October 20, 2020

Mr. Jeffrey J. Morris
President
Roxby Development, LLC
102 Carmel Road
Wheeling, WV 26003

Dear Mr. Morris:

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 Roxby Development, LLC.
[2] For ease of reference, this letter will use the term "your product" to refer to Zoe-Ann Decontamination System.
[3] For purposes of this EUA, "compatible N95 respirators" are any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed design 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.
[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 Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

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 no FDA approved or cleared devices for decontaminating compatible N95 respirators, which are needed for use by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. In evaluating this EUA, FDA reviewed the totality of scientific evidence available, which includes: scientific literature and other information related to decontamination and the use and reuse of FFRs; information related to compatible N95 respirator fit testing; and performance data for decontamination of compatible N95 respirators, such as material compatibility, residual analysis of hydrogen peroxide post-decontamination, sporicidal testing, and worst-case scenario challenges.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the Zoe-Ann 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 Zoe-Ann 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 Zoe-Ann 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 Zoe-Ann 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.[8,9]

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[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).

[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

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 Zoe-Ann Decontamination System, for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of four (4) decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Authorized Zoe-Ann Decontamination System

The Zoe-Ann Decontamination System is an 8,000 square foot chamber that utilizes a Bioquell Clarus C Hydrogen Peroxide Vapor Generator to decontaminate a maximum capacity of 22,500 compatible N95 respirators per 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.

Healthcare personnel will label their own individual compatible N95 respirators with a 3-digit facility code and a 2-digit unit code on the outside or inside of the respirator using a permanent marker. Respirators are boxed together based on the facility and unit code labels. Clear biohazard containers will be used to collect contaminated respirators and will be picked up by Roxby Development logistics staff for transport to the decontamination facility. Each step in the chain of custody and decontamination process will be logged in the Respirator Process Log by Roxby Development staff. The decontamination process involves conditioning the chamber to a humidity level of 30-42%, injecting vaporized hydrogen peroxide (VHP) into a controlled, airtight chamber and allowing concentrated VHP to dwell for a period of 150 minutes to ensure penetration into the filtration material of the compatible N95 respirators. The chamber is then aerated to reduce the VHP to a level of 1.0 parts per million (ppm) or lower. The respirators are then moved to another area to continue to "off-gas" the remaining hydrogen peroxide held within the respirators. At least 3 biological indicators and 10 chemical indicators are used to indicate a successful decontamination cycle. Following decontamination, compatible N95 respirators are then inspected and marked on the strap with a line to denote a decontamination cycle. The decontaminated respirators are then packaged based on the facility and unit code and shipped back to the respective healthcare facility.

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

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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.

emergency use, and is required to be made available to HCP and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Preparation and Collection of Compatible N95 Respirators for Decontamination by Roxby Development Using the Zoe-Ann Decontamination System; and

- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by Roxby Development Using the Zoe-Ann Decontamination System.

In addition, following decontamination, compatible N95 respirators decontaminated by the Zoe-Ann Decontamination System must be accompanied by the following labeling, developed by Roxby Development, LLC, upon return of the respirators to HCP:

- Fact Sheet for Healthcare Personnel: Zoe-Ann Decontamination System by Roxby Development for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities are collectively referred to as "authorized labeling." The above described product, when accompanied with the authorized labeling is authorized to be distributed to and administered under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the Zoe-Ann 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 Zoe-Ann 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 Zoe-Ann 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 Zoe-Ann 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 Zoe-Ann 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:

Roxby Development, LLC

A. The Zoe-Ann Decontamination System shall only be operated by Roxby Development, LLC and shall not be distributed to third parties.

B. Roxby Development, LLC 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. Roxby Development, LLC must provide to all healthcare facility customers the authorized labeling before the decontamination process begins.

D. Roxby Development, LLC must notify all healthcare facility customers about the conditions of this authorization applicable to healthcare facilities before the decontamination process begins.

E. Roxby Development, LLC 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 (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).

