

United States Food and Drug Administration

Web-Based Pilot Survey to Assess Allergy to Cosmetics in the United States

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

In the past 40 years, the cosmetics industry has evolved, including consumer habits and expectations. Technological and scientific advances have been made in cosmetics production, manufacturing, marketing, and usage, while the Internet and social media have expanded consumer access to information about cosmetic products and ingredients. A notable result is that nearly everyone in the United States, including infants, children, adults, geriatric populations, healthy people, and individuals with medical conditions use multiple cosmetic products daily. Evidence also indicates that the prevalence of allergies in the United States is increasing (Peiser et al. 2012).

However, no publicly available data has been collected on the prevalence of adverse reactions to cosmetic products in subject population representative of the US population since 1975 (Westat Corp., 1975). The U.S. Food and Drug Administration (FDA or we) 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. This new information collection is consistent with FDA's efforts to inform the public of adverse events associated with FDA-regulated products. In December 2016, we decided to make public the adverse event data in the FDA's 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 product related adverse events reported to the Agency. However, we realize that the CAERS reports represent a subset of all adverse events associated with cosmetics experienced by the public, due to the voluntary nature of these submissions. The objective of the current effort is to collect information for a more current understanding of the prevalence of adverse reactions to cosmetics. To accomplish this objective FDA proposes to conduct an exploratory consumer Web-based survey.

This ICR is for a one-time data collection that is part of a broader research study which includes the consumer surveys in this collection of information, OMB-approved consumer focus group studies, and cosmetics industry and local regulator interviews (of which there will be 9 or less interviews.) The overall objective of the study is to collect information from consumers to better understand the impact of allergens on cosmetic

users. Study participants will be asked to answer questions via a Web-based survey regarding their use of cosmetic products, whether they have experienced an adverse event caused by allergens in their cosmetics, and actions, if any, taken to avoid the allergens. FDA will use the study results to help inform consideration for possible modifications to FDA's policy on cosmetic product safety.

2. Purpose and Use of the Information Collection

Participants for this data collection are individuals who purchase and/or use cosmetic products.

A consumer Web-based survey will be conducted to collect data on consumer purchase and use of cosmetic products, the frequency of adverse events caused by allergens in cosmetics, consumer awareness of the problem, and consumer actions (if any) taken to avoid the allergens.

The survey will use a 20-minute Web-based questionnaire to collect information from 1,000 randomly selected English-speaking adult members of a probability-based Web-enabled research panel maintained by a subcontractor (see Appendix A for survey instrument). Prior to the full-scale survey, a pretest will be conducted with 100 respondents randomly selected from the panel. The purpose of the pretest is to screen for any potential difficulties in understanding survey questions.

The survey is designed to be representative of the U.S. adult population. This representation is achieved through address-based sampling (ABS), 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 on the panel. A random sample of individuals will be selected from the panel for participation in the survey.

3. Use of Improved Information Technology and Burden Reduction

The exploratory survey will use a Web-based questionnaire. Web-based questionnaires not only reduce the burden on participants but also minimize possible administration errors and expedite the timeliness of data processing. Compared to face-to-face interviews and mailed surveys, Web-based surveys are less intrusive and less costly. Therefore, FDA estimates that 100% of the participants to this collection of information will use electronic means to respond to the survey.

4. Efforts to Identify Duplication and Use of Similar Information

No comparable data on the prevalence of adverse reactions to cosmetic products have been collected by any other entities in the U.S. since 1975 (Westat Corp., 1975). The exploratory Web-based survey will provide valuable information specific to consumer purchase and use of cosmetic products, and consumer awareness and experiences related to adverse events caused by allergens in cosmetics.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection.

If this information is not collected, FDA will be missing additional necessary data to understand the impact of allergens on cosmetics. This lack of a more thorough and detailed understanding of the impact of allergens on cosmetics would impede FDA's ability to evaluate its policy on cosmetic product safety.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The pilot study will not require participants to report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus two copies of the information; or retain records for more than 3 years. The pilot study design will produce results that can be generalized to the response universe of pilot study. The study will not use statistical data that has not yet been reviewed or approved by the Office of Management and Budget (OMB). The study will not include a pledge of confidentiality that is: (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information, or other confidential information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of November 8, 2018 (83 FR 55896). FDA received 82 comments. Several addressed issues not related to the PRA, while others were PRA related. Of the comments received, several described the commenter's reactions to cosmetics, and while important, these comments do not address the PRA and will not be discussed here.

Several comments discussed the necessity and practical utility of the collection. This survey represents an ongoing effort by FDA to better understand cosmetic ingredients that may be potential allergens, and this survey constitutes the third contract over the last few years to address allergens in cosmetics. A few comments thought the proposed information collected by the survey does not appear to be necessary for proper performance of FDA's functions because of the small size of the number of respondents, but several comments described how the collection was important and needed to be

conducted so that we can better understand consumer's perception of skincare and beauty products. Several comments supported the survey because they agreed with the intention and methods being proposed and because of the topic's growing interest and concern to consumers. We appreciate these comments supporting our undertaking this survey of reactions to allergens in cosmetics.

