

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 accessories¹ 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

¹ 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration