Dated: September 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1029]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Facility Registration, Product Listing, and Labeling Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 18, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0599. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Cosmetic Facility Registration, Product Listing, and Labeling Requirements

OMB Control Number 0910–0599—Revision

This information collection supports implementation of statutory and regulatory provisions that govern cosmetics. On December 29, 2022, the President signed into law the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), which included the Modernization of Cosmetics Registration Act of 2022 (MoCRA). MoCRA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by requiring, among other requirements, manufacturers of cosmetic products to label products intended for use only by licensed professionals to bear a label that the product must be administered or used only by licensed professionals, in addition to providing the same information on the label that is required of cosmetic products intended for consumers. MoCRA also added the requirement for cosmetic product labels to include contact information through which the responsible person can receive adverse event reports. Other requirements introduced by MoCRA include facility registration, cosmetic product listing, and associated recordkeeping.

Cosmetic Labeling Requirements

The FD&C Act and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 331, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

FDA's cosmetic labeling regulations are codified in part 701 (21 CFR part 701). Section 701.3 (21 CFR 701.3) requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 (21 CFR 701.11) requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 (21 CFR 701.12) requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 (21 CFR 701.13) requires the label of a cosmetic product to declare the net quantity of contents of the product.

MoCRA amended the FD&C Act by requiring, among other requirements, manufacturers of cosmetic products to label products intended for use only by licensed professionals to bear a label that the product must be administered or used only by licensed professionals, in addition to providing the same information on the label that is required of cosmetic products intended for consumers. MoCRA also added the requirement for cosmetic product labels to include contact information (domestic address, phone number, or electronic contact information that may include a website) through which the responsible person can receive adverse event reports.

Facility Registration and Cosmetic Product Listing Program

MoCRA amended the FD&C Act by requiring, among other requirements, operators and owners of facilities manufacturing or processing cosmetic products to register with FDA and renew such registrations biennially. Facilities will also need to notify FDA of any changes to information that was required as part of registration. FDA may suspend registration if we determine that a cosmetic product manufactured or processed by a registered facility has a reasonable probability of causing serious adverse health consequences or death. Upon notice that FDA intends to suspend registration, the responsible person for the facility may submit a corrective action plan for addressing the reasons for possible suspension of the facility registration. MoCRA also added the requirement for responsible persons to submit a product listing for each of their cosmetic products to FDA.

As we update our infrastructure to include a mechanism to accept submissions for registrations and product listings consistent with the provisions in MoCRA, we have discontinued use of Forms FDA 2511, 2512, and 2512a, previously used for voluntary registration activities and have stopped accepting new submissions to the Voluntary Cosmetic Registration Program (VCRP).

Description of Respondents: Respondents to this collection of information include cosmetic manufacturers and processors. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of May 1, 2023 (88 FR 26564), we published a 60-day notice requesting public comment on the proposed collection of information. Several comments were received, however those not pertaining to the PRA topics solicited in the notice are not addressed. Comments pertaining to the necessity and practical utility of the information being collected included concerns with protecting privacy and

confidential commercial information. One comment expressed concern for the disclosure of a person's residential address while another suggested that a contract manufacturer would not be able to comply with the facility registration provisions without disclosing the brands it is manufacturing.

Comments pertaining to the accuracy of our burden estimates questioned whether FDA assumes manufactures will need to change their label due to new labeling requirements, whether our listing figures reflect only products in the U.S. market or the number of products each manufacturer makes, and another comment suggested that submissions for registration and product listing will take more time than FDA estimated based on its experience with VCRP.

Comments regarding ways to enhance the quality, utility, and clarity of the information to be collected suggested that registration under MoCRA should mirror FDA's Food Facility Registration program, including aligning the biennial registration schedule between the programs. Finally, comments regarding ways to minimize the burden of the collection of information on respondents requested that FDA extend the deadline for manufacturers to comply with the newly mandated labeling, registration, and product listing requirements. Other comments sought more information about the electronic system and forms for registration and product listing including whether there is a fee.

While we have increased burden estimates we attribute to product listing reporting activities in response to these public comments, we intend to refrain from making further modifications to our burden estimates until we have more experience with implementation of the new mandatory requirements. Privacy and trade-secret, commercial confidential information is governed by the Privacy Act of 1974 and part 20 of our regulations (21 CFR part 20). The registration and listing requirements set forth in section 605 of the FD&C Act (21 U.S.C. 364(c)) require that FDA begin receiving registration and listing information no later than December 29, 2023. We have therefore made no other modifications to the proposed collections of information.