This survey is part of an ongoing effort by FDA to better understand cosmetic ingredients that may be potential allergens, and this constitutes the third contract over the last few years to address allergens in cosmetics. The first contract in 2015-2016 conducted a comprehensive literature review of 26 fragrances that the European Union has identified as allergens. The second contract in 2016-2017 expanded the inquiry to other cosmetic ingredients, and it tested the criteria that were developed from the earlier contract on the 26 fragrance allergens. We appreciate comments of support for undertaking this survey of reactions to allergens in cosmetics.

A few comments had concerns about the study population of the survey and its size. With respect to the statistical power of the study, FDA notes that the relevant questions are binary (e.g., do you have an allergy or not, has it been medically confirmed or not), which allows precise estimates for the fraction of adults reporting an allergy and the fraction having had the allergy medically confirmed with a relatively smaller sample. Based on the power calculations performed for this study, 1,000 completed surveys will allow detection of differences of 6.6 percentage points in the estimates of allergy or not with 95% confidence, 80% power, and a Design Effect of 1.1. With respect to the study group composition, the sampling frame for the survey is the GfK Custom Research, Inc. (GfK) online consumer panel, KnowledgePanel (KP), which is a probability-based consumer panel that is designed to be representative of the U.S. adult population. Because the purpose of this survey is limited to obtaining nationally representative estimates of the U.S. population that have a medically diagnosed allergy and to obtain descriptive statistics on cosmetics use by U.S. citizens and other questions, suggested oversampling of specific groups (e.g. women, new cosmetics users and so on) would result in unequal weighting effects that would reduce our precision for the national estimates.

Several comments noted that the survey might be improved by including additional questions, rephrasing existing questions to improve accuracy, avoid potential confusion, improve the flow of the survey, and ultimately reduce time to complete the survey. Thanks to these comments, FDA has modified the survey in the following manner:

- In the introduction to the survey, we have added text that describes how the collection of this data will benefit the participant, and that data will only be presented in aggregate format to maintain confidentiality. We also added a definition of allergy.
- After Question 7, we added a question on "How often do you buy cosmetic products labeled as 'Fragrance-free'?"
- In Question 14 we added additional reactions that people might suffer from. Specifically, burning eyes or eyelid rash were added to our list of reactions.

- In questions 1, 11, 14 and 15, to products numbers 39-41 and 45, “excluding sunscreens” has been added to prevent reporting of allergies to OTC drug regulated products.
- In Question 18, we added clarifying definitions for mobility, self-care, etc.
- In Question 27, “fragrance mix ingredients” was changed to “fragrance mix allergens”.
- Questions 23-27 were moved to immediately follow Question 13 for a more logical flow.

In addition to these changes, we have carefully considered and decided not to make changes on following suggestions:

- **Adding feminine products to product list:** We recognize that the product list given in the survey is fairly aggregated. However, adding more products (or splitting existing products) may make the survey longer and more difficult to complete. A primary limitation to the length of the survey is that the survey should be short-enough so that it can be completed in 20 minutes or less. The desired sample size would be more difficult to achieve by lengthening the survey.
- **Questions regarding expiration dates:** Although cosmetic products are not required to have an expiration date printed on them (as pointed out by commenters), we have determined that some products do include expiration dates. The purpose of these questions is to determine whether this information, when available, is used by the consumer.
- **Suggestions to use another list of allergens (Question 26):** Commenters are correct that other lists of allergens are available (such as the American Contact Dermatitis Society- ACDS), in addition to the one provided in our survey. However, it is important to note that the ACDS is only one of many patch tests that could be used and is not actually the standard patch test in the United States (TRUE test is the only patch test approved for use by FDA). FDA chose the list included in the survey based on an independent review of sensitization data for various cosmetics ingredients and found these ingredients to be of most interest.
- **Clarification on “product”, “cosmetic”, and “cosmetic product”:** We had several cognitive interviews conducted and the use of these terms did not seem to create any problems for any of the participants.
- **Symptoms and clinical signs of skin allergies:** For question #14 following reactions were listed: Burning, Blistering, Hair Loss, Itchiness, Scabs or Scales, Skin Rash or Redness, and Swelling. These reactions are in agreement with the American College of Allergy, Asthma, & Immunology list of the symptoms for cosmetic dermatitis: red, irritated skin, itching, swelling, bumps or blisters, hot or tender skin (<https://acaai.org/allergies/types/skin-allergies/contact-dermatitis>). Further, research suggests that allergic contact dermatitis of the scalp can be a cause of hair loss (<https://jamanetwork.com/journals/jamadermatology/fullarticle/478194>).
- **Linking allergic reaction to a single product or ingredient:** We agree that it may be difficult to isolate an allergic reaction to a single product or causative ingredient. Still, some consumers are able to accurately pinpoint the ingredient.

