June 22, 2020

Mark S. Paxton, JD, MS
Department of the Army
Headquarters, US Army Medical Research and Development Command
810 Schreider Street
Fort Detrick, Maryland 21702

Dear Mark S. Paxton:

On May 19, 2020, based on MAJ Steven Hong's request, the U.S. Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the COVID-19 Airway Management Isolation Chamber[1] (hereafter "CAMIC") within the US Army and MHS for use by healthcare providers (HCP)[2] as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates during transport of patients with suspected or confirmed diagnosis of COVID-19 [3], at the time of definitive airway management, or when performing medical procedures on such patients during the COVID-19 pandemic.

On June 11, 2020, FDA received a request from the U.S. Army Medical Research and Development Command (USAMRDC) to amend the May 19, 2020, Emergency Use Authorization (EUA) for the CAMIC to update the authorized sponsor information from the US Army and MHS to the US Army Medical Research and Development Command. In response to the request received, and having concluded that revising the May 19, 2020, EUA is appropriate to protect public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. §360bbb-3(g)(2)(C)), the May 19, 2020, letter authorizing the emergency use of the CAMIC is being reissued in its entirety with revisions incorporated.[4]

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[1] A CAMIC device is a clear isolation chamber with a rigid internal skeleton and a clear, flexible plastic that drapes around the head, neck and shoulders of the patient that allows for internal suction and airflow and is designed to contain and remove aerosolized particles. The CAMIC is not intended to replace the need for PPE. The CAMIC is not approved or cleared for marketing in the US and is not authorized under this EUA for distribution beyond the US Army and MHS.

[2] For this EUA, HCP refers to practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or health professionals that have a role in using such a device.

[3] Under the circumstances of this public health emergency, it would not be feasible to require HCPs to limit the use of the CAMIC only to patients with suspected or confirmed COVID-19; therefore, this authorization does not restrict use to such patients.

[4] The revisions to the May 19, 2020, letter transfers ownership of the EUA for the CAMIC from US Army and Military Health System (MHS) to US Army Medical Research and Development Command, subject to the conditions of authorization set forth in this letter. Additionally, the authorized "Instructions for Healthcare Facilities - Assembly, Disassembly and Disinfection of the CAMIC," and "Instructions for Healthcare Personnel - Use of the

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

There are no FDA-approved or -cleared devices for use as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates from patients during the COVID-19 pandemic. Based on the available information, the use of the CAMIC allows for greater level of protection for HCP during high-risk procedures involving manipulation of the airway such as endotracheal intubations and in non-invasive respiratory care (such as high-flow oxygen, nebulizers and continuous positive airway pressure (CPAP)/bi-level positive airway pressure (BiPAP)) and protect HCP during high-risk procedures. FDA reviewed the available information, including bench performance testing on particle count testing using smoke and saline nebulizer models. Based on the totality of the available scientific evidence, FDA has concluded that the CAMIC may be effective as an extra layer of barrier protection, in addition to PPE, to prevent exposure to pathogenic biological airborne particulates.

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 CAMIC, 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 CAMIC, 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 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

CAMIC," have been updated to reflect the revision to the sponsor, and other clarifying edits have been made throughout.

[5] US 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).

[6] US 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).

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CAMIC may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when transporting or performing medical procedures on patients who are known or suspected to have COVID-19[7], and that the known and potential benefits of the CAMIC for such use outweigh its known and potential risks; and,

3. There is no adequate, approved, and available alternative to the emergency use of the CAMIC.[8]

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 CAMIC by HCP as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates during transport of patients at the time of definitive airway management (e.g., intubation, extubation and suctioning airways), or when performing any aerosol generating medical procedures (e.g., nebulizer treatments, manipulation of oxygen mask or BiPAP mask) during the COVID-19 pandemic. The CAMIC is not intended for use:

- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with communication disorders that might interfere with clinical care
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On children under 45 pounds (lbs)

The Authorized CAMIC

The CAMIC is authorized for use by HCP as an extra layer of barrier protection to prevent HCP exposure to pathogenic biological airborne particulates; it is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

The CAMIC system is a barrier device constructed by draping a large clear plastic bag over a box-like frame made of common polyvinyl chloride (PVC) piping. The CAMIC consists of a PVC hollow frame and a clear large plastic (polyethylene) bag that is placed over the head, neck, and shoulders of the patient to isolate airborne particulates. The CAMIC cycles out air through holes in the PVC frame. The CAMIC captures and removes particles emitted from a patient's nose and mouth using a flow of medical air, which comes in through holes in the PVC frame on one side and is sucked out by a vacuum on the other. The CAMIC is authorized for use with hospital vacuum lines, as well as portable vacuum pumps with in-line High-Efficiency Particulate Air (HEPA) filters.

