U.S. FOOD & DRUG ADMINISTRATION

May 1, 2020

To: Manufacturers of Protective Barrier Enclosures;
Health Care Providers;
Hospital Purchasing Departments and Distributors; and,
Any Other Stakeholders

The U.S. Food and Drug Administration (FDA) is issuing this Emergency Use Authorization (EUA) for protective barrier enclosures[1] in response to the evolving Coronavirus Disease 2019 (COVID-19) pandemic and concerns relating to the transmission of SARS-CoV-2, the virus that causes Coronavirus Disease 2019 (COVID-19) during patient care. FDA is issuing this EUA for the use of Protective Barrier Enclosures by healthcare providers (HCP)[2] when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment (PPE).

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.[3] 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 for emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[4]

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[1] A protective barrier enclosure is a transparent device designed to cover a patient's head and upper body that incorporates one or more ports through which the HCP's hands are passed to perform medical procedures. It does not include filtration or other features and is not intended to generate negative pressure. Protective Barrier Enclosures are used as a physical barrier and can be used by HCPs in situations including, but not limited to, airway management (e.g., intubation, extubation, and suctioning of airways) and any aerosol generating procedures (e.g., nebulizer treatments, manipulation of oxygen mask or Bilevel Positive Airway Pressure (BiPAP) mask). These products provide an additional layer of barrier protection in addition to Personal Protective Equipment (PPE) against airborne particles or droplets from the patients. These products are not intended to replace the need for PPE. These products should be removed if they impede a HCP's ability to care for a patient or impede the HCP's ability to perform a medical procedure on a patient.

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

[3] 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)

[4] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations*

Currently, there are no FDA-cleared or approved barrier protection devices that are available for use by HCPs when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates. Protective Barrier Enclosures are novel barrier protection devices that provide an extra layer of barrier protection in addition to PPE. Adequate barrier protection is especially important in conditions where exposure to bodily fluids and airborne particles or droplets from COVID-19 patients is expected. Based on available scientific evidence, FDA has concluded that the protective barrier enclosures may be an effective barrier device when used in addition to PPE.

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 protective barrier enclosures 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 protective barrier enclosures, when used by HCP on a patient in a healthcare setting to provide an extra layer of barrier protection in addition to PPE when caring for or performing medical procedures on a patient who is known or suspected to have COVID-19 to prevent HCP exposure to pathogenic biological airborne particulates, 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 authorized protective barrier enclosures may be effective at preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings and that the known and potential benefits of protective barrier enclosures, for such use, outweigh the known and potential risks of such product, and,

3. There is no adequate, approved, and available alternative to the emergency use of these protective barrier enclosures.[5,6]

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).

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

[6] These protective barrier enclosure devices can be used to provide an extra layer of barrier protection in addition to PPE to HCPs during the COVID-19 pandemic, particularly when performing airway management on the patients (e.g. intubation, extubation, airway suction, etc.). Providing authorization for the emergency use of protective barrier enclosures by manufacturers, including those that may not customarily engage in the manufacture of medical devices helps meet the needs of the healthcare system. Providing HCPs who are on the forefront of the COVID-19

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 protective barrier enclosures by HCP in healthcare settings to provide an extra layer of barrier protection in addition to PPE when caring for or performing medical procedures on a patient who is known or suspected to have COVID-19 to help prevent HCP exposure to pathogenic biological airborne particulates.

Authorized Protective Barrier Enclosures

A protective barrier enclosure is a transparent device designed to cover a patient's head and upper body that incorporates one or more ports through which the HCP's hands are passed to perform medical procedures. Protective barrier enclosures are authorized under this EUA when they are intended for use by HCPs when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE and meet the following requirements:

1. The product is labeled accurately to describe the product as a protective barrier enclosure that provides an extra layer of barrier protection in addition to PPE and includes a list of the body contacting materials (which excludes non-active drugs, biologics, antimicrobial agents, or nanoparticles).

2. The product includes labeling that clearly states that the product is not intended to replace PPE.

3. The product includes labeling that clearly describes the instructions for use, including instructions for the HCP to assess patient status prior to device use, instructions on removal of the product if it impedes patient care or communication, and specific precautions for the use on certain patients.

4. The product must be made with transparent materials to provide a clear, unobstructed view of the procedure field.

5. The product does not include fans, air filters, or other features and is not intended to generate negative pressure.

6. The product includes labeling that describes the product as intended for either single use or for multiple uses; if a protective barrier enclosure is intended for multiple uses, the device labeling must include instructions for recommended thorough cleaning and

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response with an additional layer of barrier protection may be helpful in order to reduce the risk of transmission of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

disinfection methods using a compatible EPA-registered hospital disinfectant from the EPA *List N: Disinfectants for use against CoV-2*[7].

