Animation in Direct-to-Consumer Advertising

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 non-human[1]. Despite variations in form, animated characters are often used to grab attention, increase ad memorability, and enhance persuasion to ultimately drive behavior[2]. Animated characters have long been used for low-involvement products (e.g., food products) and have also made their way into direct-to-consumer prescription drug advertising. However, to our knowledge, one study[3] 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.[4] 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

[1] Callcott MF, Lee W. Establishing the spokes-character in academic inquiry: historical overview and framework for definition. Adv Consum Res. 1995;22:144-151.

[2] Bell JA. Creativity, TV commercial popularity, and advertising expenditures. Int J Advert. 1992;11(2):165-72; Heiser RS, Sierra JJ, Torres IM. Creativity via cartoon spokespeople in print ads: Capitalizing on the distinctiveness effect. J Advert. 2008;37(4):75-85; Luo JT, McGoldrick P, Beatty S, Keeling KA. On-screen characters: their design and influence on consumer trust. J Serv Mark. 2006;20(2):112-24.

[3] Bhutada NS, Rollins BL, Perri M. Impact of animated spokes-characters in print direct-to-consumer prescription drug advertising: An elaboration likelihood model approach. Health Commun. 2016; DOI: 10.1080/10410236.2016.1138382

[4] Clayton RB, Lesher G. The uncanny valley: The effects of rotoscope animation on motivational processing of depression drug messages. J Broadcast Electron. 2015;59(1):57-75.

examined this technique in drug ads have found that animated human characters either had no effect on perceived product risk[5] or led to poorer recognition of drug side effects[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 non-human 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[7]; 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[8], emotional responses[9], brand attitudes[10], and perceived product value[11]. 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[12].

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[13], advertising content that is engaging, relevant, and maximizes audio/visual

[5] Bhutada NS, Rollins BL, Perri M. Impact of animated spokes-characters in print Direct-to-Consumer prescription drug advertising: An Elaboration Likelihood Model approach. Health Communication. Published online Jun 17 2016. doi:10.1080/10410236.2016.1138382.

[6] Clayton RB, Lesher G. The uncanny valley: The effects of rotoscope animation on motivational processing of depression drug messages. J Broadcast Electron. 2015;59(1):57-75.

[7] Pashupati K. Beavers, bubbles, bees, and moths: An examination of animated spokescharacters in DTC prescription drug advertisements and websites. J Advertising Res. 2009;49(3):373-93.

[8] Chandler J, Schwarz N. Use does not wear ragged the fabric of friendship: Thinking of objects as alive makes people less willing to replace them. J Consum Psychol. 2010;20(2):138-145.

[9] Callcott MF, Lee W. Establishing the spokes-character in academic inquiry: historical overview and framework for definition. Adv Consum Res. 1995;22:144-151; Callcott MF, Phillips BJ. Observations: Elves make good cookies: Creating likeable spokescharacter advertising. J Advertising Res. 1996;36(5):73-79; Garretson JA, Niedrich RW. Spokes-characters: Creating character trust and positive brand attitudes. J Advertising. 2004;33(2):25-36.

[10] Delbaere M, McQuarrie EF, Phillips BJ. Personification in advertising: Using a visual metaphor to trigger anthropomorphism. J Advertising. 2011;40(1):121-130.

[11] Hart PM, Jones SR, Royne MB. The human lens: How anthropomorphic reasoning varies by product complexity and enhances personal value. J Marketing Manag. 2013;29(1-2):105-121.

[12] Moyer-Guse E, Mahood C, Brookes S. Entertainment-education in the context of humor: Effects on safer sex intentions and risk perceptions. Health Comm. 2011;26(8):765-774.

[13] Lang A. The limited capacity model of motivated mediated message processing. In the Sage Handbook of Mass Media Effects. New York: Sage;2009:193-204.

redundancy should improve learning and memory[14]. However, others argue that the entertainment aspects can distract from learning key information and may lead to message complexity that interferes with message communication[15].

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) non-human 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?

