

required in the statute), and (3) data privacy and security.

This collection covers the application through which organizations provide information to CMS to determine whether they will be approved as a qualified entity. This collection also covers the triennial re-application through which organizations provide information to CMS to determine whether they are approved to continue as a qualified entity and the QECF Annual Report Worksheet (ARW). *Form Number:* CMS-10394 (OMB control number: 0938-1144); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 40; *Total Annual Responses:* 70; *Total Annual Hours:* 5,800. (For policy questions regarding this collection contact Kari Gaare at kari.gaare@cms.hhs.gov.)

2. Type of Information Collection Request: Re-instatement without change of a previously approved collection; **Title of Information Collection:** Good Cause Processes; **Use:** Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D-1(b)(1)(B)(v) of the Act generally directs us to establish rules related to enrollment, disenrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. Consistent with these sections of the Act, subpart B in each of the Parts C and D regulations sets forth requirements with respect to involuntary disenrollment procedures at 42 CFR 422.74 and 423.44, respectively. In addition, section 1876(c)(3)(B) establishes that individuals may be disenrolled from coverage as specified in regulations.

These good cause provisions authorize CMS to reinstate a disenrolled individual's enrollment without interruption in coverage if the non-payment is due to circumstances that the individual could not reasonably foresee or could not control, such as an unexpected hospitalization. At its inception, the process of accepting, reviewing, and processing beneficiary requests for reinstatement for good cause was carried out exclusively by CMS. *Form Number:* CMS-10544 (OMB control number: 0938-1271); *Frequency:* Occasionally; *Affected Public:* Individuals and Households, Private Sector and Business or other for-profits; *Number of Respondents:* 54,789; *Total Annual Responses:* 54,789; *Total Annual Hours:* 36,490. (For policy questions regarding this collection

contact AnhViet Nguyen at 667-290-9745 or anhviet.nguyen@cms.hhs.gov.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-2279]

Preparation for International Cooperation on Cosmetics Regulation Twentieth Annual Meeting (ICCR-20); Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is soliciting comments from the public on various topics pertaining to the regulation of cosmetics in preparation for the twentieth International Cooperation on Cosmetics Regulation annual meeting (ICCR-20). We may use this input to help us prepare for the ICCR-20 meeting that will be held July 7 to 9, 2026, in Tokyo, Japan.

DATES: Either electronic or written comments on this notice must be submitted by May 18, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 18, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-2026-N-2279 for "Preparation for International Cooperation on Cosmetics Regulation Twentieth Annual Meeting (ICCR-20); Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Deborah Smegal, Office of Cosmetics and Colors, Office of the Chief Scientist, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1818, Deborah.Smegal@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The intention of the International Cooperation on Cosmetics Regulation (ICCR) multilateral framework is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection. FDA is soliciting comments from the public on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the twentieth ICCR annual meeting (ICCR-20) that will be held July 7 to 9, 2026, in Tokyo, Japan.

ICCR is a voluntary international group of cosmetics regulatory authorities, including the United States. These regulatory authority members will engage in dialogue with their relevant cosmetics industry trade associations and other interested parties. The current ICCR members can be found at: <https://www.iccr-cosmetics.org/>. The ICCR generally operates on a consensus-based decision-making process (see <https://www.iccr-cosmetics.org/topics-documents/4-iccr-governance>). All decisions will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments of the ICCR members. Members will implement and/or promote actions or documents within

their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from interested parties.

ICCR considers various topics of common interest and relevance for cosmetics (see <https://www.iccr-cosmetics.org/topics-documents>).

II. Request for Comments

FDA is requesting public comment on the following questions related to topics identified for the ICCR-20 meeting.¹ FDA is also requesting public comment on any additional cosmetics topics of interest for consideration by ICCR for future work.

1. What new International Organization for Standardization (ISO) standards and technical reports should be considered for inclusion in the Updated Annex of International Standards in Cosmetics Report (Ref. 1)?

2. What new non-animal testing methods should be considered for inclusion in the Inventory of Validated Non-Animal Testing Methods Applicable for Cosmetic Products and their Ingredients in all ICCR Regions (Ref. 2)?

3. What are your suggestions to help make risk assessment using non-animal data a more common approach for safety assessments of cosmetic ingredients?

4. What general principles should be considered for electronic labeling (e-labeling) and digital information for cosmetics across ICCR member jurisdictions?

5. What are common questions and misconceptions and ways to improve understanding related to cosmetics use, safety, and regulation that arise across ICCR member jurisdictions?

6. What are your suggestions for any changes to or considerations for ICCR’s purpose, mission, and future direction?

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. ICCR, “Updated Annex of International Standards in Cosmetics Report.” 2025. Accessed March 4, 2026. Available at:

¹ Topics for the ICCR-20 meeting were identified at the ICCR-19 meeting held on July 8 to 10, 2025, in Ottawa, Ontario, Canada. Outcomes of the ICCR-19 meeting are available at <https://www.iccr-cosmetics.org/component/attachments/attachments?id=175&task=download>.

<https://www.iccr-cosmetics.org/component/attachments/?task=download&id=181>.

2. ICCR, “Inventory of Validated Non-Animal Testing Methods Applicable for Cosmetic Products and their Ingredients in all ICCR Regions.” 2025. Accessed March 4, 2026. Available at: <https://www.iccr-cosmetics.org/downloads/topics/2025-updated%20annex%20of%20validated%20non-animal%20testing%20methods%20applicable%20for%20cosmetics.pdf>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0008]

Advisory Committee; Obstetrics, Reproductive and Urologic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Obstetrics, Reproductive and Urologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Obstetrics, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 23, 2028, expiration date.

DATES: Authority for the Obstetrics, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, (301) 796-7973, ACOMSSubmissions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 21 CFR 14.40(b) and 41 CFR 102-3.65, and following approval by the Department of Health and Human Services and review by the General Services Administration, FDA is