

UNITED STATES FOOD & DRUG ADMINISTRATION

Requirements for Cosmetic Products

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 requirements that govern cosmetic products, including requirements established under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). MoCRA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, in pertinent part, sections 604, 605, 607, 608, and 609 ([21 U.S.C. 364b](#), [364c](#), [364e](#), and [364g](#)), which establish or amend definitions and requirements related to adverse events, facility registration, cosmetic product listing, safety substantiation, and labeling. For purposes of this information collection, the relevant provisions of the U.S. Food and Drug Administration’s (FDA) regulations in [Title 21 of the CFR](#) are set forth in [21 CFR part 701, subparts A, B, and C](#) (§§ 701.1-701.30), which establish cosmetic labeling requirements, including general provisions, package form requirements, and labeling requirements for specific ingredients.

The respondents to this information collection consist primarily of responsible persons as defined in section 604(4) of the FD&C Act, meaning the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FD&C Act or section 4(a) of the Fair Packaging and Labeling Act. The respondent totals and burden figures are based on facility registration, cosmetic product listing, and labeling data derived from multiple submission pathways, including Cosmetics Direct, the Electronic Submission Gateway (ESG) Next Generation (NextGen), Structured Product Labeling (SPL) authoring software, and paper submissions. Cosmetics Direct is an online submission tool that allows users to enter required data, generate an SPL submission, and submit facility registrations, product listings, and requisite renewals for cosmetic products directly to FDA. Alternatively, industry may use its own software to create an SPL-formatted submission and transmit the submission to FDA through the ESG.

To assist respondents with information collection and provide an alternative to the ESG NextGen electronic submission process, we have also developed **Form FDA 5066**, entitled “*Registration of Cosmetic Product Facility*,” and **Form FDA 5067**, entitled “*Cosmetic Product Listing*,” to be used for cosmetic product facility registrations and product listings, respectively. These forms are available electronically and in paper format at <https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products>.

We have also developed the guidance document, “*Registration and Listing of Cosmetic Product Facilities and Products*” (December 2024), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-registration-and-listing-cosmetic-product-facilities-and-products>. The guidance document is intended to provide instruction in preparing and submitting registration and product listing information as required by section 607 of

the FD&C Act. The guidance document discusses, among other things, who must register and list, when, and what information must be submitted to FDA.

We are therefore requesting OMB approval of the information collection provisions established in the applicable authorities and associated collection instruments, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information required to be disclosed by FDA's cosmetic labeling statutory provisions and regulations is used by consumers of cosmetic products when evaluating, purchasing, and using the products. The FD&C Act also requires that cosmetic products bear labels that disclose contact information through which the *responsible person* can receive adverse event reports, and that cosmetic products intended for professional use only bear a label indicating that they are for use by licensed professionals only. We use the information to evaluate cosmetic products currently on the market and to verify compliance with the requirements for labeling cosmetic products.

Registration of cosmetic product facilities provides FDA with information about the location of and contact information for each facility; all brand names under which cosmetic products manufactured or processed in the facility are sold; and cosmetic product category or categories and the responsible person for each cosmetic product manufactured or processed at the facility. We compile registration information into a computer database and use the information to help verify compliance with requirements for cosmetic products. We 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, which FDA uses to inform frequency of ingredient use, proportions of cosmetic product categories, 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 developing and planning analytical and toxicological studies pertaining to cosmetics.

The recordkeeping requirements for safety substantiation and adverse events related to cosmetic products provide important support to the Agency's public health mission. Records could assist with investigations into public health issues associated with cosmetic products. Records could provide a reliable means of facilitating identification of the root cause and/or extent of a cosmetic issue, thereby enabling FDA to more effectively focus its limited inspection resources to areas where they are most needed to protect 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 or a firmly affixed tag, tape, or card as permitted under 21 CFR 701.3(b) 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 the statutory provisions as added by MoCRA. The paper forms and screenshots of the 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 improves agency efficiency and data management.

Recordkeeping for Adverse Event Reporting and Safety Substantiation

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 to maintain records. Respondents may use whatever forms of information technology they deem appropriate for retaining the appropriate records and making them available to regulatory officials upon request or as mandated by the FD&C Act.

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 facilities that will be affected by this information collection request likely qualify as a small business. Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from cosmetic product facility registration and product 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 the FD&C Act.

We set requirements to the minimum requirements that comply with the appropriate provisions of the FD&C Act and the FPLA. In most cases, the information that establishments, including small

businesses, are required to disclose is information that is available to those establishments in the normal course of doing business.

We aid small businesses in complying with their requirements through the administrative and scientific staff. 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. The information is provided in the timing necessary to efficiently satisfy these legal requirements. Delays in reporting, disclosing, or maintaining this information may have negative impacts on public health.

