UNITED STATES FOOD & DRUG ADMINISTRATION

Cosmetic Labeling Regulations and
Voluntary Cosmetic Registration

OMB Control No. 0910-0599 - Revision

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations pertaining to cosmetic labeling and voluntary cosmetic registration. These regulations are codified in FDA regulations at 21 CFR parts 701, 710, and 720. For efficiency of agency operations we are revising the information collection to consolidate related activities.

Cosmetic Labeling Regulations

The Federal Food, Drug, and Cosmetic Act (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, 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. Under the FD&C Act and the FPLA, cosmetic labels must bear a statement of identity of the cosmetic product, the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the net quantity of contents. These requirements apply both to cosmetics that are marketed as consumer commodities (offered for retail sale) and to cosmetics that are manufactured and sold "for professional use only."

Under the FPLA, cosmetic products that are offered for retail sale must bear a declaration of the name of each ingredient in descending order of predominance, except that a fragrance or flavor may be listed as "*fragrance*" or "*flavor*." In addition, ingredients present at a concentration of less than 1 percent and color additives may be grouped at the end of the ingredient statement. The requirement for declaration of ingredients does not apply to non-retail professional-use-only products unless such declaration is specifically required by applicable regulations.

Voluntary Cosmetic Registration Program

The FD&C Act provides FDA with the authority to regulate cosmetic products in the United States. To assist us in carrying out our responsibility to regulate cosmetics, the agency developed the Voluntary Cosmetic Registration Program (VCRP). FDA forms for the VCRP (Forms FDA 2511, 2512, and 2512a) assist respondents submitting information by provide a uniform reporting instrument. Participation in the VCRP is voluntary under

provisions found in parts 710 and 720 (21 CFR parts 710 and 720) of our regulations. Participants have the option of submitting information via paper forms or via the online interface. The term "*form*" refers to both the paper form and the online system.

Pursuant to part 710, we request that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511, "*Registration of Cosmetic Product Establishment*." The online version of Form FDA 2511 is available on FDA's VCRP website at https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp. We strongly encourage online registration using Form FDA 2511 because it is faster and more efficient for the filer and the agency. A registering facility receives confirmation of online registration, including a registration number by email. The online registration system also allows for amendments to past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides us with the best information available about locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. We place registration information into a database and use the information to generate mailing lists for distributing regulatory information and inviting firms to participate in workshops on topics in which they may be interested. Registration is permanent, although we request that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

Pursuant to part 720 (21 CFR part 720), we request firms that manufacture, pack, or distribute cosmetics to file with the agency an ingredient statement for each of their products. Filing of cosmetic product ingredient statements is also voluntary. Ingredient statements for new submissions (§§ 720.1 through 720.4) are reported on Form FDA 2512, "*Cosmetic Product Ingredient Statement*," and on Form FDA 2512a, a continuation form. Amendments to product formulations (§ 720.6) are also reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, we request that the firm notify us that they have discontinued their cosmetic product by submitting an amended Form FDA 2512 (§§ 720.3 and 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality of a cosmetic ingredient under § 720.8.

Our use of an electronic system has been designed to make it easier for participants to provide cosmetic registration information to us about their products. The electronic submission system also assists participants, through interactive question and response scenarios, to identify submissions that will be ineligible to be accepted in VCRP because they do not meet parts 710 and 720 requirements. The electronic system reduces burden currently associated with the manual identification process for filers and FDA. The online version of Forms FDA 2512 and FDA 2512a are available on our VCRP website at https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp. The forms also include links between Forms FDA 2511 and 2512, clarification of what information should be entered into the forms, additional self-identifying fields, and the removal of certain duplicative fields.

Our paper-based process confirms that each submission meets the requirements established in parts 710 and 720 through the use of a manual process for both filers and FDA reviewers that may result in a long waiting period where filers must wait and then respond to questions generated by FDA, which may result in a high rejection rate. We have experienced a significant reduction in rejection rates when using the electronic forms.

We place cosmetic product filing information in a computer database and use the information when we receive inquiries about cosmetics marketed in the United States. Because filing of cosmetic product formulations is not mandatory, voluntary filings with FDA provide us with the best information available about cosmetic products, ingredients, frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. The information assists our scientists in evaluating reports of cosmetic adverse events submitted via the MedWatch and Field Operators (FACTS) systems. We also use the information in identifying future research projects, to evaluate the levels and safety of certain ingredients in cosmetics.

Accordingly, we request OMB approval of the information collection provisions associated with our cosmetic regulations in 21 CFR parts 701, 710, and 720, associated Forms FDA 2511, 2512, and 2512a, 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.

