this public workshop must register online by November 28, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Office of Communications and Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–5661, FAX: 301–847–8142, *susan.monahan@fda.hhs.gov* no later than November 21, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, and affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see special accommodations contact). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the registration Web page after November 28, 2016. Organizations are requested to view using one connection per location.

Requests for Oral Presentations: This public workshop includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by November 29, 2016. All requests to make oral presentations must be received by November 15, 2016. If selected for presentation, any presentation materials must be emailed to Jill Marion (see **FOR FURTHER INFORMATION CONTACT**) no later than December 2, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain information on the role of hospitals in evidence generation and surveillance. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is January 6, 2017.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: October 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25735 Filed 10–24–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0538]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animation in Direct-to-Consumer Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 November 25, 2016.

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 ''Animation in Direct-to-Consumer Advertising.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Animation in Direct-to-Consumer Advertising

OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

Advertisers use many techniques to increase consumer interest in their ads, including the use of animated spokes-characters. These characters may be fictional or nonfictional and human or nonhuman (Ref. 1). Despite variations in form, animated characters are often used to grab attention, increase ad memorability, and enhance persuasion to ultimately drive behavior (Refs. 2–4). Animated characters have long been used for low-involvement products (*e.g.,* food products) and have made their way into direct-to-consumer (DTC) prescription drug advertising. However, to our knowledge, one study (Ref. 5) has examined how animation affects attitudes toward products and risk perceptions in drug ads, and no studies have examined how various animation strategies (*e.g.,* symbolizing the disease vs. the benefit) and product characteristics (*e.g.,* low-risk medication vs. high-risk medication) influence these perceptions.

Animation in Drug Ads. Animation is used in prescription drug ads in a variety of ways. Perhaps the simplest way is the use of rotoscoped animation, which involves tracing live-action images frame-by-frame to create animated characters. ABILIFY has used this technique in advertisements (Ref. 6). In this instance, the animated character was not central to the informational content of the ad; instead, the animation appeared to be a visual technique to attract attention. Whether a drug ad with a rotoscoped human results in greater comprehension of product benefit and risk information than an ad with a human actor is unclear. The few studies that have examined this technique in drug ads have found that animated human characters either had no effect on perceived product risk (Ref. 7) or led to poorer recognition of drug side effects (Ref. 6).

Animation also has been used in drug ads to symbolize the disease (*e.g.,* IMITREX and LAMISIL ads), the sufferer (*e.g.,* MYBETRIQ and ZOLOFT), the benefit (*e.g.,* ROZEREM), the mode of administration (*e.g.,* FLUZONE), and the mechanism of action (*e.g.,* LUNESTA). Drug companies may use a personified nonhuman character to illustrate, in a visually memorable way, the medical condition or drug attributes. Using secondary data from copy-testing studies, Pashupati found that drug ads featuring animated characters led to much stronger brand recall and brand association scores (Ref. 8); however, the other elements of these studies (*e.g.,* ad characteristics, presence of control group) are unclear.

Animated characters may provide marketers with a way to explain product benefits in an engaging and even humorous manner. Thus, the majority of research on animated characters in advertising focuses on outcomes such as product evaluations (Ref. 9), emotional responses (Refs. 1, 10–11), brand attitudes (Ref. 12), and perceived product value (Ref. 13). The extent to which emotional responses can be fostered by animated characters is especially relevant to this study, as the positive effects these animations induce might transfer to the brands being advertised. It is also possible that animated characters may lead to lower perceived risk by minimizing or camouflaging side effects (Ref. 14).

Animation and Message Communication. Personifying animated characters may interfere with message communication. Although personification may increase involvement with the characters in the ad (*i.e.,* perceived as engaging and likeable), it may not increase involvement with the message itself (*e.g.,* risk and benefit information). Whether personified characters lead to reduced comprehension of risk and benefit information in drug ads is an important and unanswered question. Based on a theory called the limited capacity model of mediated message processing (Ref. 15), advertising content that is engaging, relevant, and maximizes audio/visual redundancy should improve learning and memory (Ref. 16). However, others argue that the entertainment aspects can distract from learning key information and may lead to message complexity that interferes with message communication (Ref. 17).

