

biology, informatics, nanotechnology, and combination products. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/science-board-food-and-drug-administration> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at

<https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: December 4, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–29231 Filed 12–11–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1716]

Registration and Listing of Cosmetic Product Facilities and Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled “Registration and Listing of Cosmetic Product Facilities and Products.” The guidance will assist persons submitting cosmetic product facility registrations and product listing submissions to FDA under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). This guidance includes three new draft frequently asked questions and answers about cosmetic product facility registrations and product listing submissions, in Appendix B, for comment purposes only. Aside from the three new draft frequently asked questions and answers, this guidance finalizes the draft Appendix B published in an otherwise final guidance on December 19, 2023. This guidance also includes minor changes to the final guidance for clarity.

DATES: The announcement of the guidance is published in the **Federal Register** on December 12, 2024. However, the portion of this guidance in Appendix B that describes three new frequently asked questions and answers, is being distributed for comment purposes only. To ensure that the Agency considers your comment on this draft section before it begins work on the final version of this section of the guidance, submit either electronic or written comments on this section by January 13, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2023–D–1716 for “Registration and Listing of Cosmetic Product Facilities and Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

“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.

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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.