7. The product does not contain or combine any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas).

8. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling should not state or imply that the authorized product is intended for any other medical purposes, such as airway management, the labeling should not state or imply that use of the authorized product alone will prevent infection from or transmission of microbes or viruses, or that it is effective protection against radiation.

Manufacturers of protective barrier enclosures that are used as described above and meet the above requirements (i.e., are within this section (the Scope of Authorization, Section II)) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA's posting and public announcement of this EUA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization serves as protective barrier enclosure manufacturers' notification of authorization.

In addition, the authorized products must be accompanied by the following information pertaining to the emergency use which are authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Emergency Use of a Protective Barrier Enclosure During the COVID-19 Pandemic
- Fact Sheet for Patients: Emergency Use of a Protective Barrier Enclosure During the COVID-19 Pandemic

The sponsor's required instructions for use and the two fact sheets are referred to as "authorized labeling."

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 protective barrier enclosures, as described within this section (Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that protective barrier enclosures may be effective as described within this section (Scope of Authorization, Section II), pursuant to Section 564(c)(2)(A) of the Act.

[7] Refer to https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.

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 protective barrier enclosures as described in this section (Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of protective barrier enclosures 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), protective barrier enclosures are authorized 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 manufacturing, 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 Part 820.[8]

IV. Conditions of Authorization

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

Manufacturers and Distributors of Authorized Products

A. Manufacturers and Distributors must make protective barrier enclosures available with the authorized labeling, which includes the following:
   - the product must be labeled accurately to describe the product as a protective barrier enclosure to provide an extra layer of barrier protection in addition to PPE and include a list of the body contacting materials (which does not include any biologic, antimicrobial agents, or nanoparticles);
   - the product must include labeling that clearly states that the product is not intended to replace PPE;
   - the product must include labeling that clearly describes the direction for use of the product;
   - the product must include labeling that clearly states that the product should be removed if it impedes ability to care for a patient or communicate with the patient or impedes the ability to perform a medical procedure on a patient,

[8] Of note, compliance with the requirements under 21 CFR Part 806 (Reports of Corrections and Removals), 21 CFR Part 807 (Registration and Listing), and Subpart B of 21 CFR Part 801 (Unique device identification requirements) are not required by this EUA.

- the product includes labeling that clearly states that the patient should be assessed for respiratory status and difficult airway prior to device use, and
- the product must be labeled accurately to describe the product as intended for single use or for multiple uses.
- The product must be labeled to include the following precaution:
  - "Precautions: The Benefits/Risks of using a protective barrier enclosure device for airway management in certain populations should be predetermined by the HCP. These populations include but are not limited to:
    - *Patients requiring emergency endotracheal intubation who have severe respiratory compromise*
    - *Patients with an anticipated or known history of difficult airway*
    - *Patients who are morbidly obese*
    - *Pregnant women in the 2nd or 3rd trimes*
    - *Individuals with severe claustrophobia and/or confined space anxiety*
    - *Individuals with certain communication disorders*
    - *Patients with other anatomical abnormalities*
    - *Patients with decreased neck mobility due to arthritis or other causes*

B. Manufacturers and Distributors of authorized products shall ensure the labeling does not state or imply that the product: 1) is intended for any other medical purposes, such as airway management; 2) also will prevent infection from the transmission of microbes or viruses; or 3) is effective protection against radiation.

C. Manufacturers and Distributors will include instructions for recommended thorough cleaning and disinfection using a compatible EPA-registered hospital disinfectant from the EPA *List N: Disinfectants for use against CoV-2*, if their authorized product(s) are reusable. Manufacturers must provide these instructions, if applicable, to each end user facility (e.g. each hospital) that receives the authorized protective barrier enclosures, and may include such instructions on each individual authorized product.

Manufacturers must make the required authorized labeling available to each end user facility (e.g. each hospital) that receives the authorized products, by including a letter in English with the information, and may include such labeling with each individual authorized product.

E. Manufacturers will have a process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA. See FDA's webpage "Medical Device Reporting (MDR): How to Report Medical Device Problems[9]" for reporting requirements and procedures.

[9] FDA guidance "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

F. Manufacturers and Distributors 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.

G. Through a process of inventory control, manufacturers will maintain records of the entities to which they distribute the protective barrier enclosures and the numbers of each such product they distribute.

H. Manufacturers and Distributors 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.

Conditions Related to Printed Materials, Advertising and Promotion

I. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized protective barrier enclosure shall be consistent with the labeling elements listed in Section II of this EUA, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

J. No descriptive printed matter, including advertising or promotional materials, relating to the use of the authorized protective barrier enclosure may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.

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

- The product has not been FDA cleared or approved
- The product has been authorized by FDA under an EUA for use by healthcare providers (HCP) while caring for or performing medical procedures on patients who are known or suspected to have COVID-19, in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as 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 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

Attachment: Fact Sheets