It is important to examine whether animation in drug ads inflates efficacy perceptions, minimizes risk, or otherwise hinders comprehension of drug risks and benefits. To investigate these issues, we will conduct a two-part experimental study to examine how: (1) Type of animation and (2) nonhuman personification in drug ads influence consumer comprehension, processing, and perception of risk and benefit information. Understanding how issues of animation and personification affect perceptions of both risks and benefits can inform FDA regarding how prescription drug risk and benefit information is processed. These strategies will be examined across two different medical conditions to see if the findings are consistent across patient populations.

General Research Questions

1. How does consumer processing of a DTC prescription drug ad differ depending on whether the ad is live-action, rotoscoped, or animated?

2. Does consumer processing differ depending on whether the sufferer, the disease, or the benefit is the focus of the animation?

Design

To test these research questions, we will conduct two experiments. Both experiments will be examined in two different medical conditions: Chronic dry eye and psoriasis. The mock drugs we will create for these conditions mimic currently available medications and were chosen for their variance in serious side effects, *i.e.,* medications for psoriasis have very long, serious lists of risks and side effects, whereas chronic dry eye medications have relatively few risks and side effects.

The first experiment will examine whether animation itself influences consumer processing, defined as consumer recall of risks and benefits, perceptions of risks and benefits, and attitudes and emotional responses to the ad, the brand, the product, and the character (table 1). We will examine two different types of animation in addition to a control ad which will be shot with live actors: An ''in-between'' animation technique, rotoscoping, in which live scenes are drawn to look animated, and full animation with nonhuman characters. The live action and rotoscoped ad will be identical except for the rotoscope treatment. The animated ad will follow the theme and message as closely as possible within the limitations of animation itself. The benefits and risks of the product will be identical, although the ad's storyline may vary somewhat to account for a nonhuman protagonist.

TABLE 1—EXPERIMENT 1: ANIMATION DESIGN

	Type of Animation		
Medical condition	Nonhuman sufferer	Rotoscoped human sufferer	Human sufferer
Chronic Dry Eye	•	•	•
Psoriasis	•	•	•

The second experiment will examine whether the object of the animation influences consumer processing of the ad (table 2), defined as consumer recall of risks and benefits, perceptions of risks and benefits, and attitudes and emotional responses to the ad, the brand, the product, and the character. The animation will focus on the animated character who will personify either the sufferer of the medical condition, the disease itself, or the

benefit from the drug. In this study, all ads will contain the same kind of full animation and the general theme will be as similar as possible, accounting for the variations in focus of character. The experiments will be conducted concurrently, and the same participants in the nonhuman sufferer groups will be part of both.

TABLE 2—EXPERIMENT 2: PERSONIFICATION DESIGN

	Nonhuman Personification		
Medical condition	Sufferer	Disease	Benefit
Chronic Dry Eye	•	•	•
Psoriasis	•	•	•

In both cases, a professional firm will create all ads such that they are indistinguishable from currently running DTC ads.

Pretesting will take place before the main study to evaluate the procedures and measures used in the main study. We will recruit adults who have experienced chronic dry eye or psoriasis. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. We propose to test 300 participants for the pretest. Each experiment will include 30 participants per condition for a total of 180 participants each, but 60 of those in the nonhuman sufferer conditions will overlap between the two experiments. We will need 1,500 unique participants for the main study to obtain 90 percent power to detect a moderately small effect size. There will be 150 participants per condition for a total of 900 participants in each experiment, with 300 participants in the overlapping nonhuman sufferer conditions.

In both experiments, participants who have been diagnosed with either chronic dry eye or psoriasis will be recruited via an opt-in Internet panel to watch one ad for a prescription drug that treats their medical condition. In experiment 1, participants will be randomly assigned to view either a live-action, rotoscoped, or fully animated ad. All themes in experiment 1 will focus on the main character as the sufferer of the condition. In experiment 2, participants will be randomly assigned to a personification condition: Sufferer, disease, or benefit. All ads in experiment 2 will be fully animated. Participants will watch the ad once and then answer an online survey with questions addressing recall of risks and benefits, perceptions of risks and benefits, and attitudes and emotional responses to the ad, the brand, the product, and the character. The questionnaire is available upon request. Participation is estimated to take approximately 25 minutes.

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance.

With online surveys, several participants may be completing the survey at the time that the total target sample is reached. Those participants are allowed to complete the survey, which can result in the number of completes going slightly over the target number. Thus, our target number of completes is 1,500, so we have rounded up by an additional 150, or 10 percent, to allow for some overage.

In the **Federal Register** of March 2, 2016 (81 FR 10867), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received a number of comments as enumerated and discussed here. Of these comments, 22 were out of the scope of the proposed project (''Ban DTC'' or ''Ban animated DTC'').

1. AbbVie

(Comment 1) Note that the accuracy of the findings will be highly dependent on the quality of the stimuli (*i.e.,* the animation).

(Response 1) We agree.

2. Lilly

(Comment 2) Assume that stimuli will conform to FDA regulations and standards.

(Response 2) Reviewers from the Office of Prescription Drug Promotion have been involved throughout the development of the stimuli to ensure that the mock ads conform to FDA regulations and standards.

(Comment 3) Question the use of such a large (n = 300) pretest and recommends the use of a qualitative, in-person pretest.

(Response 3) Before the pretests and main studies are conducted, we will conduct nine cognitive interviews to obtain verbal in-person feedback on the questionnaires and the stimuli. We believe this will accomplish what this commenter is suggesting. The pretest is designed to test procedures, verify that the online questionnaire is working as intended, identify and correct any challenges to nesting the stimuli within the questionnaire, and examine data trends to check that the manipulations and questionnaire items are appropriate. A qualitative in-person pretest would not meet those objectives.

(Comment 4) Recommend screening and quotas by length of time since diagnosis as this may influence the urgency with which individuals watch the ads and their familiarity with previous treatments.

(Response 4) We have included a question toward the end of the questionnaire to measure time since diagnosis, which will enable us to assess its association with attention to the ad and statistically control for it if necessary. However, statistical control will likely be unnecessary, since random assignment to conditions in our study design should prevent there from being systematic differences among groups in time since diagnosis or any other extraneous variable.

(Comment 5) For question 5, the item ''think rather than feel'' seems out of place in the question bank and Lilly recommends deletion.

(Response 5) The items in Question 5 make up a validated scale developed by Stephenson and Palmgreen (Ref. 18). Niederdeppe (Ref. 19) used the same scale items to measure cognitive processing. There may be psychometric consequences to deleting this item—in other words, the reliability of the scale may be reduced if we remove this item. Since it was previously validated as a scale, we will maintain the item.

(Comment 6) Questions 6 and 8 (''In your opinion, if 100 people take [DRUG X], for how many will the drug work?'') may be difficult to answer, as pharmaceutical ads rarely have specific side effect information. Recommend changing to ask how frequently side effects will occur, from ''very frequent'' to ''never occurs.''

(Response 6) We agree and will revise these questions to focus on perceived frequency or likelihood of side effects and efficacy in more general terms.

(Comment 7) Questions 13 and 14 (overall comprehension closed-ended

questions) may be too difficult to answer because they are nuanced and involve multiple concepts. Recommend changing to an open-ended response.

(Response 7) We appreciate the commenter's concerns about the complexity of the response options. We will examine the closed-ended questions in cognitive testing, with careful attention to participant's ability to understand and choose among the response options. If participants have notable difficulty with the closed-ended questions, we will revise them to enhance accessibility, or we will replace those items with open-ended items.