Registration of cosmetic product establishments is not mandatory so voluntary registrations provide FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. We place registration information into a computer database and use the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. We also use the information for estimating the size of the cosmetic industry, evaluating cosmetic products currently on the market, and for conducting onsite establishment inspections. Registration is permanent, although we request that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

Filing of cosmetic product formulations is not mandatory so voluntary filings provide FDA with the best information available about cosmetic product ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. 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.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, and distributors of cosmetics sold in the United States. Respondents are from the private sector (for-profit businesses).

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

We request that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511. The term "*Form FDA 2511*" refers to both the paper and the online registration system versions of the form. Both versions are available on FDA's VCRP website and we strongly encourage electronic registration because it is faster and more convenient. Registering facilities will receive confirmation of electronic registration including a registration number by email, usually within 7 business days. The online system also allows for amendments to past submissions.

Filing of Ingredient Statements

FDA's online filing system, available on FDA's VCRP website, contains electronic and paper versions of Forms FDA 2512 and 2512a, and we strongly encourage electronic filing because it is faster and more convenient. A filer will receive confirmation of electronic filing by email.

We estimate that approximately 95% of respondents will use information technology to develop their product labels, but also estimates that none of the respondents (0%) will actually use electronic product labels for their products. The agency also estimates that about ninety-five percent (95%) of the registrations and ingredient filings will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of efforts to collect this information by other federal agencies. FDA is the only federal agency that requires the specified information to appear on the label or labeling of every cosmetic product that the agency regulates and is the only agency who conducts the voluntary cosmetic labeling program.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately 80% of the establishments that will be affected by the cosmetic labeling information collection request probably qualify as small businesses with sales under $5,000,000 per year.

We set requirements for labeling cosmetic products to the minimum requirements that comply with the appropriate provisions of the FD&C Act 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.

With regard to the VCRP, we estimate that ten percent (10%) of respondents are small businesses. Small businesses usually can complete Form FDA 2511 just by providing the company name and address. However, the use of Forms FDA 2512 and FDA 2512a is expected to increase with the size of the reporting firm, the number of products manufactured, and the turnover of product lines. 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 have provided small business assistance on the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Respondents update the required labeling information on an occasional basis, associated with the development and marketing of their products, as required by the FD&C Act and the FPLA. If the information was not collected, that is, if we did not require this information to appear on the label or labeling of every cosmetic product that the agency regulates, then the agency's ability to enforce the relevant provisions of the FD&C Act and the FPLA would be nullified, and consumers would be unable to obtain from cosmetic product labels the information they need to evaluate and use cosmetic products.

Data collection for the voluntary cosmetic registration program also occurs occasionally. Registrations of cosmetic product establishments are submitted only once and therefore cannot be collected less frequently. Amended registrations are submitted occasionally, for example when a cosmetic product establishment site moves or the corporate structure changes. Original cosmetic product ingredient statements and notices of discontinuance are submitted only once and therefore cannot be collected less frequently. Amended cosmetic product ingredient statements are submitted only if a manufacturer changes a cosmetic product formulation.

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 accordance with 5 CFR 1320.8(d), in the *Federal Register* of April 3, 2020 (85 FR 18993), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. One comment was received which discussed cosmetic manufacturers not supplying information about the production of their products, unlisted ingredients in cosmetics, and proposing mandatory requirements for cosmetic manufacturers, packers, and distributors to provide a listing of toxic ingredients in their cosmetics submitted to FDA.

In response to this comment, we note that under the FD&C Act, cosmetic products and ingredients, with the exception of color additives, are not subject to premarket approval by FDA. However, they must not be adulterated or misbranded. This means that they must be safe for consumers under labeled or customary conditions of use, and they must be properly labeled. We do not have the authority to review the labels prior to marketing, but companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Additionally, the label of a cosmetic product must bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product (§ 740.1(a)). Labels are not expected to list contaminants or potential byproducts of manufacturing. However, if a product is found not to be in compliance with the requirements, a cosmetic may be found to be adulterated or misbranded under the FD&C Act and subject to seizure and removed from the market.

9. Explanation of Any Payment or Gift to Respondents

We do not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

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

None of the registration information supplied on Form FDA 2511 is confidential. The public and other interested parties may request copies under the provisions of the Freedom of Information Act (FOIA). However, under 21 CFR 720.8, cosmetic product ingredient filers may request confidentiality of the identity of a cosmetic ingredient if such information is a trade secret or confidential commercial or financial information as defined in 21 CFR 20.61. Requests for confidentiality are subject to the provisions of 21 CFR 20.111 and 21 CFR 20 subparts D and E. If FDA grants the request, the information is not available for public disclosure. Confidentiality of the information submitted is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). The information also is safeguarded by section 301(j) of the FD&C Act (21 U.S.C. 331(j)).

