July 24, 2020

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
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Dear Mr. Haywood:

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 single-user reuse[4] by healthcare personnel (HCP)[5] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of face-filtering 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), 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,

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[1] For ease of reference, this letter will use the term "you" and related terms to refer to the Michigan State University Animal Care Program.

[2] 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.

[3] For purposes of this EUA, "compatible N95 respirators" are 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.

[4] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination.

[5] 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*

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.[7]

Your product has not been previously cleared or approved by FDA for any indication. In addition, there are insufficient supplies of compatible N95 respirators to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic, and there are no FDA approved or cleared devices for decontaminating compatible N95 respirators. 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.

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 decontamination of compatible N95 respirators to

Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

[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).

prevent exposure to SARS-CoV-2 and 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 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.

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. N95 respirators containing cellulose-based materials and respirators with exhalation valves are incompatible with the MSU Decontamination System.

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 number of compatible N95 respirators that can be placed in this manner ranges as shown in Table 1:

[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.

Table 1

Decontamination chamber room number	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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), 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 make changes to the process, procedures, and/or labeling for the authorized product, upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

F. MSU may make changes to the scope of this EUA, upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of Chief Scientist (OCS)/Office of the Commissioner (OC).

G. 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.

H. MSU is authorized to decontaminate compatible N95 respirators for up to a maximum of 3 decontamination cycles, consistent with the data provided to FDA. MSU is authorized to increase the maximum number of decontamination cycles per compatible N95 respirator based on valid scientific evidence provided in advance to FDA, and upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery/OPEQ/CDRH and OCET/OCS/OC.

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.

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 comply with 21 CFR Part 803, including putting in place a process to collect information on the performance of the MSU Decontamination System and compatible N95 respirators that have undergone decontamination using the MSU Decontamination System ("the decontaminated, compatible N95 respirators"), and will report adverse events of which MSU becomes aware to FDA. This process shall include reports concerning infection or potential infection of their personnel involved in the use of the 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.

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.

Healthcare Facilities

P. 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.

Q. 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.

R. 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.

S. 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.

T. Healthcare facilities will comply with 21 CFR Part 803, including putting in place a process to collect information on the decontaminated, compatible N95 respirators, and will report adverse events of which they become aware to FDA. This process shall include monitoring HCPs 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.

U. 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.

V. 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. 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.

<u>Conditions Related to Printed Materials, Advertising, and Promotion</u>

W. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.

X. No descriptive printed matter, including 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.

Y. All descriptive printed matter, including 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 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 MSU Decontamination System has been authorized by FDA under an EUA;

- the 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization 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