating compatible N95 respirators for single-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 MSU Decontamination System for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for up to 3 decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

[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.

The MSU Decontamination System is not authorized for use in decontaminating incompatible N95 respirators. N95 respirators containing cellulose-based materials, and respirators with exhalation valves, antimicrobial agents, or a duck-billed design are incompatible with the MSU 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.

Authorized MSU Decontamination System

The MSU Decontamination System is a decontamination system used in nine rooms within Building J of the MSU University Animal Care Program. These nine rooms have been repurposed specifically for use as a vaporized hydrogen peroxide (VHP) decontamination system. The MSU Decontamination System uses VHP to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2. The MSU Decontamination System uses a Halosil VHP system, including the HaloFogger FLX machine with HaloMist fluid.

MSU staff within Campus Animal Resources are solely responsible for set up of the HaloFogger equipment and chemical and biological indicators within the MSU facility. MSU Staff are also solely responsible for verifying successful VHP exposure with chemical indicators, initiation of the post-cycle exhaust phase, and verifying successful decontamination with biological indicator results. Operator Teams are healthcare and safety personnel who work for the healthcare facility that is using the MSU decontamination system. Operator Teams are trained by MSU staff in the preparation, transportation, and initiation of the decontamination of compatible N95 respirators using the MSU Decontamination System at the MSU facility in accordance with this EUA. Operator Teams previously have been trained in sterile technique, donning/doffing of PPE, and understanding of clean-to-dirty personnel traffic (e.g., sterile supply technicians, medical technicians).

Depending on the room, with larger rooms generally accommodating more shelves, the capacity of compatible N95 respirators that can be placed in this manner ranges as shown in Table 1:

Table 1

Decontamination chamber room number	**Capacity of compatible N95 respirators per cycle**
10	500
11	700
12	700
13	700
14	1000
15	1000
16	700
17	700
18	700

Each decontamination cycle in the MSU Decontamination System consists of injecting VHP into the dedicated decontamination room until achieving a saturated atmosphere indicated by microcondensation, maintaining the VHP exposure for a 240-minute dwell time, and allowing the VHP to off gas to a level below 1 ppm prior to post decontamination processing. At least five 6-log biological indicators are placed throughout the room prior to each cycle to indicate a successful decontamination cycle. The three-phase decontamination cycle of a 20 minute fog, a 240 minute dwell, and a 90 minute exhaust 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.

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 healthcare providers and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Emergency Use of the MSU System for Decontamination and Reuse of Compatible N95 Respirators with Vaporized Hydrogen Peroxide; and

- Instructions for Healthcare Facilities and Operator Teams: Emergency Use of the MSU System for Decontamination and Reuse of Compatible N95 Respirators with Vaporized Hydrogen Peroxide; and

- Instructions for Michigan State University Staff: Emergency Use of the MSU System for Decontamination and Reuse of Compatible N95 Respirators with Vaporized Hydrogen Peroxide

In addition, following decontamination, compatible N95 respirators decontaminated by the MSU Decontamination System must be accompanied by the following labeling, developed by Michigan State University Animal Care Program, upon return of the respirators to a healthcare facility:

- Fact Sheet for Healthcare Personnel: MSU System for Decontamination and Reuse of Compatible N95 Respirators with Vaporized Hydrogen Peroxide

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities and Operator Teams, and Instructions for MSU Staff 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 MSU 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 MSU Decontamination System may be effective at decontaminating compatible N95 respirators for single-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 MSU 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 MSU 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 MSU 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 820.

IV. Conditions of Authorization

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

Michigan State University Animal Care Program ("MSU")

A. MSU 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, Scope of Authorization.

B. MSU must provide to all healthcare facility customers the authorized labeling before the decontamination process begins.

C. MSU must notify all healthcare facility customers about the conditions of this authorization applicable to healthcare facilities before the decontamination process begins.

D. The MSU Decontamination System shall only be set up by MSU in rooms 10, 11, 12, 13, 14, 15, 16, 17, and 18 of Building J of the animal care facility at MSU, and shall not be distributed to third parties. The animal care facility must be vacant of animals during its use as a decontamination facility.

E. MSU may request changes to this EUA for the MSU 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.

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

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

H. Use of the MSU 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. MSU is authorized to decontaminate up to 500, 700, 700, 700, 1000, 1000, 700, 700, and 700 compatible N95 respirators per load in the MSU decontamination chamber rooms 10, 11, 12, 13, 14, 15, 16, 17, and 18 of Building J of the animal care facility at MSU, respectively, based on chamber dimensions and geometry for supporting shelving units, consistent with data provided to FDA. MSU 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. MSU must use biological indicators and chemical indicators to confirm decontamination cycles were effectively conducted.

J. MSU will ensure that MSU staff are adequately equipped and trained on the use of the MSU Decontamination System, as described in Section II of this EUA, and shall maintain records of such training.

[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.

K. MSU staff will ensure Healthcare Facility Operator Teams, as described in Section II, are adequately trained in the use of the MSU Decontamination System, as described in Section II of this EUA, and shall maintain records of such training.

L. MSU will 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 MSU becomes aware related to the MSU Decontamination System and compatible N95 respirators that have undergone decontamination using the MSU 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 MSU 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 MSU. 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.

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

N. MSU 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.

O. MSU 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.

P. MSU 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 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 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 3 decontamination cycles.
    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 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[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 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.

Q. Following completion of Condition P, MSU may request and be allowed to increase the maximum number of decontamination cycles per compatible N95 respirator under Condition E. To support such a request, MSU 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 P.

Healthcare Facilities

R. Healthcare facilities, including healthcare facility personnel and staff designated by the healthcare facility as Operator Teams for use of the MSU Decontamination System, shall follow MSU's Instructions for Use for Healthcare Facilities and Operator Teams to ensure compatible N95 respirators are appropriately prepared for decontamination using the MSU Decontamination System.

[13] 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.
[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.

S. Healthcare facilities shall ensure that healthcare facility personnel and staff designated as Operator Teams for use of the MSU Decontamination System have been previously trained in sterile technique, donning/doffing of PPE, and understanding of clean-to-dirty personnel traffic, and shall maintain records of such training and/or qualifications.

T. Healthcare facilities shall ensure that their designated Operator Teams undergo training by MSU in the use of the MSU Decontamination System, as described in Section II of this EUA, and shall maintain records of such training.

U. 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 and Instructions for Healthcare Personnel that is required to be provided by MSU.

V. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the MSU 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.

W. Healthcare facilities using the decontaminated, compatible N95 respirators 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 MSU, and the healthcare facility must discard the respirator.

X. Healthcare facilities must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of 3 decontamination cycles per compatible N95 respirator. Any decontaminated compatible N95 respirator that has exceeded 3 decontamination cycles shall be discarded. Healthcare facilities must ensure that the decontaminated, compatible N95 respirator is returned to its previous user. Healthcare facilities shall maintain documentation for use of the MSU Decontamination System consistent with current healthcare facility protocols.

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) 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 single-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 MSU 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 single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;

- the emergency use of MSU 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.

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