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

We published a 60-day notice requesting public comment on the proposed collection of information in the *Federal Register* on July 17, 2026 (91 FR 44850). Two comments were received. While neither directly discussed the information collection topics solicited under 5 CFR 1320.8(d)(1), both comments suggested potential updates to FDA's registration system intended to increase efficiency. We appreciate these comments and plan to undertake updates and enhancements to our information collection systems as resources permit.

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

The Privacy Act of 1974

We consulted with our Privacy Office to ensure appropriate handling of information collected. Although the information collection is collecting personally identifiable information (PII) or other data of a personal nature, it is collected in the context of the individual's professional capacity. Information submitted through Cosmetics Direct, ESG NextGen, Form FDA 5066 (*Registration of Cosmetic Product Facility*), and Form FDA 5067 (*Cosmetic Product Listing*) includes name, phone number, and email address. The collection of information for this information collection request is found in the FD&C Act 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.

The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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 Reporting and Recordkeeping Burden¹

Information Collection Activity; FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Sec. 605(e)(1): adverse event recordkeeping	1,165	1.2	1,398	0.6 (36 minutes)	839
Sec. 607(a)(1): initial facility registrations	8,343	1	8,343	0.5 (30 minutes)	4,172
Sec. 607(a)(2) and (5): biennial facility registration renewals and abbreviated facility registration renewals	2,107	1	2,107	0.17 (10 minutes)	358
Sec. 607(a)(4): facility registration updates	3,141	1	3,141	0.25 (15 minutes)	785
Sec. 607(f): post-hearing corrective action plan	5	1	5	10	50
Sec. 607(c)(1) & (2): initial cosmetic product listing	22,564	14.64	330,337	1	330,337
Sec. 607(c)(3): abbreviated cosmetic product listing renewals	25,190	1	25,190	0.10 (6 minutes)	2,519
Sec. 607(c)(5): cosmetic product listing updates	3,020	8.15	24,613	0.25 (15 minutes)	6,153
Sec. 608(a): safety substantiation recordkeeping	22,564	1	22,564	1	22,564
TOTAL			417,698		367,777

¹There are no capital or operating and maintenance costs associated with the information collection.

Because 5 CFR 1320.3(m) defines a recordkeeping requirement to include the reporting to the Federal government regarding such records, we have denoted table 1 as recordkeeping burden, noting that applicable requirements include the submission of information to FDA. We estimate a total burden of 367,777 hours associated with annual reporting and recordkeeping requirements cumulatively.

For facility registration activity, we assume approximately 8,343 annual respondents will engage in initial facility registration. Respondents are required to register their facility only once and

based on internal trials and communication with industry, we estimate that registration will take approximately 30 minutes to complete for a total of 4,172 burden hours. Facility registration renewal occurs every two years. Therefore, the initial facility registration figure does not represent all currently active registrations and may appear low compared to the number of cosmetic product listing activity respondents. Differences in the timing of respondents completing initial facility registrations account for differences in respondent totals for initial facility registration, registration renewals, and registration updates. Additionally, renewals and updates typically involve less information input than the initial registration which accounts for their smaller average burden per response and total burden hours.

For cosmetic product listing activity, we assume a total of approximately 22,564 cosmetic product listing respondents and 25,190 cosmetic product listing renewal respondents. However, these figures may overestimate the total number of unique respondents because some respondents may both list new products in compliance with section 607(c)(1) and (2) of the FD&C Act and renew or update existing cosmetic product listings under section 607(c)(5) of the FD&C Act. Additionally, the total number of initial cosmetic product listing and listing renewal respondents will differ due to variation in the timing of respondents completing initial cosmetic product listings, as well as the voluntary nature of product listing renewals. For cosmetic product listing, we estimate an average of ~ 14.64 responses per respondent, which amounts to 330,337 responses, at an average rate of 1 hour response, for a total of 330,337 total burden hours. Like facility registration, cosmetic product listing renewals and updates typically involve less information input than the initial product listing which accounts for their smaller average burden per response and total burden hours.

Adverse event reporting is captured on **FDA Form 3500A**, and the associated data are collected under OMB Control Number 0910-0291 (FDA’s Adverse Event and Product Experience Reporting Program: MedWatch and the Safety Reporting Portal). Under section 605(e)(1) of the FD&C Act, a *responsible person* must maintain a record for six years (three years for qualifying small businesses) for each adverse event report that they are required to submit. Accordingly, the adverse event recordkeeping estimates presented in Table 1 are aligned with the data collected under OMB Control Number 0910-0291. However, because that information collection combines cosmetics-related adverse event reports with food and infant formula adverse event reports, the actual number of cosmetics adverse event reports may be lower than the figure presented here. We will update the estimate if more precise data becomes available.

We estimate that each of the 22,564 respondents will maintain, on average, one safety substantiation record. Because section 608(a) requires responsible persons to maintain records supporting the “adequate substantiation of safety” of cosmetic products, and because responsible persons have discretion in determining which records satisfy this requirement, we estimate that each respondent will create and maintain at least one record for compliance purposes.