F. Roxby Development, LLC may make changes to the scope of this EUA, including addition of chamber(s) for added capacity, upon request and subject to review and concurrence of DHT4B/OHT4/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 Zoe-Ann 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. Roxby Development, LLC 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 Roxby Development, LLC becomes aware related to the Zoe-Ann Decontamination System and compatible N95 respirators that have undergone decontamination using the Zoe-Ann Decontamination System ("the decontaminated, compatible N95 respirators"). This includes but is not limited to reports concerning infection or potential infection of the personnel involved in the use of the Zoe-Ann 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 Roxby Development, LLC.

I. Roxby Development, LLC will have a process in place to collect information on the performance of the Zoe-Ann Decontamination System, including information regarding degradation of decontaminated, compatible N95 respirators, and evaluate this information to determine whether adverse event reporting in accordance with 21 CFR Part 803 is warranted.

J. Roxby Development, LLC will maintain records of the chain of custody of the compatible N95 respirators sent to Roxby Development, LLC from all healthcare facilities for decontamination through use of a Respirator Process Log. Roxby Development, LLC will provide the Respirator Process Log upon delivery of decontaminated, compatible N95 respirators to the healthcare facility.

K. Roxby Development, LLC 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.

L. Roxby Development, LLC 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.

M. Roxby Development, LLC 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 will not be decontaminated, and Roxby Development, LLC must discard the respirator.

N. Roxby Development, LLC must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of four (4) decontamination cycles per compatible N95 respirator.

O. Roxby Development, LLC is authorized to decontaminate up to 22,500 compatible N95 respirators per chamber load, consistent with the data provided to FDA.

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

1. For the first two-week period, Roxby Development, LLC must use biological indicators to support release of decontaminated, compatible N95 respirators.
2. If no positive growth is observed for the biological indicators used through the two-week period, Roxby Development, LLC may use parametric release criteria using chemical indicators to support release of decontaminated, compatible N95 respirators.

Q. Roxby Development, LLC must collect and submit to FDA real-world use data for FDA review to confirm the continued fit and performance of compatible N95 respirators 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.

1. Study Plan: Prior to initiating your study, you must submit a study plan to FDA for review and concurrence of DHT4B/OHT4/OPEQ/CDRH within 7 days of this authorization. Following FDA concurrence of the study plan, the study must be initiated within 7 days. You may seek adjustment of these timeframes where agreed upon by DHT4B/OHT4/OPEQ/CDRH.
   The study design must include the following:
   - Rationale for the sampling method, including the number of decontaminated, compatible N95 respirators ("samples") to collect for testing. Samples must be collected for testing after the 4th decontamination cycle (after 4th 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 type, model, materials, number of decontamination cycles, etc., must be kept for each sample tested.
   - At a minimum, the following respirator assessments must be performed on each decontaminated, compatible N95 respirator: fit on human subjects, filtration efficiency, odor detection limit, strap integrity, legibility of cycle number, and chain of custody marking.
   - Pre-specified criteria (e.g., < x % that fail respirator assessments) that would result in revision to the maximum number of decontamination cycles per compatible N95 respirator (e.g., maximum number of authorized decontamination cycles per respirator reduced to three (3) instead of four (4)) and the rationale for this criterion.
2. Study Results: You must complete the study within 45 days of its initiation and 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.

R. Following completion of Condition Q, Roxby Development, LLC may increase the maximum number of decontamination cycles per compatible N95 respirator upon request and subject to review and concurrence of DHT4B/OHT4/OPEQ/CDRH. In advance of, and to support such a request, Roxby Development, LLC must provide to FDA information regarding strap integrity testing as demonstrated by visual inspection, filtration efficiency, breathability, and strap integrity and respirator fit testing based on real-world evidence, including but not limited to, use of the study design and methods adopted in accordance with Condition Q.

Healthcare Facilities

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 are required to be provided by Roxby Development, LLC.

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

U. Healthcare facilities using the decontaminated, compatible N95 respirators shall review the chain of custody form (Respirator Process Log), 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 Roxby Development, LLC, and the healthcare facility shall discard the respirator. Any decontaminated, compatible N95 respirator that has exceeded four (4) decontamination cycles shall be discarded.

Conditions Related to Printed Materials, Advertising and Promotion

V. 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.

W. 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.

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

- the Zoe-Ann 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 Zoe-Ann Decontamination System has been authorized by FDA under an EUA;

- the Zoe-Ann 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