DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1029]

Agency Information Collection Activities; Proposed Collection; Comment Request; Cosmetic Labeling Requirements and Facility Registration and Cosmetic Product Listing Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions in FDA's cosmetic labeling regulations and new statutory provisions for cosmetic labeling, facility registration, and products listing.

DATES: Either electronic or written comments on the collection of information must be submitted by June 30, 2023.

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 June 30, 2023. 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–2023–N–1029 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Cosmetic Labeling Requirements and Facility Registration and Cosmetic Product Listing Program.'' 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Cosmetic Labeling Requirements and Facility Registration and Cosmetic Product Listing Program

OMB Control Number 0910–0599—Revision

This information collection supports FDA's cosmetic labeling regulations and new statutory provisions for cosmetic labeling, facility registration, and products listing. 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 and cosmetic product listing.

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 develop a process 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).

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

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

21 CFR or FD&C Act section; 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. We estimate that the total third-party disclosure burden is 178,806 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

MoCRA citation; activity	Number of respondents	Number 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	1	3,400
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	5	17,000	0.50 (30 minutes)	8,500
Sec. 607(c)(3) of the FD&C Act; product listing renewals.	3,400	5	17,000	0.25 (15 minutes)	4,250
Sec. 607(c)(5) of the FD&C Act; product listing updates.	200	1	200	0.25 (15 minutes)	50
Total	.....	.....	.....	.....	16,700

[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. Accordingly, we 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. 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 resulting from new statutory requirements.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09178 Filed 4–28–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1052]

Food and Drug Administration Data and Technology Strategic Plan; Request for Information and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice announcing a request for information and comments that appeared in the **Federal Register** of April 13, 2023. In that notice, FDA requested information and comments on the FDA Data and Technology Strategic Plan. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published April 13, 2023 (88 FR 22453). Either electronic or written comments must be submitted by June 12, 2023, to ensure that the Agency considers your comment on this request for information and comments before it begins work on the strategic plan.

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 June 12, 2023. 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