UNITED STATES FOOD & DRUG ADMINISTRATION

Cosmetic Facility Registration, Product Listing, and Labeling Requirements

OMB Control No. 0910-0599 – Revision

SUPPORTING STATEMENT **Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

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). We have established and maintain updates and informational resources on our website at https://www.fda.gov/cosmetics/cosmetics-news-events to communicate ongoing implementation activities. We discuss our outreach efforts more fully in Q-8 of this supporting statement and 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 no. 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.

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

We are therefore requesting OMB approval of the information collections as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information required to be disclosed in FDA's cosmetic labeling regulations is used by consumers of cosmetic products when evaluating, purchasing, and using the products. We use the information to evaluate cosmetic products currently on the market and to verify compliance with the requirements for labeling cosmetic products. MoCRA also added labeling requirements for cosmetic products to disclose contact information through which the responsible person can receive adverse event reports and for a cosmetic product that is for professional use only.

Registration of cosmetic product establishments provides FDA with information about the location of each cosmetic product facility; all brand names under which cosmetic products manufactured or processed in the facility are sold; cosmetic product category or categories; and the responsible person for each cosmetic product manufactured or processed at the facility. We will place registration information into a computer database and use the information to help verify compliance with requirements for cosmetic products. We will also use the information for estimating the size of the cosmetic industry, evaluating cosmetic products currently on the market, and conducting onsite establishment inspections.

Product listings provide FDA with information about cosmetic products and their ingredients including frequency of ingredient use, as well as the businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance. The information assists FDA scientists in evaluating reports of alleged injuries and adverse reactions from the use of cosmetics. The information also is used in defining and planning analytical and toxicological studies pertaining to cosmetics**.**

The recordkeeping requirements for adverse events related to cosmetic products are important for public health reasons. Records could assist with investigations into public health or safety issues associated with cosmetic products. Records could provide a reliable mechanism to track patterns of adulteration in cosmetics that would support efforts by FDA to target limited inspection resources to protect the public health.

3. Use of Improved Information Technology and Burden Reduction

Labeling

Cosmetic product manufacturers, packers, and distributors may use any available information technology to develop their product labels. However, there is currently no information technology that establishments can use as a substitute for conventional product labels to deliver the necessary information to consumers.

Registration and Product Listings

We have developed an option for electronic submission of registrations and product listings consistent with provisions in MoCRA. 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 strongly encourage use of the electronic system for submission because we believe it will improve agency efficiency and responsiveness to the public.

Recordkeeping for Adverse Event Reporting

The information collection does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Respondents may use whatever forms of information technology for retaining the appropriate records and making them available to regulatory officials upon request or as mandated by MoCRA for submission of serious adverse events to FDA.

We estimate that approximately ninety-five percent (95%) of respondents will use information technology to accomplish their information collection needs.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately eighty percent (80%) of the establishments that will be affected by this information collection request probably qualify as a small business with sales under $5,000,000 per year. Certain small businesses, as defined in section 612 of the FD&C Act are exempt from registration and listing requirements. Responsible persons, and owners and operators of facilities, whose average gross annual sales in the United States of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, are exempt from registration and listing requirements unless they manufacture, or process certain products specified in MoCRA.

We set requirements to the minimum requirements that comply with the appropriate provisions of the FD&C Act, including MoCRA, and the FPLA. In most cases, the information that FDA requires establishments, including small businesses, to disclose is information that is available to those establishments in the normal course of doing business.

We aid small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the agency. We also help via our Small Business Assistance webpage at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with applicable statutory and regulatory authorities. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

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 were 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 increased the burden we attribute to product listing reporting activities in response to these public comments, we communicated in our 30-day notice of September 18, 2023 (88 FR 63960) that we intend to refrain from making further modifications to our burden estimates until

we have more experience with implementation of the new mandatory requirements. We also communicated that 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); and that registration and listing requirements are set forth in section 605 of the FD&C Act (21 U.S.C. 364(c)) and mandate that FDA begin receiving registration and listing information no later than December 29, 2023.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. The information collection request (ICR) is collecting personally identifiable information (PII) or other data of a personal nature. Information is collected via Form FDA 5066 (*Registration for Cosmetic Product Facility*) and Form FDA 5067 (*Cosmetic Product Listing*). The PII collected is name, phone number, and email address in both forms. PII is collected in the context of the individual's professional capacity. The collection of information for this ICR is found in MoCRA and 21 CFR parts 701, 710, and 720.

We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, we do not use name or any other personal identifier to retrieve records from the information collected.