[7] See footnote 3.
[8] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

The CAMIC is comprised of the following components:

- Hollow, perforated PVC piping (reusable);
- Plastic (polyethylene) bag (disposable);
- Wall-mounted vacuum pump, or portable vacuum pump with in-line HEPA filter;
- Portable or wall-mounted medical air.

The CAMIC must be assembled according to the "Instructions for Use for Healthcare Facilities - Assembly, Disassembly and Disinfection of the CAMIC." The PVC frame of the CAMIC is authorized for reuse and must be disinfected according to these instructions. The clear large plastic (polyethylene) bag is single-use only.

The CAMIC is authorized for use during patient transport. During patient transport, the CAMIC maintains negative pressure via a portable vacuum pump with an in-line HEPA filter, and oxygenation is supplied via a portable medical air tank.

The above described CAMIC is authorized to be accompanied with labeling entitled "Instructions for Healthcare Facilities - Assembly, Disassembly and Disinfection of the CAMIC," and "Instructions for Healthcare Personnel (HCP) - Use of the CAMIC" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), together with the following product-specific information pertaining to the emergency use, which is required to be made available to HCP and patients, respectively:

- Fact Sheet for Healthcare Providers: Emergency Use of the COVID-19 Airway Management Isolation Chamber (CAMIC)
- Fact Sheet for Patients: Emergency Use of the COVID-19 Airway Management Isolation Chamber (CAMIC)

The above described product, when accompanied with the two Instructions for Use (identified above) and the two Fact Sheets (collectively referred to as "authorized labeling") is authorized to be distributed 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 CAMIC when used and labeled consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of this 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 authorized CAMIC may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when transporting or performing medical procedures on patients who are known or suspected to have COVID-19, 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 authorized CAMIC, 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 emergency use of the CAMIC 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) and the Secretary of HHS's corresponding declaration under section 564(b)(1), the CAMIC is authorized for use by HCP as an extra layer of barrier protection under the terms and conditions of this EUA.

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 practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under sections 520(f)(1). 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:

US Army Medical Research and Development Command (USAMRDC), as Sponsor of Authorized Product

A. USAMRDC will make the authorized labeling available with the CAMIC. USAMRDC may request changes to the authorized labeling. Such changes require review and concurrence from Office of Health Technology 4 (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

B. USAMRDC may request changes to the Scope of Authorization (Section II in this letter) of the authorized CAMIC. Such requests will be made by USAMRDC, in consultation with OHT4/OPEQ/CDRH and require concurrence of the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and OHT4/OPEQ/CDRH.

C. USAMRDC may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT4/OPEQ/CDRH.

D. USAMRDC must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices),

as well as those described in Section II of this letter, Scope of Authorization. As such, compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

E. USAMRDC will have process in place for reporting adverse events in accordance with 21 CFR Part 803. Adverse events of which USAMRDC becomes aware will be reported to FDA.

F. USAMRDC will distribute the authorized CAMIC with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the CAMIC. Distribution is limited to US Army and MHS healthcare facilities.

G. Through a process of inventory control, USAMRDC will maintain records of the healthcare facilities to which they distribute the authorized CAMIC with the authorized labeling.

H. USAMRDC are 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.

I. USAMRDC 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.

Healthcare Facilities and Healthcare Providers

J. Healthcare facilities using the authorized CAMIC must make available to patients the accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet.

K. Healthcare facilities using the CAMIC must follow the procedure for reporting adverse events developed by the USAMRDC.

L. Healthcare facilities will ensure HCP using the CAMIC are adequately equipped, trained, capable, and will maintain records of device usage.

Conditions Related to Printed Materials, Advertising and Promotion

M. All descriptive printed matter, include advertising and promotional material, relating to the use of the authorized CAMIC 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.

N. No descriptive printed matter, include advertising or promotional material, relating to the use of the authorized CAMIC may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.

O. All descriptive printed matter, include advertising and promotional materials relating to the use of the authorized CAMIC shall clearly and conspicuously state that:

- The CAMIC has neither been cleared or approved for use by HCP as an extra layer of barrier protection in addition to PPE to protect against pathogenic biological airborne particulates during transport of patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing medical procedures on such patients during the COVID-19 pandemic;

- The CAMIC has been authorized for the above emergency use by FDA under an EUA; and,

- The CAMIC has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices 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 the 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