FOOD AND DRUG ADMINISTRATION

Voluntary Cosmetic Registration Program

OMB Control No. 0910-0027

SUPPORTING STATEMENT

Terms of Clearance: None**.**

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides FDA with the authority to regulate cosmetic products in the United States. Cosmetic products that are adulterated under section 601 of the FD&C Act (21 U.S.C. 361) or misbranded under section 602 of the FD&C Act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, the agency has developed the Voluntary Cosmetic Registration Program (VCRP).

FDA is revising forms for the VCRP (Forms FDA 2511, 2512, 2512a, and 2514) currently approved under this OMB control number 0910-0027, "*Voluntary Cosmetic Registration Program,*" for the following reasons: (1) Modernizing the forms; (2) making it easier for respondents who complete the forms; and (3) increasing FDA's efficiency by reducing the time necessary to review each submission. In addition, Form FDA 2514 will be eliminated as it is duplicative of Form FDA 2512.

Participation in the VCRP is voluntary under provisions found in sections 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.

In 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled "*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/RegistrationProgram/default.htm. FDA strongly encourages online registration using Form FDA 2511 because it is faster and more efficient for the filer and the agency. After registering online, the registering facility will receive confirmation of online registration, including a registration number by email. The online registration system also allows the participant to amend past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA uses information which has been placed into a database to generate

mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

Under part 720 (21 CFR part 720), FDA requests that 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 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, FDA requests that the firm use 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.

FDA's proposed changes to the forms through the use of an electronic submission system have been designed to make it easier for participants to provide information to FDA about their products. They also assist 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 is expected to make it easier to submit information when compared to the manual identification process for filers and FDA and reduce rejection errors. The rejection rate for ineligible submissions when using paper forms is high: 51 percent for new accounts, 43 percent for Form FDA 2511 registrations, and 7 percent for FDA Form 2512 filings (2010 to 2016).

The revised forms include the addition of links between Forms FDA 2511 and 2512, clarification of what information should be entered into the forms, additional self-identifying fields, removal of certain duplicative fields, and the deletion of Form FDA 2514. These changes are needed because both VCRP voluntary filer participation and FDA resources required to administer VCRP have increased significantly since 2014 (i.e., increases in new accounts (156 percent), Form FDA 2511 registrations (405 percent), Form FDA 2512 filings (67 percent), and FDA review hours (59 percent) in 2016.)

FDA's current paper-based process confirms that each submission meets the requirements established in parts 710 and 720 by using a manual process for both filers and FDA reviewers that may result in a long waiting period where filers must wait and respond to questions generated by FDA, which may result in a high rejection rate. FDA projects a significant reduction in rejection rates when using the revised forms. Examples of possible burden savings for participants and FDA include:

(1) Form FDA 2511 asks filers if they are a manufacturer or packer; however, in the past, distributors and retailers have checked these boxes in error when neither applies to them because there are no distributor or retailer checkboxes on Form FDA 2511. Retailers have also filed Form FDA 2512 in error even though only manufacturers, packers, and distributors are permitted to do so. To correct these issues, FDA revised Form FDA 2511 by updating

the field that allows filers to indicate the "TYPE OF ESTABLISHMENT: MANUFACTURER/PACKER/OTHER (Distributor or Retailer)" and updating the field on Form FDA 2512 allowing the filer to indicate "WHO IS FILING THIS STATEMENT: MANUFACTURER/PACKER/DISTRIBUTOR/OTHER (Retailer)."

(2) FDA revised Form FDA 2511 and added questions asking, "Are you the owner or operator of this facility?" and "Is the address on this form the location of a cosmetic manufacturing and/or packing facility?"

(3) FDA also revised Form FDA 2512 and added questions asking, "Is this product currently commercially distributed (annual sales exceed $1,000) in the United States?", "PRODUCT WEBSITE", and "Attach images of the front and back product labels to this form" to ensure that only cosmetics in commercial distribution in the United States are filed in the VCRP.

(4) FDA linked Forms FDA 2511 and 2512 to reduce rejection errors for filers who create multiple copies of Form FDA 2512 that share the same establishment addresses.

(5) FDA clarified the information that should be included on the forms by attaching simplified instructions and a link to VCRP online on Forms FDA 2511, 2512, and 2512a and adding titles and locations of various fields throughout Forms FDA 2511, 2512, and 2512a. We also added self-identifying information such as phone number, email, and alternative authorized individual fields to Form FDA 2511 and 2512 to facilitate communication with the filers.

(6) We also removed fields that have no modern use or request redundant information in multiple locations.

(7) We removed Form FDA 2514 in its entirety due to redundancy. (As noted, filers may notify FDA that they are discontinuing a cosmetic product formulation on Form FDA 2512).

FDA's online filing system is available on FDA's VCRP Web site at https://www.fda.gov/cosmetics/registrationprogram/default.htm. The online filing system contains the online versions of Forms FDA 2511, 2512, and 2512a.