(Comment 8) Question 16b for Chronic Dry Eye does not have any question or response options.

(Response 8) We have since developed question and response options for this item.

(Comment 9) Recommend moving questions 17–28 to before question 15 because questions 15 and 16 are specific and starting with question 17, questions again refer to general ad perceptions.

(Response 9) We always approach question ordering carefully, attempting to balance a number of considerations, including the reduction of bias from one question to another, flow, and importance of each item. In this case, we feel that specific claim comprehension is more important than the other more general questions in our questionnaire, which is why they are placed afterwards. We will examine this issue closer in cognitive testing.

(Comment 10) Recommend reducing question 18 to only ''like/dislike'' because the results will be too similar and will be confounded.

(Response 10) We selected these items because they have been used consistently in past research. We use three items rather than one to achieve reliability, which provides a fuller understanding of the dependent variable. However, we will pay close attention to this in cognitive testing to ensure that participants are not confused or annoyed by the three questions.

(Comment 11) For question 21, recommend adding clarifying language: ''. . . in terms of dealing with your psoriasis/chronic dry eye'' to provide context for participant to understand how to compare themselves with the character.

(Response 11) We will present the additional context as an alternative way of asking the question in cognitive interviews.

(Comment 12) Recommend removing question 26 about how ''eerie'' the character is because the essence of this question is answered in question 25 and the question is leading, as it directs participants to respond only negatively about their perceptions of the character.

(Response 12) Given the uncanny valley theory concerning rotoscoped images (Ref. 6), we feel it is crucial to maintain this specific question about the eeriness of the character.

(Comment 13) Recommend adding an open-ended question, preferably near the beginning of the survey (*e.g.,* after question 2), about how well they feel they took away all of the relevant information and understood the risks and benefits of the drug after viewing the ad.

(Response 13) Although we do not include questions that directly measure perceived understanding of the overall message, risks, and benefits, much of the questionnaire is focused on measuring participants' memory and comprehension of that information in the ad.

(Comment 14) Recommend adding demographic questions about how much television participants watch per week and whether English is their primary language to provide extra detail for analyses.

(Response 14) We appreciate this suggestion and will add the recommended demographic items to the questionnaire.

(Comment 15) Recommend adding another open-ended question about whether any additional information could have or should have been included in the ad (*e.g.,* disease information, accessibility of the drug) to provide information on what participants feel could be added and communicated via DTC ads.

(Response 15) This is a great question and may provide fruitful avenues for future research. We will include the item in the pretest and if timing is not an issue, we will maintain it in the main study.

3. Merck

(Comment 16) Concerned that execution-specific learnings from this research may not translate readily into FDA DTC policy/guidance. The research may not have practical utility for the general public and may be unnecessary for the proper performance of FDA's functions.

(Response 16) On the contrary, this particular study has the potential to directly influence policy in an area that we have no prior research on. We have attempted to address the execution-specific nature of the research by investigating our questions in two distinct medical conditions with two distinct products and ad executions. Although one research study cannot answer all questions, we believe we have designed the study in such a way that we will be able to provide information on the issue of animation in DTC ads. Because there is no previous research of this kind, this will be an informative study that will help FDA develop guidance and policy in the future, should the research reveal a need to.

(Comment 17) FDA should conduct research on how all of the elements investigated previously combine to influence DTC viewing.

(Response 17) We appreciate this suggestion and will look for opportunities to do so in the future. Note we have conducted research combining the results of two previous studies—toll-free wording and distraction—in our recent eye-tracking study.

4. GSK

(Comment 18) Suggests a number of additional reasons for animation besides those stated in the FRN: Education, to help consumers quickly identify relevant ads, and to de-personalize an ad to make it more relevant to a variety of people.

(Response 18) We will keep these in mind in writing up the results of the studies.

