

Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

**Chyana Woodyard,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2023–24850 Filed 11–8–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–D–1716]

#### Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing; Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry and the public on the requirements related to cosmetic product facility registration and cosmetic product listing under the Federal Food, Drug, and Cosmetic Act (FD&C Act) entitled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.” This guidance announces FDA’s intention to delay enforcement of the requirements related to cosmetic product facility registration and cosmetic product listing for an additional 6 months after the initial December 29, 2023, deadline.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 9, 2023.

**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 “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing; Guidance for Industry; Availability.” 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 the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

#### **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), email: [QuestionsAboutMoCRA@fda.hhs.gov](mailto:QuestionsAboutMoCRA@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a guidance for industry and the public entitled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.” This guidance is intended to assist owners or operators of cosmetic product facilities that are subject to the requirements related to facility registration and responsible persons that are subject to the requirements related to cosmetic product listing under the FD&C Act. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public

participation is not feasible or appropriate (§ 10.115(g)(2)) as it provides time-sensitive information to industry about our intent to delay enforcement of the cosmetic product facility registration and product listing requirements under section 607 of the FD&C Act (21 U.S.C. 364c), which become effective on December 29, 2023, for 6 months until July 1, 2024. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation (§ 10.115(g)(5)).

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) into law, which included the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the FD&C Act, establishing requirements for cosmetic product facility registration and product listing. Section 607 of the FD&C Act generally imposes an initial registration and listing deadline of December 29, 2023, for facilities that engaged in manufacturing or processing of a cosmetic product and cosmetic products that were marketed as of December 29, 2022, the date MoCRA was enacted. This guidance announces FDA's intent to delay enforcement of the requirements related to cosmetic product facility registration and cosmetic product listing under section 607 of the FD&C Act related to cosmetic product facility registration and cosmetic product listing until July 1, 2024, to provide regulated industry additional time to comply with these requirements.

FDA issued a draft guidance entitled "Registration and Listing of Cosmetic Product Facilities and Products" on August 8, 2023 (88 FR 53490). The draft guidance, when finalized, will provide recommendations and instructions to assist persons submitting cosmetic product facility registrations and product listings to FDA. FDA intends to delay enforcement of the cosmetic product facility registration and product listing requirements to help ensure that owners or operators of cosmetic product facilities and responsible persons for cosmetic products have sufficient time to gather the relevant information required for facility registration and product listing, including obtaining facility registration numbers to associate with cosmetic product listings, obtaining access to the electronic submissions database, and verifying accurate registration and listing information for submission.

The guidance represents the current thinking of FDA on the issues within. 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

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.fda.gov/CosmeticGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: November 3, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–24731 Filed 11–8–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH VideoCasting at the following link: <http://videocast.nih.gov/>.

A portion of this meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Council on Alcohol Abuse and Alcoholism.  
*Date:* February 8, 2024.

*Closed:* 11:00 a.m. to 11:55 a.m.

*Agenda:* To review and evaluate grant applications.

*Open:* 12:00 p.m. to 4:00 p.m.

*Agenda:* Presentations and other business of the Council.

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive Bethesda, MD 20817 (Virtual Meeting).

*Contact Person:* Philippe Marmillot, Ph.D., Acting Director, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Room 2118 Bethesda, MD 20892, (301) 443–2861, [marmillotp@mail.nih.gov](mailto:marmillotp@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://www.niaaa.nih.gov/AboutNIAAA/AdvisoryCouncil/Pages/default.aspx>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs, National Institutes of Health, HHS)

Dated: November 6, 2023.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2023–24807 Filed 11–8–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.