Dated: February 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0623]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 28, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0027. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Voluntary Cosmetic Registration Program—21 CFR Parts 710 and 720 (OMB Control Number 0910–0027)—Revision

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." 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 e-mail, usually within 7 business days. The online system also allows for amendments to past submissions.

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.

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.

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 e-mail.

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.

Information from the database is releasable to the public under FDA compliance with the Freedom of Information Act. FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry.

In the **Federal Register** of December 15, 2010 (75 FR 78257), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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.

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.

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.

Dated: February 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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