Estimated Total Annual Burden Hours: 54,934.99.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20202; Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–11234 Filed 5–30–17; 8:45 am]

BILLING CODE 4184–01–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 July 31, 2017.

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 July 31, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 31, 2017. 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.	Number of respondents	Number 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.

[FR Doc. 2017–11188 Filed 5–30–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the program in general, contact the Acting Clerk of the Court, Lisa L. Reyes, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our Web site at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on April 1, 2017, through April 30, 2017. This list provides the name of the petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of the petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, MD 20857. The Court's caption (*Petitioner's Name* v. *Secretary of HHS*) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the program.

Dated: May 19, 2017.

George Sigounas,

Administrator.

List of Petitions Filed

1. Anissa E. Rogers on behalf of L. C., Fullerton, California, Court of Federal Claims No: 17–0470V.
2. John Solak, Binghamton, New York, Court of Federal Claims No: 17–0472V.
3. Dolores Justice, Pittsburgh, Pennsylvania, Court of Federal Claims No: 17–0476V.
4. Ruben Abeyta, Flagstaff, Arizona, Court of Federal Claims No: 17–0477V.
5. Hillary Adams, Phoenix, Arizona, Court of Federal Claims No: 17–0478V.
6. Emma Sullivan, Phoenix, Arizona, Court of Federal Claims No: 17–0480V.
7. Joanne Gurney, Fall River, Massachusetts, Court of Federal Claims No: 17–0481V.
8. Daniel Jenson, Hillsboro, North Dakota, Court of Federal Claims No: 17–0482V.