At the same time, on our own initiative we have taken the following actions:

- We have developed Form FDA 5066 entitled ''Registration of Cosmetic Product Facility,'' and Form FDA 5067 entitled ''Cosmetic Product Listing,'' to be used for registrations and product listings, respectively. These forms will be available in paper format or via an electronic system for submission. Draft screenshots of the paper forms and electronic system for submission are available for viewing at *https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products.*
- We developed Agency guidance to further assist industry with cosmetic registration and product listing requirements. In the **Federal Register** of August 8, 2023 (88 FR 53490), we announced the availability of a draft guidance for industry entitled ''Registration and Listing of Cosmetic Product Facilities and Products'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-registration-and-listing-cosmetic-product-facilities-and-products*). The draft guidance, when finalized, is intended to provide instruction and further assist industry in preparing and submitting registrations and product listings required by MoCRA. The draft guidance discusses, among other things, who must register and list, when, and what must be submitted.
- Also in the **Federal Register** of August 8, 2023 (88 FR 53499), we announced a pilot, including instruction on participation, intended to gather input to inform evaluation of the new electronic cosmetic registration and listing submission portal.
- We have added information collection elements to account for mandatory adverse event recordkeeping requirements under new section 605 of the FD&C Act added by MoCRA, and we are revising OMB control number 0910–0291 to include corresponding adverse event reporting. We are currently modifying our MedWatch forms, approved in 0910–0291, to receive mandated adverse event reporting elements associated with cosmetic products as introduced by MoCRA.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Legal authority; information collection activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [2]
§ 701.3; ingredients in order of predominance	1,518	21	31,878	1	31,878	.....
§ 701.11; statement of identity	1,518	24	36,432	1	36,432	.....
§ 701.12; name and place of business	1,518	24	36,432	1	36,432	.....
§ 701.13; net quantity of contents	1,518	24	36,432	1	36,432	.....
Sec. 609(a) of the FD&C Act (MoCRA); contact information to send adverse event reports	1,518	24	36,432	1	36,432	$91,080,000
Sec. 609(c) of the FD&C Act (MoCRA); professional use only	100	12	1,200	1	1,200	3,000,000
Total	.....	.....	.....	.....	178,806	94,080,000

[1] There are no operating and maintenance costs associated with this collection of information.
[2] One-time burden for capital costs.

The estimated annual third-party disclosure burden for labeling is based on data available to the Agency, our knowledge of and experience with cosmetics, and informal communications with industry. The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: a declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a

declaration of the net quantity of contents. These requirements increase the time establishments needed to design labels because they increase the number of label elements that establishments must consider when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices. Regarding the new statutory labeling requirements for products intended for professional use only and contact information for manufacturers to receive reports of adverse events, we estimate that there will be a capital cost of $94,080,000 associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time cost.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Legal authority; information collection activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Sec. 607(a)(1) of the FD&C Act; initial registrations.	3,400	1	3,400	0.5 (30 minutes)	1,700
Sec. 607(a)(2) and (5) of the FD&C Act; biennial registration renewals.	1,700	1	1,700	0.25 (15 minutes)	425
Sec. 607(a)(4) of the FD&C Act; registration updates.	100	1	100	0.25 (15 minutes)	25
Sec. 607(f) of the FD&C Act; post-hearing corrective action plan.	5	1	5	10	50
Sec. 607(c)(1) and (2) of the FD&C Act; cosmetic product listing.	3,400	10	34,000	1	34,000
Sec. 607(c)(3) of the FD&C Act; product listing abbreviated renewals.	3,400	10	34,000	0.25 (15 minutes)	8,500
Sec. 607(c)(5) of the FD&C Act; product listing updates.	200	1	200	0.25 (15 minutes)	50
Total					44,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of reporting burden hours on information from the VCRP, because it provided the best available data to FDA in terms of the number of respondents and responses. We believe that the VCRP reflected less than half of cosmetic manufacturers and processors because it was a voluntary system. We initially doubled our estimate for the number of respondents registering and used this number to estimate other activities related to facility registration and cosmetic product listing. We have since further increased the number of product listings per respondent, which also increases the number of responses (products). Based on a review of the information collection since our last request for OMB approval, we have increased our estimate to account for an anticipated increase in respondents and responses resulting from new statutory requirements.

MoCRA amended the FD&C Act by adding section 605 to require, among other requirements, responsible persons to submit reports of serious adverse events to FDA no later than 15 business days after receiving the report, including any new medical information received within 1 year of the initial report. The responsible person shall receive adverse event reports through the domestic address, domestic telephone number, or electronic contact information included on the label. Further, FDA may request a complete list of ingredients in specific fragrances or flavors in a cosmetic product if FDA has reasonable grounds to believe that an ingredient or combination of ingredients has caused a serious adverse event. We are revising the scope of OMB control number 0910–0291 to include this reporting activity as we modify corresponding electronic and paper-based forms.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Legal authority; information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Sec. 605(e) of the FD&C Act; adverse events records.	1,000	1	1,000	0.5 (30 minutes)	500

[1] There are no capital costs or operating costs associated with the collection of information.

