



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-2216]

### Revocation of Authorizations of Emergency Use of Certain Medical Devices during COVID-19; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocations of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Manufacturers of Protective Barrier Enclosures and Other Stakeholders for certain protective barrier enclosures (“PBE Authorization”) and to Manufacturers of Infusion Pumps and Infusion Pump Accessories and Other Stakeholders for certain infusion pumps and infusion pump accessories (“Infusion Pump Authorization”). FDA revoked the PBE Authorization on August 20, 2020, and the Infusion Pump Authorization on September 21, 2020, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

**DATES:** The PBE Authorization is revoked as of August 20, 2020. The Infusion Pump Authorization is revoked as of September 21, 2020.

**ADDRESSES:** Submit written requests for single copies of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

**FOR FURTHER INFORMATION CONTACT:** Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 240-402-8155 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On May 1, 2020, FDA issued the PBE Authorization. On May 13, 2020, FDA issued the Infusion Pump Authorization. Of note, these were both “umbrella” Authorizations, i.e., for certain types of products that met the requirements as described in their respective Authorizations. Any product with an individual Authorization is not affected by revocation of these two umbrella Authorizations. Notice of the issuance of the Authorizations was published in the *Federal Register* on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent to the issuance of the PBE Authorization, FDA considered new information, specifically from new preliminary evidence from simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure. Subsequent to the issuance of the Infusion Pump Authorization, FDA considered that no device had been listed under the EUA and that circumstances instead support allowing for tailored requirements of authorization in individual EUAs.

II. EUA Criteria for Issuance No Longer Met and Other Circumstances Make Revocation

Appropriate to Protect the Public Health or Safety

Under section 564(g)(2)(B) and (C) of the FD&C Act, the Secretary of the Department of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public

health or safety. On August 20, 2020, FDA revoked the PBE Authorization because the criteria for issuance were no longer met and other circumstances make such revocation appropriate to protect the public health or safety. Under section 564(c)(2) of the FD&C Act, an EUA may be issued only if FDA concludes that, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such disease or condition and that 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.

Given the 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 literature articles, FDA has concluded it is not reasonable to believe the product may be effective in decreasing healthcare provider exposure to airborne particles and may instead contribute to an increase in healthcare provider exposure to airborne particles. Additionally, the literature articles note potential risks of protective barrier enclosures, such as increased intubation times, lower first-pass intubation success rates, damage to personal protective equipment from intubation boxes, particles escaping from intubation boxes through arm access holes reaching the face of the healthcare provider performing the endotracheal intubation, and human factors issues contributing to increased endotracheal intubation times. Further, based on the same information and the risks to public health, including from the device's potential contribution to an increase in healthcare provider exposure to airborne particles, FDA has concluded under section 564(g)(2)(C) of the FD&C Act that other circumstances make revocation appropriate to protect the public health or safety. Accordingly, FDA has revoked the PBE Authorization, pursuant to section 564(g)(2)(B) and (C) of the FD&C Act.

On September 21, 2020, FDA revoked the Infusion Pump Authorization because other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act), considering that no device has been listed under the EUA, and circumstances instead support allowing for tailored requirements of authorization in individual EUAs.

### III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at <https://www.regulations.gov>, and <https://www.fda.gov/media/142374/download> and <https://www.fda.gov/media/141415/download>.

### IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g) of the FD&C Act are met, FDA has revoked the EUAs for certain protective barrier enclosures and certain infusion pumps and infusion pump accessories. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.



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 enclosures<sup>1</sup> by healthcare providers (HCP)<sup>2</sup> 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 [...].”

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<sup>1</sup> 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.

<sup>2</sup> 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.<sup>3,4</sup> 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(e) 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.

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<sup>3</sup> 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.

<sup>4</sup> 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.

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

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



September 21, 2020

To Manufacturers and Other Stakeholders:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) issued May 13, 2020, for emergency use of infusion pumps and infusion pump accessories<sup>1</sup> for use by healthcare providers (HCPs) to treat conditions caused by the Coronavirus Disease 2019 (COVID-19) with the controlled infusion of medications, total parenteral nutrition (TPN), and/or other fluids.

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.

FDA has determined that circumstances make revocation of this EUA appropriate to protect the public health or safety. Any infusion pumps and infusion pump accessories added to the list of authorized devices in Appendix A of the May 13, 2020, letter of authorization would have been authorized for use by HCPs to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids. This includes infusion pumps with remote monitoring or remote manual control features or administration sets and other accessories with increased length that help maintain a safe physical distance between HCPs and patients with confirmed or suspected COVID-19 to reduce HCP exposure to the virus that causes COVID-19. To date, no device has been listed in Appendix A.

Based on information and experience since issuance of the umbrella EUA, FDA has determined that circumstances support revocation of the umbrella EUA. Individual EUAs will allow for tailored indications and scopes of authorization, including but not limited to those for different environments of use, routes of administration, and patient populations. In addition, this would allow for individualized conditions of authorization to address any issue unique to a specific device, and more streamlined EUA amendments, such as additional uses that would not fall under this umbrella EUA. Accordingly, FDA has decided to revoke this EUA. Instead, FDA

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<sup>1</sup> The infusion pumps authorized under the EUA had to fall within the scope of devices and meet the safety, performance, and labeling criteria set forth in the EUA. Regarding scope, infusion pumps had to pump fluids, including medications, total parenteral nutrition (TPN), and/or other fluids, into a patient in a controlled manner. The "authorized devices" included those that may use a piston pump, roller pump, a peristaltic pump, or other pumping mechanism and those that may be powered electrically or mechanically. The EUA also authorized use of infusion pumps accessories intended to support, supplement, and/or augment the performance of infusion pumps, including those that may include intravenous administration sets, stopcocks, and different catheters.

may issue individual EUAs for infusion pumps and infusion pump accessories that meet the requisite EUA statutory criteria.

FDA has determined that circumstances make revocation of this EUA appropriate to protect the public health or safety for purposes of section 564(g)(2)(C) of the Act.

Accordingly, pursuant to section 564(g)(2) of the Act, FDA revokes the EUA issued on May 13, 2020.

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

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Dated: November 30, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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