None of the information required to appear on the label or labeling of cosmetic products that the agency regulates is confidential.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR or FD&C Act Section; Activity	No. of Respondents	No. 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	1,518	24	36,432	1	36,432	$91,080,000

21 CFR or FD&C Act Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs[2]
Act (MoCRA); contact information to send adverse event reports						
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 FDA, 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 need 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	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	0.50 (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

MoCRA Citation; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
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.

Table 3.--Estimated Annual Recordkeeping Burden[1]

MoCRA Citation; Activity	No. of Recordkeepers	No. 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.

We base our estimate of recordkeeping burden hours on estimates found in the information collection approved under OMB control no. 0910-0291 (FDA's Adverse Event and Product Experience Reporting Program). The collection currently estimates 1,793 paper reports & 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.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be approximately $20,227,775.68.

We estimate that the label design process will involve an employee making an average wage similar that of a Federal government employee at the GS-12/Step-1 rate for the Washington-

Baltimore locality pay area for the year 2023, which is $45.14 per hour. To account for overhead, this cost is increased by 100 percent, which is $90.28 per hour. Thus, the estimated cost imposed by third-party disclosures is approximately $16,142,605.68 (178,806 hours x $90.28 per hour).

We estimate that the average hourly wage for the employee preparing and submitting the registrations and product listings would also be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2023, approximately $45.14/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $90.28/hour. Thus, the estimated cost incurred by reporting is $4,040,030 (44,750 burden hours x $90.28/hr).

We estimate that the average hourly wage for the employee assembling and retaining records for adverse event reporting required by MoCRA would also be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2023, approximately $45.14/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $90.28/hour. Thus, the estimated cost incurred by recordkeeping is $45,140 (500 burden hours x $90.28/hr).

Table 4.--Annual Cost Burden Estimate

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Label Design Process	178,806	$90.28	$16,142,605.68
Preparation and submission of registration and product listing	44,750	$90.28	$4,040,030.00
Recordkeeping for adverse event	500	$90.28	$45,140.00
Total			$20,227,775.68

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

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.

14. Annualized Cost to the Federal Government

As part of FDA's responsibility to enforce the provisions of the FD&C Act (including MoCRA) and the FPLA, the agency conducts the Cosmetics Compliance Program to evaluate cosmetic products for compliance with the labeling requirements. Under this program, FDA's field offices carry out investigations, inspections, sample collections, sample analyses, and other compliance activities, and FDA's headquarters provides guidance for field office activities. In addition, we provide advice to representatives of cosmetic establishments and start-up businesses regarding the labeling requirements for cosmetic products. We estimate that the agency needs six professional staff persons per year (12,480 hours) to review compliance and regulatory activities related to cosmetic labeling. Using an hourly cost to the agency of $45.14 per hour (the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2023, increased by 100 percent, which

is $90.28 to account for overhead), we estimate the annual cost to the Federal government to be $1,126,694.40 (12,480 x $90.28 per hour).

We have also allocated FTEs to review the submissions and maintain computer files, which requires about 200 hours annually for registrations and 12,000 hours annually for product listings, for a total of 12,200 hours annually. We estimate that, on average, the hourly cost for review and evaluation of the submissions is approximately $45.14 per hour, the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2023. To account for overhead, this cost is increased by 100 percent, making the total cost $90.28 per hour. Thus, we estimate the cost to the Federal government for the review of submissions to be $1,101,416 ($90.28/hour x 12,200 hours).

Our review of the retained records occurs as part of inspection activities. We devote approximately 5 hours per inspection to the inspection of records. We estimate the cost to the Federal government for the review of records retained by a firm to be $491.90 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation to be $49.19 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2020. Five hours multiplied by $49.19 per hour equals $245.95. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government $491.90 per review. If we inspected 1,000 firms annually, we estimate that the total annual cost to the Federal government would be $491,900 ($491.90 x 1,000).

Therefore, the total government cost for this collection of information is **$2,720,010.40** ($1,126,694.40 [labeling] + $1,101,416 [registration and product listing] + $491,900 [recordkeeping]).

15. Explanation for Program Changes or Adjustments

This information collection reflects program changes introduced by new legislation. The burden for this information collection reflects an overall increase of 79,838 burden hours and an increase of 100,782 responses annually. We have also proposed new collection instruments as we continue to implement the new statutory provisions.

16. Plans for Tabulation and Publication and Project Time Schedule

We intend to develop a mechanism to provide public access to relevant information found in cosmetic product facility registrations and listings to the extent permitted by law. We are not specifying that mechanism as we continue to contemplate the most efficient method available.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.