Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss biologics license application (BLA) 761143, teprotumumab solution for intravenous use, submitted by Horizon Pharma Ireland, Ltd., proposed for the treatment of active thyroid eye disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before December 4, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 26, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 27, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jay Fajiculay (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25247 Filed 11–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3442]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 December 23, 2019.

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–NEW and title ''Web-Based Pilot Survey to Assess Allergy to Cosmetics in the United States.'' Also include the FDA docket number 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, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

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 that 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.

In the **Federal Register** of November 8, 2018 (83 FR 55896), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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, etc.), 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 form to maintain confidentiality. We also added a definition of allergy and text that describes how the collection will benefit the participant, and only be presented in aggregate format to maintain confidentiality.
- After Question (Q) 7, we added the question, ''How often do you buy cosmetic products labeled as 'Fragrance-free?' ''.
- In Q14 we added additional reactions that people might suffer, such as burning eyes or eyelid rash.
- In Qs 1, 11, 14 and 15, to products numbers 39–41 and 45,''excluding sunscreens'' has been added to prevent reporting of allergies to over the counter drug regulated products.
- In Q18, we added clarifying definitions for mobility, self-care, etc.
- In Q27, ''fragrance mix ingredients'' was changed to ''fragrance mix allergens''.
- Qs 23–27 were moved to immediately follow Q13 for a more logical flow.

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

• *Suggestion to add 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.

• *Suggestion to omit 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 (Q26):* 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.

• *Suggestion to clarify the terms ''product'', ''cosmetic'', and ''cosmetic product'':* We conducted several cognitive interviews and the use of these terms did not seem to create any problems for the participants.

• *Symptoms and clinical signs of skin allergies:* For question 14, the 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 and making the survey longer would likely make it more difficult to achieve the desired sample size.

Finally, a few comments indicated 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 discussed earlier, the survey will be conducted using the GfK online consumer panel, KP. GfK routinely conducts surveys of this length using their panel and we are confident we will achieve 1,000 completes.

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 marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25274 Filed 11–20–19; 8:45 am]

BILLING CODE 4164–01–P