MoCRA also amended the FD&C Act by adding recordkeeping requirements. Responsible persons are required to maintain records related to each report of an adverse event for a period of 6 years (or 3 years for a small business that does not manufacture or process certain cosmetic products) and authorizes FDA to have access to such records during an inspection. We base our estimate of recordkeeping burden hours on estimates found in the information collection approved under OMB control number 0910–0291 (FDA's Adverse Event and Product Experience Reporting Program). The collection currently estimates 1,793 paper reports and 1,398 Safety Reporting Portal submissions, for CFSAN which includes food, infant formula, and cosmetic products, equaling 3,191. We estimate that cosmetic products account for around a third of the reports (estimating 1,000) with each report corresponding to a separate recordkeeping. We estimate that maintaining the record will take 30 minutes. However, once the

documents pertaining to an adverse event report have been assembled and filed in accordance with MoCRA, we expect the records retention burden to be minimal, as we believe most responsible persons would normally keep this kind of record for at least several years after creating the document, as a matter of usual and customary business practice.

Dated: September 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report, OMB No. 0915–0172—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than October 18, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Title V Maternal and Child Health (MCH) Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915–0172—Revision

Abstract: The Title V MCH Services Block Grant to States Program is authorized by Sections 501–509 of Title V of the Social Security Act (42 U.S.C. 701–709). HRSA is updating the *Title V MCH Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* (''Guidance''). The updated edition will be the tenth edition of the Guidance. This Guidance is used annually by the 50 states and nine jurisdictions [1] (hereafter referred to as ''state'') in applying for Block Grants under Title V of the Social Security Act and in preparing the required Annual Report. The updates being proposed by HRSA's Maternal and Child Health Bureau for the tenth edition of the Guidance continue to support the federal-state partnership that is supported by the Title V MCH Services Block Grant and the state's role in developing a 5-Year Action Plan that addresses its individual priority needs. These proposed updates build on and further refine the reporting structure and vision that was outlined in the previous ninth edition. As such, they are intended to enable a state to articulate a comprehensive description of its Title V program activities and its leadership efforts in advancing and assuring a public health system that serves the MCH population. HRSA's proposed updates to the tenth edition of the Guidance were informed by consultation with State Title V MCH agencies, and by comments received from State Title V program leadership, national MCH leaders, other MCH stakeholders, and the public. A 60-day notice was published in the **Federal Register** on May 5, 2023, vol. 88, No. 87; pp. 29135–37 FR 29135–37. HRSA received 170 comments on the proposed updates to the tenth edition of the Guidance, from a variety of responders, including state Title V Programs, other state agencies, public health organizations, universities, members of the community, and other stakeholders. Of the 170 comments, 80 requested that stillbirth be addressed in the Guidance, and 71 requested that the oral health performance measures be retained as a national performance measure. The remainder of 19 comments included suggestions for clarifying instructions in certain sections of the Guidance, including examples of partnership with non-governmental organizations and family organizations, or responding to reporting burden on the universal performance measures. HRSA considered all public comments as part of its deliberative process in finalizing updates to the tenth edition of the *Title V MCH Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report.*

A discussion of the public comments received during the 60-day comment period and HRSA's response to the comments is set below:

(1) *Revised Approach for Interim-Year Reporting:* States and diverse stakeholders expressed strong support for the proposed approach that would allow states to decide whether updates are needed to numerous sections of the guidance during interim years 2 through 5, following submission of the 5-year Needs Assessment in year 1. In response to these comments, HRSA will maintain this approach in the tenth edition of the Guidance.

(2) *Streamlining and Reorganizing of the Guidance:* States and diverse stakeholders expressed strong support for the proposed approach of streamlining and reorganizing the requirements for state narrative reporting, in order to eliminate duplication. In response to these comments, HRSA will maintain this approach in the tenth edition of the Guidance.

(3) *Family and Community Partnership:* HRSA received comments related to clarifying expectations on reporting about family and community partnerships. In response to these comments, expectations around state Title V reporting on family and community partnerships will be clarified, such as reporting on partnership with HRSA's Family-to-Family Health Information Centers, discussion on the impact these partnerships have on the MCH population, and their value in improving outcomes.

(4) *Health Equity:* Comments received from states and stakeholders support the stronger emphasis on health equity, including it being a guiding principle of the Title V Program. In response to these comments, HRSA will maintain this approach in the tenth edition of the Guidance.

[1] The following nine jurisdictions receive Title V Maternal and Child Health Block Grant Program funding: the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, the Commonwealth of Puerto Rico, the US Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.