Voluntary Registration of Cosmetic Product Establishments

0910-0027

SUPPORTING STATEMENT

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).

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." In part 720 (21 CFR part 720), FDA requests that firms that manufacture, pack, or distribute cosmetics file with the Agency an ingredient statement for each of their products. 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) also are reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514, "Notice of Discontinuance of Commercial Distribution of Cosmetic Product Formulation" (§§ 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 under § 720.8.

This is a revision request in which the burden hours for the information collection request (ICR) under OMB control number 0910-0030, "Cosmetic Product Voluntary Reporting Program" are being consolidated under the ICR assigned OMB control number 0910-0027," Voluntary Registration of Cosmetic Product Establishments," which expires February 28, 2011. The revised ICR for 0910-0027 has been renamed "Voluntary Cosmetic Registration Program." Upon approval of this revision request, the ICR for OMB control number 0910-0030 will be discontinued.

We request OMB approval of the paper and/or electronic versions of Forms FDA 2011, FDA 2512, FDA 2512a, and FDA 2514 and the reporting burdens contained in the following citations:

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, FDA 2512a, and FDA 2514 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 2514 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

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 electronic versions of the form. The electronic version of Form FDA 2511 is available on FDA's VCRP Web site at http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm. FDA's online registration system, intended to make it easier to participate in the VCRP, was made available industrywide on December 1, 2005. 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.

FDA's online filing system is available on FDA's VCRP Web site at http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm. The online filing system contains the electronic versions of Forms FDA 2512, 2512a, and 2514, which are collectively found within the electronic version of Form FDA 2512. 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, FDA 2512a, and FDA 2514 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 throughthe 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 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), FDA published a 60-day notice for public comment in the Federal Register of December 15, 2010 (75 FR 78257). FDA received one letter, containing multiple comments in response to the notice.

(Comment 1) One comment was generally supportive of the necessity of the information collection and its practical utility.

(Response) FDA agrees that the VCRP provides the Agency with useful information about cosmetic product ingredients and the cosmetics industry.

(Comment 2) One comment stated that, to increase participation in the registration program, FDA should conduct an audit of the cosmetics industry to determine the current participation rate in the registration program and to estimate how many ingredients and products FDA receives into the database compared to the total produced.

(Response) FDA disagrees with the suggested audit of the cosmetics industry. Given that FDA does not have the statutory authority to make registration in the VCRP mandatory, and taking into consideration the cost of completing such a project, the audit would not be a wise use of Agency funds in the current economic environment.

(Comment 4) As another means of increasing participation in the registration program, one comment suggested that FDA launch a certification system where companies can indicate to consumers that they have participated in the VCRP.

(Response) FDA disagrees with the suggested certification program at this time. Before instituting such a program, FDA would need to conduct research to understand how consumers would interpret such a certification claim and would have to consider how the accuracy of such a claim would be enforced.

(Comment 5) One comment stated that FDA should permit companies that produce professional-use products to submit contact and ingredient information.

(Response) FDA disagrees with the suggested change to its registration program. Cosmetic products marketed in the United States are regulated by FDA in accordance with the requirements of the FD&C Act and, if offered for sale as consumer commodities, the Fair Packaging and Labeling Act (FPLA). The FPLA defines a consumer commodity as a product distributed through retail sales for consumption by individuals. Professional products used in salons, and free samples are not available through retail sale to consumers, so they are not considered to be in "commercial distribution." Because the VCRP program only applies to cosmetic products in commercial distribution as defined in the FPLA, FDA is unable to file professional cosmetic products.

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 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, FDA 2512a, and FDA 2514 in secured work areas. When not being evaluated, the forms are stored in locked file cabinets. As part of the evaluation, authorized personnel add the filing information to a computer data base. Security of the computer data base meets all mandated Department of Health and Human Services requirements. Access to the forms and computer data base 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	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 710 (registrations)	FDA 2511[2]	135	1	135	0.2	27
720.1 through 720.4 (new submissions)	FDA 2512[3]	141	31	4,371	0.33	1,442
720.6 (amendments)	FDA 2512	109	7	763	0.17	130
720.6 (notices of discontinuance)	FDA 2512	55	41	2,255	0.1	226
720.8 (requests for confidentiality)		1	1	1	2.0	2.0
Total						1,827

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

[3] The term "Form FDA 2512" refers to the paper Forms FDA 2512, 2512a, and 2514 and electronic Form FDA 2512 in the electronic system known as the VCRP, which is available at http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm.

FDA bases its estimate of the number of responses on submissions received from fiscal years 2005 to 2007. FDA bases its estimate of the hours per response upon information from cosmetic industry personnel and FDA experience entering data submitted on paper Forms 2511, 2512, 2512a, and 2514. FDA estimates that, annually, 135 establishments that manufacture or package cosmetic products will each submit 1 registration on Form FDA 2511, for a total of 135 annual responses. Each submission is estimated to take 0.2 hour per response for a total of 27 hours. FDA estimates that, annually, 141 firms that manufacture, pack, or distribute cosmetics will file 31 ingredient statements for new submissions on Forms FDA 2512 and FDA 2512a, for a total of 4,371 annual responses. Each submission is estimated to take 0.33 hour per response for a total of 1,442.43 hours, rounded to 1,442. FDA estimates that, annually, 109 firms that manufacture, pack, or distribute cosmetics will file 7 amendments to product formulations on Forms FDA 2512 and FDA 2512a, for a total of 763 annual responses. Each submission is estimated to take 0.17 hour per response for a total of 129.71 hours, rounded to 130. FDA estimates that, annually, 55 firms that manufacture, pack, or distribute cosmetics will file 41 notices of discontinuance on Form FDA 2514, for a total of 2,255 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 225.50 hours, rounded to 226. 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 2.0 hours. Thus, the total estimated hour burden for this information collection is 1,827 hours.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $131,105.52 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 2011, approximately $35.88/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $71.76/hour. Thus, the overall estimated cost incurred by the respondents is $131,105.52 (1,827 burden hours x $71.76/hr = $131,105.52).

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

At the agency, professional employees review the submissions and maintain computer files, which requires about 100 hours annually for registrations and 5,824 hours annually for ingredient filings, a total of 5,924 hours annually. FDA estimates that, on average, the hourly cost for review and evaluation of the submissions is approximately $35.88 per hour, the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2011. To account for overhead, this cost is increased by 100 percent, making the total cost $71.76 per hour. Thus, FDA estimates the cost to the Federal Government for the review of submissions to be $425,106.24 ($71.76/hour x 5,924 hours = $425,106.24).

15. Explanation for Program Changes or Adjustments

This is a revision request in which the burden hours for the information collection request (ICR) under OMB control number 0910-0030, “Cosmetic Product Voluntary Reporting Program” are being consolidated under the ICR assigned OMB control number 0910-0027,“ Voluntary Registration of Cosmetic Product Establishments,” which expires February 28, 2011. The revised ICR for 0910-0027 has been renamed “Voluntary Cosmetic Registration Program.” Upon approval of this revision request, the ICR for OMB control number 0910-0030 will be discontinued. Because these two collections are so closely related, consolidation will make the OMB approval process more efficient.

16. Plans for Tabulation and Publication and Project Time Schedule

No comprehensive 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.