



August 20, 2020

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

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) issued May 1, 2020, for emergency use of protective barrier enclosures¹ 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).

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

Since issuance of the May 1, 2020 umbrella EUA, FDA has become aware of information that supports a determination to revoke the umbrella EUA on the grounds that the criteria under section 564(c) of the Act for issuance of an EUA are no longer met (see section 564(g)(2)(B)). Under section 564(c) of the Act, an EUA may be issued only if FDA concludes “that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing ---(i) such disease or condition [...]; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product [...].”

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. The authorized protective barrier enclosures were passive—they did not include fans, air filters, or other features and were not intended to generate negative pressure. The authorized Protective Barrier Enclosures were intended to be used as a physical barrier 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 were intended to provide an additional layer of barrier protection in addition to Personal Protective Equipment (PPE) against airborne particles or droplets from the patients. These products were not intended to replace the need for PPE.

² For the EUA, HCP referred 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.

In addition, FDA has determined that revocation is appropriate to protect the public health or safety (see section 564(g)(2)(C) of the Act), and that individualized consideration of each EUA request for protective barrier enclosures would better protect the public health.

Specifically, FDA has become aware of new preliminary evidence from simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure recently reported in the literature.^{3,4} Overall, these literature articles provide new evidence that protective barrier devices covered under the umbrella EUA may not be effective in decreasing HCP exposure to airborne particles and may instead contribute to an increase in HCP exposure to airborne particles. Additionally, the articles note potential risks of protective barrier enclosures, such as increased intubation times, lower first-pass intubation success rates, damage to PPE from intubation boxes, particles escaping from intubation boxes through arm access holes reaching the face of the HCP performing the endotracheal intubation, and human factors issues contributing to increased endotracheal intubation times.

After reviewing the totality of the data and information received by FDA since issuance of the May 1, 2020, EUA, FDA has determined that revocation of the umbrella EUA for protective barrier enclosures is appropriate. FDA believes it is no longer 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 FDA can no longer conclude that the known and potential benefits of protective barrier enclosures, for such use, outweigh the known and potential risks of such product; thus, the criteria under section 564(c) of the Act for issuance of an EUA are no longer met. In addition, based on the risks identified in the currently available data and information, including the device's potential contribution to an increase in HCP exposure to airborne particles, FDA has concluded that revocation of the EUA is appropriate to protect the public health or safety, and that individualized consideration of each EUA request for protective barrier enclosures would better protect the public health.

Accordingly, pursuant to section 564(g)(2)(B)&(C) of the Act, FDA revokes the EUA issued on May 1, 2020.

The devices covered by the May 1, 2020 EUA are not approved or authorized by FDA for any indication and therefore cannot be legally introduced into interstate commerce. In addition, under section 564(f)(2) of the Act, devices that were distributed under this EUA remain authorized for emergency use to continue to prevent HCP exposure to pathogenic biological particulates when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 for which the authorized product has already been administered prior to the date of revocation, to the extent found necessary by such patient's attending physician.

³ Simpson J.P., et al. Measurement of airborne particle exposure during simulated tracheal intubation using various proposed aerosol containment devices during the COVID-19 pandemic. *Anesthesia*, 19 June 2020, 1-9.

⁴ Begley J.I., et al. The Aerosol box for intubation in COVID-19 patients: an in-situ simulation crossover study. *Anesthesia*, August 2020. 75 (8), 1014-1021.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration