''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., WO1, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–4880 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Registration and Listing of Cosmetic Product Facilities and Products.''

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) into law, which included MoCRA. Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing. Section 607(a) of the FD&C Act (21 U.S.C. 364c(a)) requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility. In addition to the registration requirements, section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA ''a cosmetic product listing.'' Certain small businesses, as defined in section 612 of the FD&C Act (21 U.S.C. 364h), are exempt from the registration and listing requirements.

In the **Federal Register** of December 19, 2023 (88 FR 87780), we made available a final guidance for industry entitled ''Registration and Listing of Cosmetic Product Facilities and Products.'' This guidance also included a new draft section, Appendix B, for comment purposes only, that describes frequently asked questions and answers about cosmetic product facility registrations and product listing submissions and gave interested parties an opportunity to submit comments by January 18, 2024, for us to consider before beginning work on the final version of Appendix B. We received a few comments on the draft guidance Appendix B frequently asked questions and answers and have modified the final guidance Appendix B in response to these comments and for clarity, where appropriate. In addition, we made editorial changes to the final guidance to improve clarity. Finally, three new frequently asked questions and answers in Appendix B of this guidance are highlighted in grey and are marked ''for comment purposes only'' to provide an opportunity for comment before they are finalized. Aside from the three new frequently asked questions and answers in Appendix B, this guidance finalizes the draft guidance Appendix B that was published on December 19, 2023 (88 FR 87780) and reissues the final guidance with minor changes for clarity. No changes were made to Appendix A of the final guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Registration and Listing of Cosmetic Product Facilities and Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in section 607 of the FD&C Act have been approved under 0910–0599.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/CosmeticGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 5, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–29237 Filed 12–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5375]

Revocation of Authorization of Emergency Use of B. Braun Medical's Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to B. Braun Medical, Inc., for the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES. FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reasons for revocation, is reprinted at the end of this document.

DATES: The revocation of the Authorization for the B. Braun Medical, Inc.'s Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES is effective as of October 1, 2024.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jacqueline Gertz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 240–402–9677 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or 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 April 11, 2020, FDA issued the Authorization to B. Braun Medical, Inc., for the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES, subject to the terms of the Authorization. Notice of the issuance of this Authorization 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 updates to the Authorization were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. Authorization Revocation Request

In a request received by FDA on August 6, 2024, B. Braun Medical, Inc., requested the withdrawal of, and on October 1, 2024, FDA revoked, the Authorization for the B. Braun Medical Inc.'s Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES. Because B. Braun Medical Inc., notified FDA about the lack of customer interest and lack of need for use of the device for the indications granted under this EUA considering the improved COVID–19 situation and requested FDA withdraw the B. Braun Medical Inc.'s Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of the B. Braun Medical Inc.'s Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

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U.S. FOOD & DRUG ADMINISTRATION

October 1, 2024

Venkata Vempati
B. Braun Medical, Inc.
3773 Corporate Pkwy
Center Valley, PA 18034

Re: Revocation of EUA200227

Dear Venkata Vempati:

This letter serves to correct an error in our October 1, 2024, revocation letter. We inadvertently stated that this EUA had been issued on April 1, 2020. We have corrected that date below to reflect the April 11, 2020, issuance. The signature on this letter will reflect the date of the correction but the October 1, 2024 date of the letter reflects the effective date of the revocation.

This letter is in response to your request dated August 6, 2024, that the Food and Drug Administration (FDA) provide advice about the process for withdrawing the Emergency Use Authorization (EUA200227) issued on April 11, 2020, for B. Braun Medical's Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES. We are considering this as a request to revoke this EUA. Your request is in response to the lack of customer interest and lack of need for use of the device for the indications granted under this EUA considering the improved COVID-19 situation. The B. Braun Medical's Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES were authorized for emergency use by FDA for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or suspected of having COVID-19 and for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System.

FDA understands that B. Braun Medical does not plan to continue to distribute the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES for the indications authorized in EUA200227. If you decide later that you want to do so, those indications would require emergency use authorization or marketing authorization (premarket approval under section 515 of the Federal Food Drug and Cosmetic Act (the Act), 510(k) clearance (premarket notification under section 510(k) of the Act), or De Novo classification (under section 513 of the Act)).

You indicated in your email dated September 16, 2024, that the EUA included additional indications beyond the 510(k)-cleared device indications and that the only changes that you made to the 510(k)-cleared device were to include an addendum to the instructions for use and to add fact sheets to the existing labeling. In that email, you committed to, upon EUA revocation, do the following:

1) Post a customer letter on your website and send the letter to customers to direct them to dispose of the EUA-related labeling;

2) Remove from the website the current EUA Customer Letter, the Fact Sheets for Healthcare Providers, and the corresponding Instructions for Use addendum for the B. Braun Space and Outlook Pumps; and
3) Notify customers, via the B. Braun website, that the EUA for the B. Braun infusion pumps has been revoked, and that customers should dispose of the Customer Letter, the Fact Sheets for Healthcare Providers, and the Instructions for Use addendum for the B. Braun Space and Outlook Pumps.

In an additional email, dated September 25, 2024, you indicated that you also intend to:

1) Instruct customers to dispose of the EUA-specific IFU addendum and to use the device with the 510(k) cleared labeling; and

2) Offer customers the ability to either download the electronic copy of the 510(k)-cleared device labeling from B. Braun's website or contact the customer representative to request a paper copy of the same, as needed.

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 revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because B. Braun Medical Inc. has requested that FDA revoke the EUA for the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes, pursuant to 564(g)(2)(C), EUA200227 for the B. Braun Perfusor Syringe Infusion Pump System, Outlook ES and the Infusomat Space Volumetric Infusion Pump. As of the date of this letter, the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES are no longer authorized for emergency use by FDA[1].

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

Sincerely,

//s//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

[1] As outlined in our April 1, 2020, EUA letter, the B. Braun Space and Outlook Pumps have each respectively received marketing authorization from FDA under section 510(k) of the Act. This EUA revocation does not impact the 510(k)-cleared devices or their indications for use.

Dated: December 4, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–29247 Filed 12–11–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of the General Counsel, Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: This document revises and restates the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Office of the General Counsel (OGC). Issuance of this Statement of Organization rescinds all prior Statements of Organization.

FOR FURTHER INFORMATION CONTACT: Rachel Park, Principal Deputy General Counsel, Office of the General Counsel, Office of the Secretary, 200