We place cosmetic product filing information in a computer database and use the information when FDA receives 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 adverse events submitted via MedWatch and Field Operators (FACTS). We also use the information in identifying future research projects, to evaluate the levels and safety of certain ingredients in cosmetics.

Links to explanations of the revisions to Forms FDA 2511, 2512, and 2512a and instructions are available at https://www.fda.gov/cosmetics/registrationprogram/default.htm and entitled "Voluntary Cosmetic Registration Program."

Accordingly, we request OMB approval of the information collection provisions found in the regulations discussed below and revised paper and electronic versions of Forms FDA 2511, FDA 2512, and FDA 2512a.

21 CFR 710.1 Reporting

Requests a cosmetic product establishment to register with FDA.

21 CFR 710.4 -- Reporting

Sets forth the requested information. The information requested on Form FDA 2511 includes the name and address of the cosmetic product establishment, all business trading names used by the cosmetic product manufacturer, and the type of business (manufacturer and/or packer).

21 CFR 710.5 -- Reporting

Requests a facility to submit timely updates within 30 days of a change to any information contained in a registration submission.

21 CFR 720.1 -- Reporting

Who should file.—Manufacturers, packers, and distributors of cosmetic products are requested to file Forms FDA 2512 and FDA 2512a, whether or not the cosmetic product enters interstate commerce. This request extends to foreign manufacturers, packers, and distributors of cosmetic products exported for sale in the U.S.

21 CFR 720.2 -- Reporting

Times for filing.—Forms FDA 2512 and FDA 2512a should be filed within 60 days after the beginning of commercial distribution of any cosmetic product.

21 CFR 720.3 -- Reporting

How and where to file.—Forms FDA 2512 and FDA 2512a, should be mailed to the FDA address specified in this regulation.

21 CFR 720.4 -- Reporting

Information requested about cosmetic products.—Form FDA 2512 requests information on the name and address of the manufacturer, packer, or distributor, brand name(s), and product category or categories of the cosmetic product being filed. Form FDA 2512a requests

information on the ingredients in the cosmetic product. Forms should be signed by an authorized representative of the firm.

21 CFR 720.6 -- Reporting

Amendments to statement.—Amended Forms FDA 2512 and FDA 2512a should be submitted within 60 days after the product is entered into commercial distribution if an ingredient or product brand name is changed from that previously filed or within a year if other changes are made. Form FDA 2512 should be submitted within 180 days after discontinuance of commercial distribution of a filed product.

21 CFR 720.8 -- Reporting

Confidentiality of statements.—Cosmetic product 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 this regulation and 21 CFR 20.111.

2. Purpose and Use of the Information Collection

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA places the registration information in a computer database and uses 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. FDA also uses the information for estimating the size of the cosmetic industry and for conducting onsite establishment inspections. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

FDA places cosmetic product filing information in a computer database and uses the information for evaluation of cosmetic products currently on the market. Because filing of cosmetic product formulations is not mandatory, 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: The likely respondents include businesses engaged in the manufacture, packing, and distribution 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

Registration

As noted above, in 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled "Registration of Cosmetic Product Establishment." The term "Form FDA 2511" refers to both the paper and the online registration system versions of the form. Both versions of Form FDA 2511 are available on FDA's VCRP Web site at http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm. The agency strongly encourages electronic registration of Form FDA 2511 because it is faster and more convenient. A registering facility 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 is available on FDA's VCRP Web site at http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm. The online filing system contains the electronic versions of Forms FDA 2512 and 2512a, which are collectively found within the electronic version of Form FDA 2512. The paper versions of Forms FDA 2512 and 2512a are also available on FDA's VCRP Web site. The agency strongly encourages electronic filing of Form FDA 2512 because it is faster and more convenient. A filer will receive confirmation of electronic filing by email.

The agency 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

To the best of FDA's knowledge, no other Federal Government agency is engaged in the collection of this information.

5. Impact on Small Businesses or Other Small Entities

FDA estimates 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. FDA aids 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. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection 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 for 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), FDA published a 60-day notice for public comment in the Federal Register of May 31, 2017 (82 FR 24977). Two comments were received. One comment appeared to be a submission under 21 CFR 10.35 and 10.40(b)(3) and therefore is not addressed here. The second comment offered suggestions that FDA might consider regarding the content and format of reporting elements, but made no suggestion for FDA to revise its burden estimate. Accordingly, while the agency is currently reviewing these suggestions to determine whether our current IT system may be upgraded to the benefit of respondents, we retain the burden estimate from our 60-day notice.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

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).

Accordingly, authorized personnel in FDA's Office of Cosmetics and Colors receive, evaluate, and store all information filed on Forms FDA 2512 and FDA 2512a in secured work areas. When not being evaluated, the forms are secured. As part of the evaluation, authorized personnel add the filing information to a computer database. Security of the computer database meets all mandated Department of Health and Human Services requirements. Access to the forms and computer database is limited to authorized personnel.

