4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0623]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on the collection of information associated with our Voluntary Cosmetic Registration Program (VCRP).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov/. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov/ will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov/.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2010-N-0623 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Cosmetic Registration Program." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov/ or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov/. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov/ and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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) decreasing burden to 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 term "Form FDA 2511" refers to both the paper and online versions of the form. The online version of Form FDA 2511 is available on our VCRP Web site at https://www.fda.gov/Cosmetics/RegistrationProgram/default.htm. We strongly encourage online registration of 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 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 we request that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

Currently, under part 720, FDA requests 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 are reported on Form FDA 2512, "Cosmetic Product Ingredient Statement," and on Form FDA 2512a, a continuation form. Amendments to product formulations 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"; however, filers may also notify FDA that they have discontinued a cosmetic product formulation by submitting an amended Form FDA 2512, which would obviate the need for Form FDA 2514. If any of the information submitted on these forms is confidential, the firm may submit a request for confidentiality of a cosmetic ingredient.

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 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 through the use of a manual process for both filers and FDA reviewers that can 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, 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 fields such as phone number, email, and alternative authorized individual 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."

We estimate 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 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: May 25, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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