(Comment 19) The proposed research may oversimplify animation by not incorporating multiple types of animation or examining ads that are 100 percent versus partially animated, and thus be unlikely to yield any general conclusions about the use of animation.

(Response 19) We acknowledge that we are not studying all types and executions of animation. As the first study of its kind, we feel the animation manipulations that we propose to examine will provide information on a reasonable number of variations (*i.e.,* full animation, rotoscoping, and three different foci of animated character). We will ensure that our conclusions are reasonable with regard to the issues we studied.

(Comment 20) The proposed methodology fails to measure the relevance of the ads. A copy-testing methodology, whereby the ads are embedded in a clutter reel, may more accurately gauge the recall of risks and benefits that might occur in the real world.

(Response 20) We needed to make difficult choices in this study, as in all of our studies, regarding the tradeoff between experimental control and real-world generalizability. Given the lack of data available regarding animation in DTC, we chose to err on the side of experimental control in this study. Our

research questions involve the issue of recall and comprehension of the ads when people have watched the ads. Depending on the findings of the current study, further research examining the effects of animation within a clutter reel or considering other variables may be warranted.

(Comment 21) Advertising concepts are generally not designed to be adapted or translated to different creative formats, and because whether an ad is animated or in live action is an integral part of the concept itself, this is an inherent limitation of the research.

(Response 21) We agree that animated ads often have different storylines or different approaches to conveying information from live action ads. However, if we were to use completely different ads for our animated, rotoscoped, and live-action ads, we would be unable to determine what caused any differences in our dependent variables. Indeed, by maintaining as much similarity as possible among these three conditions, we will be able to determine whether it is the animation form per se that causes differences or not.

5. Regeneron Pharmaceuticals

(Comment 22) Encourage FDA to acknowledge that this study is exploratory and that results will not be generalizable beyond the two medical conditions studied.

(Response 22) We acknowledge that this is the first study to directly examine animation in DTC advertising. We are always mindful of how far we can extrapolate our research. We chose to examine two different medical conditions because this will provide some assurance that our findings are not exclusive to one medical condition or execution, if that is what we find. We note that the strength of the study is in its experimental design. Participants will be randomly assigned to cells, which will allow us to determine whether differences exist between different levels of our independent variables. Random assignment will somewhat allay concerns about demographic differences and other individual characteristics, which should even out across cells. However, we agree that other medical situations may cause different reactions and we will acknowledge the limitations of our study, which include not examining all medical conditions and levels of risk, in any writeup we produce.

(Comment 24) The major statement is required to be in the audio and the amount and type of risk information will vary by drug. We request that the professional ad agency designing the TV ads ensure that the major statement is presented consistently across the ads studied for the given ''mock drug.''

(Response 24) We have designed the fictitious ads to very closely align with both FDA policies and with the types of DTC ads that currently air on TV. Our ads have been reviewed by staffers in the Office of Prescription Drug Promotion multiple times throughout the ads' development. The mock products closely mimic existing drugs in their respective classes. We agree that the quality of the ads strongly influences the success of our research and the professional development of these ads is a high priority.

(Comment 25) An imbalance of gender distribution in the diseases and study groups could skew the results due to potential gender differences in consumer processing and perception of information from drug ads. To ensure a gender balance between the study groups, we propose a randomization scheme stratified by gender. Also, please capture patient demographic information and important confounding factors and report on a comparison of the baseline patient characteristics.

(Response 25) Stratified randomization by gender would be methodologically appropriate and conservative, but in practice would make our already complex survey even more complicated. We will acknowledge a potential gender-disease confound as a limitation of the design in reports of the results.

(Comment 26) While the results from this proposed study may suggest hypotheses on difference in how prescription drug risk and benefit information may be perceived by consumers viewing live versus animation ads, the results from this study should not be used to guide or influence FDA's current thinking on the use of animation in DTC ads. More robust and controlled studies will be required in the future to test specific hypotheses generated from this two-part survey experiment.