Asking first whether a person has an allergy (Q12) and then following it up with questions about whether it has been medically confirmed (Q23) should allow one to adequately estimate the fraction of adults that believe they have an allergy (based on data from Q12) and the fraction that have actually confirmed this allergy (based on data from Q23). This should provide a more complete picture of the incidence of allergies to cosmetics that is currently lacking.

- **Suggestions to include additional questions:** Allergic reactions to cosmetics worn by other individuals, caused by other products (e.g. laundry detergents), health conditions beyond allergies, and economic costs, are beyond the scope of this survey. A primary limitation is that the survey needs to be short-enough so that it can be completed in 20 minutes or less. Making the survey longer than this would likely make it more difficult to achieve the desired sample size.

Finally, a few comments believed that the estimated time to complete the survey is too low and that a reduction in survey length could positively improve survey results. These comments also believe the survey will reflect inadequacies and access which will impact respondent input and FDA discovery. As pointed out earlier, the survey will be conducted using the GfK Custom Research, Inc. (GfK) online consumer panel, KnowledgePanel (KP). GfK routinely conducts surveys of this length using their panel and we are confident we will achieve 1,000 completes.

9. Explanation of Any Payment or Gift to Respondents

The sampling frame for the survey is the GfK Custom Research, Inc. (GfK) online consumer panel, KnowledgePanel (KP), which is a probability-based consumer panel that is designed to be representative of the U.S. adult population.

Households without existing computers and Internet access that are invited to participate in KP are provided a free tablet computer and Internet access in return for their participation. Households with existing computers and Internet access use their own equipment and Internet connection to complete surveys and receive points for completing a survey (1,000 points = \$1). Members are allowed to use their points to exchange for vouchers and gifts from a partner network. Internet panel participants are enrolled into a points program that is analogous to a “frequent flyer” card; respondents are credited with sweepstakes entries or bonus points in proportion to their regular participation in surveys. (For the households provided an Internet device and connection, their incentive includes the hardware and Internet service in addition to the sweepstakes entries and bonus points.) Traditionally, panelists earn sweepstakes entries on some surveys (including surveys more than 15 minutes in length) and bonus points for surveys that are longer or require special tasks by panel members. Panelists may elect to redeem their points for checks or raffle entries as they accrue them. For this study, respondents with existing computers and Internet access receive the equivalent of a \$1 incentive, lunch, etc.).

10. Assurance of Confidentiality Provided to Respondents

This ICR does collect personally identifiable information (PII) or data of a personal nature. All personal data will be collected with an assurance that the participants' answers will remain secure. The PII collected by contractors for the web survey is personal contact information. PII will not be included in the data files delivered by contractors to FDA. The contractors will share data and/or information with FDA in an aggregated form or format only, which does not permit FDA to identify individual participants. The study instrument will contain a statement that responses will be kept secure. Information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the Agency's regulations (21 CFR part 20).

FDA determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records about the individual from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

11. Justification for Sensitive Questions

The survey does not include any questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The estimated total burden for this collection of information is 428 hours. Table 1 details the estimated annual reporting burden.

Activity	No. of Respondents	No. 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

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

12b. Annualized Cost Burden Estimate

The annualized cost to all participants for the hour burden for the collection of information is \$7,622.68 (428 x 17.81) at \$17.81 per hour (the May 2016 U. S. median hourly wage rate). See http://www.bls.gov/oes/current/oes_nat.htm.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pretest Invitation	7	\$17.81	\$124.67
Pretest	33	\$17.81	\$587.73
Survey Invitation	55	\$17.81	\$979.55
Survey	333	\$17.81	\$5,930.73
Total			\$7,622.68

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection is \$440,263.00.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency will use the study results to help inform consideration for the possible modifications of FDA’s policy on cosmetic product safety. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. Final results of the study may be summarized for publication in a peer-reviewed scientific journal. The planned schedule for project activities is shown in Table 3.

Date	Activity	Audience
Within 3 days after receipt of OMB approval of collection of information	Notification to the contractor to proceed with data collection activities	Not applicable
Within 75 days after notification to contractor	Completion of data collection	Not applicable
Within 90 days after completion of data collection	Delivery by the contractor of final data files	Not applicable
Within 90 days after completion of data collection	Delivery by the contractor of written final reports	FDA
Within 18 months after receipt of final data files	Response to information requests	FDA and public

Activities associated with the outcomes of this research will primarily consist of written and oral presentations as well as a written final report. The dialogues will help improve the effectiveness of the Agency’s regulatory and education initiatives in promoting and protecting the public health.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References:

- (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.