Table 2.--Estimated Annual Third-Party Disclosure Burden¹

Regulatory Authority: Information Collection Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
21 CFR § 701.3: declaration of ingredients in order of predominance	5,738	21	120,498	1	120,498

Regulatory Authority: Information Collection Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
21 CFR § 701.11: statement of identity	5,738	24	137,712	1	137,712
21 CFR § 701.12: name and place of business	5,738	24	137,712	1	137,712
21 CFR § 701.13: net quantity of contents	5,738	24	137,712	1	137,712
FD&C sec. 609(a): contact information to send adverse event reports	5,738	24	137,712	1	137,712
FD&C sec. 609(c): professional use only	402	12	4,824	1	4,824
TOTAL			676170		676170

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

We estimate that 5,738 respondents will expend a total of 120,498 - 137,712 burden hours annually (21 CFR § § 701.3, 701.11-13) including required disclosures on an average of 21 - 24 product labels per respondent. Similarly, we estimate 5,738 respondents will expend a total of 137,712 hours per label annually to ensure that an average of 24 product labels display requisite adverse event reporting information, and that 402 respondents will expend an average of 4,824 hours annually disclosing requisite “professional use only” labeling on an average of 12 products.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for processes associated with this collection of information to be approximately \$102,452,958.58.

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 2026, which is \$49.07 per hour. To account for overhead, this cost is increased by 100 percent, which is \$98.14 per hour. Thus, the estimated cost imposed by third-party disclosures is approximately \$66,359,323.80 (676,170 hours x \$98.14 per hour).

We estimate that the average hourly wage for the employee preparing and submitting the facility registrations and product listings, as well as the employee assembling and retaining adverse event and safety substantiation records, would be equivalent to a GS-12/Step-1 level in the Washington-Baltimore locality pay area in 2026, or approximately \$49.07/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be \$98.14/hour. Thus, the estimated cost incurred by reporting is \$36,093,634.78 (367,777 burden hours x \$98.14/hr).

Table 4 – Annual Cost Burden Estimate

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Label design process	676,170	\$98.14	\$66,359,323.80
Preparation and submission of facility registration and product listing and adverse event and safety substantiation recordkeeping	367,777	\$98.14	\$36,093,634.78
Total			\$102,452,958.58

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

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

As part of FDA’s responsibility to enforce the provisions of the FD&C Act and the FPLA, the agency conducts the Cosmetics Compliance Program to evaluate cosmetic products for compliance with the labeling requirements. Under this program, FDA 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 to review compliance and regulatory activities related to cosmetic labeling for a total of 12,480 hours. Using an hourly cost to the agency of \$49.07 per hour (the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2026, increased by 100 percent, which is \$98.14 to account for overhead), we estimate the annual cost to the Federal government to be \$1,224,787.20 (12,480 x \$98.14 per hour).

We have also allocated FTEs to review the submissions and maintain electronic files, which requires about 200 hours annually for facility 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 \$49.07 per hour, the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2026. To account for overhead, this cost is increased by 100 percent, making the total hourly cost \$98.14 per hour. Thus, we estimate the cost to the Federal government for the review of submissions to be \$1,197,308 (\$98.14/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 \$583.50 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation to be \$58.35 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2026. To account for overhead, this cost is increased by 100 percent, making the total hourly cost \$116.70 per hour. Thus, making the total annualized cost to the Federal government \$583.50 per review. If

we inspected 1,000 firms annually, we estimate that the total annual cost to the Federal government would be \$583,500 (\$583.50 x 1,000).

Therefore, the total government cost for this collection of information is **\$3,005,595.20** (\$1,224,787.20 [labeling] + \$1,197,308 [facility registration and product listing] + \$583,500 [recordkeeping]).

15. Explanation for Program Changes or Adjustments

The information collection reflects both changes and adjustment. The increase in burden and respondents reflects continued implementation of program requirements mandated by the FD&C Act, as amended by MoCRA. Since the previous renewal of this information collection, more facilities have registered and undertaken applicable requirements. Cumulatively, the information collection reflects an increase of 819,891 burden hours and 840,657 responses annually. We have characterized this request as a revision because we have added instructional information for **Forms FDA 5066** and **5067** to include tutorials. As we continue to refine the collection instruments and the corresponding data elements we intend the tutorials for registration and product listing to assist respondents in providing the requisite elements. Similarly, we developed procedural guidance to assist respondents in understanding statutory requirements applicable to cosmetic products.

16. Plans for Tabulation and Publication and Project Time Schedule

We provide public access to information about cosmetic product facility registrations and listings to the extent permitted by law. Information about current registration and listing processes and figures is available at <https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products>.

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

For purposes of this information collection, there is no reason that the display of the OMB expiration date would be 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.