



4164-01-P

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, Agency, or we) 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 (PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 emailed to oir_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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASstaff@fda.hhs.gov.

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--Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides us 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. We have developed the Voluntary Cosmetic Registration Program (VCRP) to assist us in carrying out our responsibility to regulate cosmetics.

FDA is revising forms for the VCRP (Forms FDA 2511, 2512, 2512a, and 2514) currently approved under OMB control number 0910-0027, "Voluntary Cosmetic Registration Program," for the following reasons: (1) modernizing the forms; (2) making it easier for filers who complete the forms; and (3) reducing the time it will take FDA to review each submission. In addition, Form FDA 2514 will be eliminated as it duplicates information that is currently located on Form FDA 2512. FDA requests PRA approval for the proposed changes to these forms, and for the elimination of Form FDA 2514.

Participation in the VCRP is voluntary under provisions found in sections parts 710 and 720 (21 CFR parts 710 and 720). 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.

Currently, in part 710, we request that establishments that manufacture or package cosmetic products voluntarily register with us using Form FDA 2511 entitled "Registration of

Cosmetic Product Establishment." The online version of Form FDA 2511 is available on our VCRP website at <https://www.fda.gov/Cosmetics/RegistrationProgram/default.htm>. We strongly encourage online registration with Form FDA 2511 because it is faster and more efficient for the filer and the Agency. A registering facility will receive confirmation of online registration, including a registration number by email. 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. We place the registration information in a computer database and use the information to generate 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 we request that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

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. The 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 submission system is expected to reduce burden currently associated with the manual identification process for filers and FDA. The rejection rate for ineligible submissions when using the current forms is high: 51 percent for new accounts, 43 percent for Form FDA 2511 registrations, and 7 percent for Form FDA 2512 filings (2010-2016).

The revised forms include the addition of links between Forms FDA 2511 and 2512, clarification of what information should be entered onto 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 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 burden to 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 Forms 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 website 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."

In the *Federal Register* of May 31, 2017 (82 FR 24977), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. 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.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

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 online Form FDA 2511 in the online system known as the VCRP, which is available at <https://www.fda.gov/Cosmetics/RegistrationProgram/default.htm>.

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/RegistrationProgram/default.htm>.

We base our estimate of the total annual responses on paper and online submissions received during calendar year 2016. We base our 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.

We estimate 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. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 7,108 ingredient statements for new or amended submissions on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take 0.33 hour per response for a total of 2345.64 hours, rounded to 2,346. We estimate the number of Form FDA 2512 submissions to increase 67 percent

compared to 2014 and we have no indication that this submission rate will stop increasing. We estimate 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. We estimate 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 0.10 hour per response for a total of 9.5 hours, rounded to 10. 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 total estimated hour burden for this information collection is 3,233 hours.

Dated: August 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-17701 Filed: 8/21/2017 8:45 am; Publication Date: 8/22/2017]