(Response 26) Although this is the first study to directly examine animation in DTC ads the way we have proposed here, the research we have designed is robust and well controlled. As trained research psychologists, we adhere to the highest standards in terms of rigorous control, prespecified hypotheses, appropriate statistical analyses, and reasonable and responsible interpretations. Our research undergoes many internal and external reviews before and after data collection, including a stringent OMB review (of which public comment is a part), multiple levels of internal clearance, and peer review at well-respected academic journals in relevant fields. Although FDA never exclusively uses the findings of one scientific study to make policy decisions, the quantitative research we conduct is one part of the calculus that FDA uses to inform policy decisions.

6. AstraZeneca

(Comment 27) Recommend that questions 18 and 19 be switched in order to avoid participants being confused by the questions. Also suggest some kind of bolding for emphasis.

(Response 27) We agree that formatting these questions to emphasize and differentiate the target object will be useful and have no problem changing the order of questions 18 and 19 and will do so.

(Comment 28) The term ''main character'' needs to be clarified. As it is, it could mean the human character or the animated character which may, or may not, be the human character.

(Response 28) Participants will only view one version of the ad corresponding to the ad condition to which they've been randomized, and each ad will either be animated or live action. In terms of screen time and storyline, a single character will be dominant in each ad. We do not expect ambiguity surrounding who the main character is in each ad, but we will test this phrase in cognitive interviewing.

(Comment 29) For question 23, the commenter agrees that trust is a useful metric to study but questions whether our options are valid measures of trust, particularly ''ethical.'' Suggest the use of the following adjectives instead: Exaggerated, deceptive, manipulative, trustworthy, informative, credible.

(Response 29) The negative adjectives on the list are from an existing scale (Refs. 20–21) and we would like to keep those consistent with the prior literature. We will revise the positive adjectives to reflect the commenter's suggestion: Trustworthy, informative, credible, and reliable.

(Comment 30) For questions 24 and 25, suggest the addition of ''hopeful,'' ''empowered,'' and ''informed.''

(Response 30) The emotional reaction questions were adapted from existing scales (Ref. 22), but we think it would be useful to test a longer set of emotions in cognitive interviews and narrow down from there.

(Comment 31) We feel that question 26 should be deleted because it is a leading question. If not deleted, change ''eerie'' to ''strange.''

(Response 31) We agree that this is an unusual question and may seem offputting without context. However,

previous research has compared live action and rotoscoped action in advertisements and has determined that people feel uncomfortable with rotoscoping because it is very similar to what we expect from live renditions, but not exactly. This theory is called the uncanny valley theory (Ref. 6). Question 26 comes directly from this previous research and we feel strongly that we need the question as it is to ground our comparison of live action and rotoscoping in the prior literature.

(Comment 32) Question 29 about anthropomorphism seems inappropriate to gauge audience acceptance of the premise. Suggest using a question such as: ''To what extent do/can bodily organs or pills have personalities?''

(Response 32) The purpose of question 29 is to measure an individual difference variable, namely to what extent people tend to anthropomorphize. The question is modified from a validated measure (Ref. 23). We do not intend to assess people's acceptance of animated DTC ads through this question. Instead, we are using this as a possible moderator variable to explain some of the variance we might find in responses to other questions. Indeed, another commenter wrote that we should measure demographics and other possibly confounding variables. This is one of these variables. The amount of humanization people ascribe to nonhuman objects may influence their attitudes and perceptions, and these items have been validated in past research. It is not an outcome measure.