2. Purpose and Use of the Information Collection

The purpose of this project is to investigate how different aspects of animation in television DTC ads influence the communication of benefit and risk information. Pharmaceutical companies sometimes use animated ads to attract attention for their products. To our knowledge, no studies have comprehensively examined how animation affects consumers' benefit and risk perceptions in drug ads or 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. Part of FDA's public health mission is to ensure the safe use of prescription drugs; therefore it is important to communicate the risks and benefits of prescription drugs to consumers as clearly and usefully as possible. This study will inform FDA of the value of further exploring animated television ads from a communication perspective.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. One hundred percent (100%) of participants will self-administer the survey via a computer, which will record responses and provide appropriate probes when needed. In addition to its use

[14] Garretson JA, Burton S. The role of spokescharacters as advertisement and package cues in integrated marketing campaigns. J Marketing. 2005;69(4):118-132.

[15] Lang A. Using the limited capacity model of motivated mediated message processing to design effective cancer communication messages. J Comm. 2006;56:557-580.

in data collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time basis for each participant, and by keeping the written parts of surveys to less than 30 minutes in both the pretests and main study.

4. Efforts to Identify Duplication and Use of Similar Information

Although the literature revealed a rich background on which to base the current research, we found no studies that have examined the issues we propose to study.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The proposed data collection is one-time only. There are no plans for successive data collections.

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

There are no special circumstances for this collection of 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 in the Federal Register of March 2, 2016, (81 FR 10867) requesting public comment on the proposed collection of information. FDA received 29 comments total. Of these comments, 22 were beyond the scope of the proposed project ("Ban DTC" or "Ban animated DTC"), leaving seven substantive comments as discussed in our 30 day notice (81 FR and here:

1. AbbVie
    a. *Comment*: Supportive comment about the usefulness of this line of research.

       Response: Thank you.

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

       Response: We agree.

2. Lilly
    a. *Comment*: Supportive statement about FDA using research to develop evidence-based policies.

       Response: Thank you.

b. *Comment*: Assume that stimuli will conform to FDA regulations and standards.

Response: 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.

c. *Comment*: In general, the research objectives and study approach are reasonable.

Response: Thank you.

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

Response: 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.

e. *Comment*: 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: 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.

f. *Comment*: For question 5, the item "think rather than feel" seems out of place in the question bank and Lilly recommends deletion.

Response: The items in Question 5 make up a validated scale developed by Stephenson & Palmgreen (2001)[16]. Niederdeppe (2005)[17] 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

[16] Stephenson MT, Palmgreen P. Sensation seeking, perceived message value, personal involvement, and processing of anti-marijuana PSAs. Commun Monographs. 2001;68:49–71.

[17] Niederdeppe JD. Syntactic indeterminancy, perceived message sensation, value-enhancing features, and message processing in the context of anti-tobacco advertisements. Commun Monographs. 2005;72(3):324-344.

we remove this item. Since it was previously validated as a scale, we will maintain the item.

g. *Comment*: 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: Thank you for this recommendation. We agree and will revise these questions to focus on perceived frequency or likelihood of side effects and efficacy in more general terms.

h. *Comment*: 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: 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.

i. *Comment*: Question 16b for Chronic Dry Eye does not have any question or response options.

   Response: Thank you for this comment. We have since developed questions and response options for this item.

j. *Comment*: 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: We appreciate this suggestion. 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.

k. *Comment*: Recommend reducing question 18 to only "like/dislike" because the results will be too similar and will be confounded.

   Response: 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.

l. *Comment*: 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: We will present the additional context as an alternative way of asking the question in cognitive interviews.

m. *Comment*: 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: Given the Uncanny Valley Theory concerning rotoscoped images[18], we feel it is crucial to maintain this specific question about the eeriness of the character.

n. *Comment*: 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: 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.

o. *Comment*: 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: We appreciate this suggestion and will add the recommended demographic items to the questionnaire.

p. *Comment*: 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: 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.