Privacy Act

This information collection request (ICR) is collecting personally identifiable information (PII) or other data of a personal nature. Information is collected via Form FDA 2511 (*Registration for Cosmetic Product Establishment*) and Form FDA 2512 (*Cosmetic Product Ingredient Statement*). Form FDA 2512a (*Cosmetic Product Ingredient Statement*) is part of this ICR but no PII is collected. PII collected is name, phone number, and email address for Form FDA 2511 and Form FDA 2512. PII is collected in the context of the individual's professional capacity. This consolidated collection of information involves both the labeling of cosmetic products and the voluntary registration of cosmetic products to FDA. The collection of information for this ICR is found in 21 CFR parts 701, 710, and 720.

We 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 Act do not apply. Specifically, we do not use name or any other personal identifier to retrieve records from the information collected.

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of 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

This information collection does not involve questions of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
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
Total					141,174

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

The estimated annual third-party disclosure burden is based on data available to the agency, our knowledge of and experience with cosmetics, and 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. We estimate that the total third-party disclosure burden is 141,174 hours.

Table 2.--Estimated Annual Reporting Burden[1]

21 CFR Section/Part; Activity	Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Part 710; registrations	2511[2]	1,702	1	1,702	0.20 (12 mins)	340
720.1 – 720.4; new submissions	2512[3]	6,843	1	6,843	0.33 (20 mins)	2,258
720.6; amendments	2512	2,477	1	2,477	0.17 (10 mins)	421
720.6; notices of discontinuance	2512	232	1	232	0.10 (6 mins)	23
720.8; requests for confidentiality		1	1	1	2	2
Total						3,044

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 2511" refers to both the paper Form FDA 2511 and online Form FDA 2511 in the online system known as the VCRP, which is available at https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp.
[3] The term "Form FDA 2512" refers to the paper Forms FDA 2512 and 2512a and online Form FDA 2512 in the online system known as the VCRP, which is available at https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp.

We base our estimate of reporting burden hours on information from cosmetic industry personnel and FDA experience entering data submitted on paper Forms FDA 2511, 2512, and 2512a into the online system. We estimate that, annually, 1,702 establishments that manufacture or package cosmetic products will each submit 1 registration on Form FDA 2511, for a total of 1,702 annual responses. Each submission is estimated to take about 0.20 hour per response for a total of 340.4 hours, rounded to 340. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 6,843 ingredient statements for new submissions on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take about 0.33 hour per response for a total of 2,258.19 hours, rounded to 2,258. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 2,477, amendments to product formulations on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take about 0.17 hour per response for a total of 421.09 hours, rounded to 421. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 232 notices of discontinuance on Form FDA 2512. Each submission is estimated to take about 0.10 hour per response for a total of 23.2 hours, rounded to 23. We estimate that, annually, one firm will file one request for confidentiality. Each such request is estimated to take 2 hours to prepare for a total of 2 hours. Thus, the estimated total reporting burden is 3,044 hours.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be approximately $11,932,597.32.

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 2020, which is $41.37 per hour. To account for overhead, this cost is increased by 100 percent, which is $82.74 per hour. Thus, the estimated cost imposed by third-party disclosures is approximately $11,680,736.76 (141,174 hours x $82.74 per hour).

We estimate that the average hourly wage for the employee preparing and submitting the registrations and ingredient filings would also be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2020, approximately $41.37/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $82.74/hour. Thus, the estimated cost incurred by reporting is $251,860.56 (3,044 burden hours x $82.74/hr).

Table 3.--Annual Cost Burden Estimate			
Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Label Design Process	144,218	$82.74	$11,680,736.76
Preparation and submission of registration and ingredient filing	3,044	$82.74	$251,860.56
Total			11,932,597.32

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 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'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 $41.37 per hour (the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2020, increased by 100 percent, which is $82.74 to account for overhead), we

estimate the annual cost to the Federal government to be $1,032,595.20 (12,480 x $82.74 per hour).

We have also allocated FTEs to review the submissions and maintain computer files, which requires about 100 hours annually for registrations and 5,824 hours annually for ingredient filings, for a total of 5,924 hours annually. We estimate that, on average, the hourly cost for review and evaluation of the submissions is approximately $41.37 per hour, the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2020. To account for overhead, this cost is increased by 100 percent, making the total cost $82.74 per hour. Thus, we estimate the cost to the Federal Government for the review of submissions to be $490,151.76 ($82.74/hour x 5,924 hours).

Therefore, the total government cost for this collection of information is $1,522,746.96 ($1,032,595.20 [labeling] + $490,151.76 [VCRP]).

15. Explanation for Program Changes or Adjustments

The burden for this information collection reflects an overall increase of 3,044 burden hours and a corresponding increase of 11,255 burden responses due to a revision to consolidate two similar collections of information. We have consolidated the information collection provisions from OMB control number 0910-0027 into this collection. Once this collection has been approved by OMB, we will request for OMB control no. 0910-0027 to be discontinued.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published or tabulated.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.