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

TABLE 3—ESTIMATED BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Pretesting					
Number to complete the screener (assumes 50% eligible).	660	1	660	.08 (5 minutes)	53
Number of completes	330	1	330	.42 (25 minutes)	139
Main Study					
Number to complete the screener (assumes 50% eligible).	3,300	1	3,300	.08 (5 minutes)	264
Number of completes	1,650	1	1,650	.42 (25 minutes)	693
Total Hours					1,149

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

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Dated: October 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25727 Filed 10–24–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–AKR–GLBA–22231; PPWOBSADA0, PPMPSAS1Y.Y00000 (177)]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Glacier Bay National Park and Preserve Bear Sighting and Encounter Reports

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before November 25, 2016.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to Madonna L. Baucum, Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive, Mail Stop 242, Reston, VA 20192; or *madonna_baucum@nps.gov* (email). Please include ''1024–GLBA'' in the subject line of your comments. You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Margaret Hazen, Supervisory Park Ranger, Glacier Bay National Park and Preserve at *Margaret_Hazen@nps.gov* (email) or at (907) 697–2608 (telephone).

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Park Service Organic Act, 54 U.S.C. 100101(a) *et seq.*), requires that the NPS preserve national parks for the enjoyment, education, and inspiration of this and future generations. Permit requirements and restrictions for recreational activities in the backcountry are governed in accordance with the regulations found at Title 36, Code of Federal Regulations, Sections 1.5, 1.6, and 2.10 (36 CFR 1.5, 1.6, 2.10, and 13.116). In order to monitor resources and wildlife in the Glacier Bay National Park and Preserve (GLBA) and to enhance the safety of future visitors, the park monitors all sightings and interactions by visitors with bears. The bear sighting and encounter reporting forms are an extension of our statutory authority and responsibility to protect the park areas we administer and to manage the public use thereof. NPS regulations codified in 36 CFR 1–7, 12 and 13, are designated to implement statutory mandates that provide for resource protection and public enjoyment.

Bear sighting data provides the park with important data used to determine bear movements, habitat use, and species distribution. This information can be used in backcountry management and planning, field research planning, and educational outreach for visitors. Bear-human interaction data is vital to understand how bears respond to people, detecting changes in bear behavior, and identifying potential areas of high bear-human conflict. Obtaining immediate information on bear-human conflicts allows managers to respond promptly to mitigate further conflicts. Proactive mitigation includes notifying other backcountry users, issuing advisories or recommendations, or issuing closures to prevent further conflicts and maintain public safety. Additionally, managers may respond to reports of bear-human conflict with bear management techniques such as hazing or aversive conditioning. Obtaining current accurate information on bear sightings and interactions is essential for public safety and to effectively manage bears and people to minimize conflicts. Summary statistics (without personal information) may be generated to examine long-term trends in types and locations of bear-human interactions. Observations and interactions by visitors are recorded via the two forms: NPS Form 10–405 and NPS Form 10–406.

The NPS requires the submission of NPS Form 10–405 upon exiting the park backcountry in order to collect information regarding bear sightings within GLBA. The collection and timeliness of the data collection is critical for the NPS' ability to enhance the safety of future visitors and to protect the bear population at the park. Information collected via NPS Form 10–405 includes:

- Group name;
- Take-out date;
- Whether visitor encountered dirty campsites left by previous users or observe unsafe or inappropriate behavior by other groups; and
- Detailed information for each sighting documented on the form, to include:
  - Date/time;
  - Species type
  - Total number of bears seen together (for each sighting);
  - Bear unit type;
  - Estimation of distance between visitor and bear(s);
  - Whether the bear was aware of the group;
  - Bear reaction to group;
  - Activity of group;
  - Number of observers; and
  - Location description/campsite name/GPS position/other comments.

Submission of a completed NPS Form 10–406 is required when a bear enters camp, approaches the group, damages gear, obtains food, and/or acts in an aggressive or threatening manner towards the group. The collection and timeliness of data concerning bear-human contact is critical for the NPS' ability to enhance the safety of future visitors and to protect the bear population at the park. Information collected via NPS Form 10–406 includes:

- Name and phone number of the primary person involved in the interaction;
- Group type: Park visitor, concession employee, contractor, researcher, NPS employee, or other;
- Number of people who encountered the bear;
- Corresponding sighting number on NPS Form 10–405; Location 1–28 (Backcountry vs. Developed Area A and B);