[18] Clayton RB, Leshner G. The Uncanny Valley: The effects of rotoscope animation on motivational processing of depression drug messages. J Broadcast Electronic Media. 2015;59:57-75.

3. Merck
    a. *Comment*: 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: 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.

    b. *Comment*: FDA should conduct research on how all of the elements investigated previously combine to influence DTC viewing.

       Response: 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[19].

4. GSK
    a. *Comment*: 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: Thank you for adding these reasons. We will keep these in mind in writing up the results of the studies.

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

       Response: 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.

[19] https://www.regulations.gov/searchResults?rpp=25&po=0&s=0910-0772&fp=true&ns=true

c. *Comment*: The proposed methodology fails to measure the relevance of the ads. A copytesting 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: 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.

d. *Comment*: 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: 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. The Advertising Coalition
   a. *Comment*: Animated advertising is protected under the First Amendment.

   Response: Please be advised that the study is designed to determine how animation affects the comprehension of direct-to-consumer (DTC) television advisement for prescription drugs. The final results of the study do not establish FDA policy.

6. Regeneron Pharmaceuticals
   a. *Comment*: Encourage FDA to acknowledge that this study is exploratory and that results will not be generalizable beyond the two medical conditions studied.

   Response: 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 write-up we produce.

b. *Comment*: The commenter was not sure if the questionnaire was available for stakeholders, but acknowledged that it was available upon request. The commenter is not sure if the questionnaire is appropriate because they have not looked at it.

   Response: As the commenter noted, the questionnaire is available to anyone who requests a copy.

c. *Comment*: 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: 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.

d. *Comment*: 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: 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.

e. *Comment*: 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: 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, pre-specified 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.

7. AstraZeneca
    a. *Comment*: 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: 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.

    b. *Comment*: 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: 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.

    c. *Comment*: 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: The negative adjectives on the list are from an existing scale[20] 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.

[20] Parvanta S, Gobson L, Forquer H, Shapiro-Luft D, Dean L, Freres D, et al. Applying quantitative approaches to the formative evaluation of antismoking campaign messages. Soc Market Quarterly. 2013;19(4):242-264; Thomas V, Fowler K, Grimm P. Conceptualization and exploration of attitude toward advertising disclosures and its impact on perceptions of manipulative intent. J Consum Aff. 2013;47(3):564–87.

d. *Comment*: For questions 24 and 25, suggest the addition of "hopeful," "empowered," and "informed."

Response: Thank you for offering additional adjectives for us to consider. The emotional reaction questions were adapted from existing scales[21], but we think it would be useful to test a longer set of emotions in cognitive interviews and narrow down from there.

e. *Comment*: We feel that question 26 should be deleted because it is a leading question. If not deleted, change "eerie" to "strange."

Response: We agree that this is an unusual question and may seem off-putting 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.[22] 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.

f. *Comment*: 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: 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[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 non-human objects may influence their attitudes and perceptions, and these items have been validated in past research. It is not an outcome measure.

External Reviewers

In addition to public comment, OPDP solicited peer-review comments from academic researchers in fields relevant to the communication of DTC prescription drug information

[21] Richins, M. Measuring emotions in the consumption experience. J Consum Res. 1997;24:127-146.
[22] Clayton RB, Leshner G. The Uncanny Valley: The effects of rotoscope animation on motivational processing of depression drug messages. J Broadcast Electronic Media. 2015;59:57-75.
[23] Waytz A, Cacioppo J, Epley N. Who sees human? The stability and importance of individual differences in anthropomophism. Perspectives Psychol Sci. 2010;5:219-32.

and specifically animation. We received responses and incorporated the thoughts of the follow individuals:

