approach to data exchange? This might include timing (procurement, fiscal year, or legislative cycles), cost, availability of required expertise, needed regulatory change, impacts on current practices, etc.

5. If a more standards-based approach to data exchange were adopted, what kinds of technical assistance or training would you anticipate needing, if any?

ACF appreciates any and all comments on the above questions, or related recommendations. Comments will be considered carefully and used to inform the development of a planned Notice of Proposed Rulemaking, which is anticipated to be published in the spring of 2019.

Dated: October 25, 2018.

Lynn A. Johnson,

Assistant Secretary for Children and Families.

[FR Doc. 2018–24459 Filed 11–7–18; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3442]

Agency Information Collection Activities; Proposed Collection; Comment Request; Web-Based Pilot Survey To Assess Allergy to Cosmetics in the United States

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a pilot study entitled ''Web-based Pilot Survey to Assess Allergy to Cosmetics in the United States.''

DATES: Submit either electronic or written comments on the collection of information by January 7, 2019.

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 January 7, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 7, 2019. 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): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–3442 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Web-based Pilot Survey to Assess Allergy to Cosmetics in the United States.'' 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 Dockets Management Staff 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 Dockets Management Staff. 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 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.

Web-Based Pilot Survey To Assess Allergy to Cosmetics in the United States; OMB Control Number 0910—New

I. Background

In the past 40 years, the cosmetics industry, as well as consumer behaviors and expectations related to cosmetics, have evolved. Technological and scientific advances have been made in cosmetics production, manufacturing, marketing, and usage, while consumer access to information about cosmetic products and ingredients has expanded, because of the internet and social media influences. Most notably, multiple cosmetic products such as lotions, perfume, body wash, hand wash, shampoo, deodorant, hair spray, baby wipes, nail polish, etc. are used daily by nearly everyone in the United States, including infants, children, adults, geriatric populations, healthy people, and individuals with medical conditions.

Evidence indicates that the prevalence of allergies in the U.S. population is increasing (Ref. 1). However, no publicly available data has been collected on the prevalence of adverse reactions to cosmetic products since 1975 (Ref. 2). FDA proposes a pilot study to collect the data needed for a current and detailed understanding of the impact of allergens on consumer use of cosmetics. In addition to updating our knowledge about cosmetics, this new information collection is consistent with FDA's efforts to improve public awareness of adverse events associated with FDA-regulated products. In December 2016, FDA decided to make public the adverse event data in the Center for Food Safety and Applied Nutrition (CFSAN) Adverse Events Reporting System (CAERS). CAERS (and its imminent successor the CFSAN Adverse Events Management System or CAEMS) provides the public with transparent access to all food and cosmetic related adverse events reported to FDA. However, the information that we have collected and which will be collected through CAERS is an underestimate of adverse events to cosmetics in the United States, as not every adverse event is reported by consumers through CAERS because some consumers are not aware of CAERS or some choose not to report.

To obtain additional relevant data, FDA proposes to conduct a pilot study. ''Web-based Pilot Survey to Assess Allergy to Cosmetics in the United States.'' The objective of the current effort is to collect information needed for a more current understanding of the prevalence of adverse reactions to cosmetics. FDA proposes to conduct an exploratory consumer web-based survey to collect data on consumer use of cosmetic products, the frequency of adverse events believed to be caused by allergens in cosmetics, consumer awareness of the problem, and actions (if any) taken to avoid the allergens.

The proposed survey will use a 20-minute web-based questionnaire to collect information from 1,000 English-speaking adult members of a probability-based web-enabled research panel maintained by a contractor. Selected panel members will be sent an email invitation to participate in the survey. After clicking on the link in the email invitation, panelists will be directed to the online instrument. On the first screen, panelists will provide disclosure information which includes informed consent and be asked if they would like to proceed with the survey. Consenting respondents will be prompted to complete the survey. After OMB approval of this collection and prior to the full-scale survey, a pretest will be conducted with 100 respondents randomly selected from the panel.

The web-based panel is designed to be representative of the U.S. adult population. This representation is achieved through address-based sampling where every U.S. adult with an address (including those who do not have a landline phone number) has an equal probability of being selected for participation.

This pilot study is part of the Agency's continuing effort to understand the impact of allergens on cosmetics.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Study component	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest invitation	200	1	200	0.033 (2 minutes)	7
Pretest	100	1	100	0.333 (20 minutes)	33
Survey invitation	1,667	1	1,667	0.033 (2 minutes)	55
Survey	1,000	1	1,000	0.333 (20 minutes)	333
Total					428

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected.

1. Peiser, M., T. Traulau, J. Heidler, et al., ''Allergic Contact Dermatitis: Epidemiology, Molecular Mechanisms, In Vitro Methods and Regulatory Aspects. Current Knowledge Assembled at an International Workshop at BfR, Germany.'' *Cellular and Molecular Life Sciences,* 69:763–781, 2012.

2. Westat, Inc. ''An Investigation of Consumers' Perceptions of Adverse Reactions to Cosmetic Products.'' Final report submitted to U.S. Department of Health, Education, and Welfare, Food and Drug Administration. June 1975.

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24441 Filed 11–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0742]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

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 December 10, 2018.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0045. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@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.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—21 CFR Part 207; OMB Control Number 0910–0045—Extension

This information collection supports FDA's drug establishment registration and listing regulations and associated guidance intended to assist respondents in this regard. Requirements for drug establishment registration and drug listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360), and section 351 of the Public Health Service Act (42 U.S.C. 262). Section 224 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) amended section 510(p) of the FD&C Act to require electronic drug establishment registration and drug listing. Regulations implementing these provisions are established under part 207 (21 CFR part 207). Except as provided in § 207.65, all information submitted must be transmitted to FDA in electronic format by using our electronic drug registration and listing system, in a form that we can process, review, and archive. Establishment registration information helps FDA identify who is manufacturing, repacking, relabeling, and salvaging drugs and where those operations are performed. Drug listing information gives FDA a current inventory of drugs manufactured, repacked, relabeled, or salvaged for commercial distribution. Both types of information facilitate implementation and enforcement of the FD&C Act and are used for many important public health purposes.

I. Registration Under Part 207

Unless otherwise exempt under section 510(g) of the FD&C Act or § 207.13, all manufacturers, repackers, relabelers, and salvagers must register each domestic establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, and each foreign establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States. When operations are conducted at more than one establishment and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments.

Private label distributors who do not also manufacture, repack, relabel, or salvage drugs are not required to register under part 207. FDA will accept registration or listing information submitted by a private label distributor only if it is acting as an authorized agent for and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.

Under § 207.21, domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers must complete initial registration of each establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug. In addition, foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers must register each establishment before the drug is imported or offered for import into the United States.

The information that must be provided to FDA for registration is described in § 207.25 and includes the following: (1) Name of the owner or operator of each establishment; if a partnership, the name of each partner; if a corporation, the name of each corporate officer and director, and the place of incorporation; (2) each establishment's name, physical address, and telephone number(s); (3) all name(s) of the establishment, including names under which the establishment conducts business or names by which the establishment is known; (4) registration number of each establishment, if previously assigned by FDA; (5) a Unique Facility Identifier in accordance with the system specified under section 510 of the FD&C Act; (6) all types of operations performed at each establishment; (7) name, mailing address, telephone number, and email address of the official contact for the establishment, as provided in § 207.69(a); and (8) additionally, with respect to foreign establishments subject to registration, the name, mailing address, telephone number, and email address must be provided for: (a) The U.S. agent, as provided in § 207.69(b); (b) each importer in the United States of drugs manufactured, repacked,