FDA shares non-confidential information from its files on cosmetics with consumers, medical professionals, and the cosmetic industry. Non-confidential information is releasable to the public under FDA compliance with the Freedom of Information Act. All release of information must be authorized by management staff in FDA's Office of Cosmetics and Colors and is processed by the agency's Division of Freedom of Information.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

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

21 CFR Section or Part	Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Part 710 (registrations)	FDA 2511[2]	934	1	934	0.20 (12 minutes)	187
720.1 through 720.4 (new submissions)	FDA 2512[3]	7,108	1	7,108	0.33 (20 minutes)	2,346
720.6 (amendments)	FDA 2512	4,049	1	4,049	0.17 (10 minutes)	688
720.6 (notices of discontinuance)	FDA 2512	95	1	95	0.10 (6 minutes)	10
720.8 (requests for confidentiality)		1	1	1	2	2
Total						3,233

[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 electronic Form FDA 2511 in the electronic system known as the VCRP, which is available at http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm.

[3] The term "Form FDA 2512" refers to the paper Forms FDA 2512 and 2512a and electronic Form FDA 2512 in the electronic system known as the VCRP, which is available at http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm.

FDA bases its estimate of the total annual responses on paper and electronic submissions received during calendar year 2016. FDA bases its estimate of the hours per response upon information from cosmetic industry personnel and FDA experience entering data submitted on paper Forms FDA 2511, 2512, and 2512a into the online system.

FDA estimates that, annually, 934 establishments that manufacture or package cosmetic products will each submit 1 registration on Form FDA 2511, for a total of 934 annual responses. Each submission is estimated to take 0.20 hour per response for a total of 186.8 hours, rounded to 187. The number of Form FDA 2511 submissions has increased 405 percent compared to 2014 and we have no indication that this submission rate will stop increasing. FDA estimates that, annually, firms that manufacture, pack, or distribute cosmetics will file 7,108 ingredient statements for new submissions on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take 0.33 hour per response for a total of 2,345.64 hours, rounded to 2,346. We estimate the number of FDA Form 2512 submissions to increase 67 percent compared to 2014 and we have no indication that this submission rate will stop increasing. FDA estimates that, annually, firms that manufacture, pack, or distribute cosmetics will file 4,049 amendments to product formulations on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take 0.17 hour per response for a total of 688.33 hours, rounded to 688. FDA estimates that, annually, firms that manufacture, pack, or distribute cosmetics will file 95 notices of discontinuance on Form FDA 2512. Each submission is estimated to take 0.1 hour per response for a total of 9.5 hours, rounded to 10. FDA estimates 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 total estimated hour burden for this information collection is 3,233 hours.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $247,001.20 per year. FDA estimates that the average hourly wage for the employee preparing and submitting the registrations and ingredient filings would be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2017, approximately $38.20/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $76.40/hour. Thus, the overall estimated cost incurred by the respondents is $143,978.02 (3,233 burden hours x $76.40/hr = $247,001.20).

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Employees preparing and submitting registrations and ingredient filings	3,233	$76.40	$247,001.20

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

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

14. Annualized Cost to the Federal Government

FDA has 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 $38.20 per hour, the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017. To account for overhead, this cost is increased by 100 percent, making the total cost $76.40 per hour. Thus, FDA estimates the cost to the Federal Government for the review of submissions to be $452,593.60 ($76.40/hour x 5,924 hours = $452,593.60).

15. Explanation for Program Changes or Adjustments

This information collection reflects agency adjustments. The total annual number of responses reflects an overall increase from 7,827 to 12,187 responses (an increase of 4,360 responses) and a total annual hour burden increase from 1,987 to 3,233 hours (an increase of 1,246 hours). We attribute the increase to industry growth, specifically an increase in the number of respondents. Specific fluctuations to the individual information collections are summarized and discussed here:

Table 3—Summary of Change in Responses and Hour Burden		
IC Number	Change in Responses	Change in Hour Burden
IC#1	+853	+171
IC#2	+2,231	+737
IC#3	+3,007	+511
IC#4	-1,731	-173
IC#5	0	0
Total Change	4,360	1,246

For IC#1, we estimate an increase in respondents from 81 to 934, with corresponding increases in responses from 81 to 934 (an increase of 853) and annual hourly burden from 16 to 187 hours (an increase of 171).

For IC#2, we estimate an increase in respondents from 4,877 to 7,108, with corresponding increases in the annual number of responses from 4,877 to 7,108 (an increase of 2,231) and annual hourly burden from 1,609 to 2,346 hours (an increase of 737).

For IC#3, we estimate an increase in respondents from 1,042 to 4,049, with corresponding increases in annual number responses from 1,042 to 4,049 (an increase of 3,007) and annual hourly burden from 177 to 688 (an increase of 511).

For IC#4, we estimate a decrease from 1,826 to 95. Based on the decrease in the number of reports received by FDA in calendar year 2016, we estimate only 1 notice of discontinuance will be submitted annually. This results in a corresponding decrease in annual responses from 1,826 to 95 (a decrease of 1,731) and annual hourly burden from 183 to 10 (a decrease of 173).

IC#5 remains unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

No statistical reporting, tabulation, or publication of the data are planned.

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

FDA has no reason for not displaying the OMB approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.