Dr. Annie Lang, Indiana University Bloomington, The Media School

Dr. Glenn Leshner, The University of Oklahoma, Gaylord College

Dr. Brent Rollins, Philadelphia College of Osteopathic Medicine – Georgia Campus

9. Explanation of Any Payment or Gift to Respondents

Internet panelists are rewarded for taking part in surveys with a structured incentive scheme, reflecting the length of survey and nature of sample. The incentive is paid in the form of a virtual currency, referred to as "e-Rewards currency". The incentive options allow panelists to redeem from a large range of gift cards, points programs, and partner products or services. Internet panel participants are enrolled into an incentive program that is analogous to a frequent flyer card: respondents are credited with incentives in proportion to their regular participation in surveys. Traditionally, panelists earn higher incentives for surveys that are longer or require special tasks by the panel member. When a panelist's e-Rewards currency balance reaches $10, the panelist may elect to redeem the e-Rewards currency for vouchers to a variety of national retailers, or choose to save and build up more currency for larger rewards. Participants who complete the 25 minute survey will receive an estimated $6.25 in e-Rewards currency.

These amounts have been carefully considered for their appropriateness to ensure the ability to attract a reasonable cross-section of participants, including reasonable diversity in age, income, and education.

10. Assurance of Confidentiality Provided to Respondents

All participants will be provided with an assurance of privacy to the extent allowable by law. See Appendix A for the consent form.

No personally identifiable information will be sent to FDA. Data from completed surveys will be compiled into a SPSS data set by the vendor and sent to RTI, with no personally identifiable information (PII) for analysis. All information that can identify individual respondents will be maintained by the subcontractor in a form that is separate from the data provided to FDA. The information will be kept in a secured fashion that will not permit unauthorized access. Confidentiality of the information submitted 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). These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee, RIHSC) prior to collecting any information.

All participants will be assured that the information will be used only for research purposes and will be kept private to the extent allowable by law. The experimental instructions will include

information explaining this to respondents. The pretest and main study instructions and informed consent will include information explaining to respondents that their information will be kept confidential. Participants will be assured that their answers to screener and survey questions will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Participants will be told that the information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

The Internet panel includes a privacy policy that is easily accessible from any page on the site. A link to the privacy policy will be included on all survey invitations. The panel complies with established industry guidelines and states that members' personally identifiable information will never be rented, sold, or revealed to third parties except in cases where required by law. These standards and codes of conduct comply with those set forth by American Marketing Association, the Council of American Survey Research Organizations, and others. All Research Now employees and contractors are required to take yearly security awareness and ethic training, which is based on these standards.

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' ADP Systems Security Policy as described in the DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products). Upon final delivery of data files to RTI and completion of the project, Research Now will destroy all study records, including data files, upon request.

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The complete list of questions is available in Appendix B.

12. Estimates of Annualized Burden Hours and Costs

For both the pretests and main study, the questionnaire is expected to last no more than 30 minutes. This will be a one-time (rather than annual) collection of information. FDA estimates the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response[1]	Total Hours
Pretesting					
Number to complete the screener (assumes 50% eligible)	660	1	660	0.08 (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	0.08 (5 minutes)	264
Number of completes	1,650	1	1,650	.42 (25 minutes)	693
Total					1,149

These estimates are based on FDA's and the contractor's experience with previous consumer studies.

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 total estimated cost to the Federal Government for the collection of data is $743,818 ($185,955 per year for four years). This includes the costs paid to the contractors to manipulate the stimuli, program the study, draw the sample, collect the data, and create and analyze a database of the results. The contract was awarded as a result of competition. Specific cost information other than the award amount is proprietary to the contractor and is not public information. The cost also includes FDA staff time to design and manage the study, to analyze the resultant data, and to draft a report ($96,000; 8 hours per week for four years).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for experimental data, such as descriptive statistics, analysis of variance, and regression models, will be used to analyze the data. See section B for detailed information on the design, hypotheses, and analysis plan. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared.

The exact timing and nature of any such dissemination has not been determined, but may include presentations at trade and academic conferences, publications, articles, and Internet posting.

Table 2. – Project Time Schedule

Task	**Estimated Number of Weeks after OMB Approval**
Pretest completed	11 weeks
Main study data collected	48 weeks
Final methods report completed	52 weeks
Final results report completed	88 weeks
Manuscript submitted for internal review	97 weeks
Manuscript submitted for peer-review journal publication	100 weeks

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

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.