Estimated Total Annual Burden Hours: 1,694.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–04582 Filed 3–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0538]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animation in Direct-to-Consumer Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled ''Animation in Direct-to-Consumer Advertising.'' This study will examine how animation affects the comprehension of direct-to-consumer (DTC) television advertisements for prescription drugs.

DATES: Submit either electronic or written comments on the collection of information by May 2, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–0538 for ''Animation in Direct-to-Consumer Advertising.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB

for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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(d)(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 (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, 3, and 4). Although animated characters have long been used for low-involvement products (*e.g.,* food products), animation has made its way into direct-to-consumer prescription drug advertising. However, to our knowledge, no studies have comprehensively examined how animation affects consumers' benefit and risk perceptions in drug ads, how various animation strategies (*e.g.,* symbolizing the disease vs. the benefit) influence these perceptions, and whether these effects are generalizable across different patient populations.

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. 5). 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. 6) or led to poorer recognition of drug side effects (Ref. 5).

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 (Ref. 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 (Ref. 8), emotional responses (Refs. 1, 9, and 10), brand attitudes (Ref. 11), and perceived product value (Ref. 12). 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. 13).

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. 14), advertising content that is engaging, relevant, and maximizes audio/visual redundancy should improve learning and memory (Ref. 15). 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. 16).

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 and medications with different levels of risk.

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	Non-human 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

[Non-Human 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 fall into one of four age brackets shown in table 1. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. A prior power analyses revealed that we need 300 participants for the pretest to obtain 80% power to detect a moderately small effect size. 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% 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 studies, participants who have been diagnosed with either chronic dry eye or psoriasis will be recruited via opt-in Internet panel to watch one ad for a prescription drug that treats their medical condition. In study 1, participants will be randomly assigned to view either a live-action, rotoscoped, or fully animated ad. All themes in study 1 will focus on the main character as the sufferer of the condition. In study 2, participants will be randomly assigned to a personification condition: sufferer, disease, or benefit. All ads in study 2 will be fully animated. Participants will watch the ad twice 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 (ANOVA).

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%, to allow for some overage.

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total Hours
Pretesting					
Number to complete the screener (assumes 50% eligible)	660	1	660	0.08 (5 min.)	53
Number of completes	330	1	330	.42 (25 min.)	139

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total Hours
Main Study					
Number to complete the screener (assumes 50% eligible)	3,300	1	3,300	0.08 (5 min.)	264
Number of completes	1,650	1	1,650	.42 (25 min.)	693
Total Hours	.....	.....	.....	.....	1,149

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

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

References

1. Callcott MF, Lee W. ''Establishing the Spokes-Character in Academic Inquiry: Historical Overview and Framework for Definition,'' *Advances in Consumer Research,* 1995;22:144–151.
2. Bell JA. Creativity, TV Commercial Popularity, and Advertising Expenditures, *Internationl Journal of Advertising,* 1992;11(2):165–72.
3. Heiser RS, Sierra JJ, Torres IM. ''Creativity Via Cartoon Spokespeople in Print Ads: Capitalizing on the Distinctiveness Effect,'' *Journal of Advertising,* 2008;37(4):75–85.
4. Luo JT, McGoldrick P, Beatty S, et al, ''On-Screen Characters: Their Design and Influence on Consumer Trust,'' *Journal of Services Marketing,* 2006;20(2):112–24.
5. Clayton RB, Lesher G. ''The Uncanny Valley: The Effects of Rotoscope Animation on Motivational Processing of Depression Drug Messages,'' *Journal of Broadcasting and Electronic Media,* 2015;59(1):57–75.
6. Bhutada NS, Rollins BL, Perri M. ''Animation in Print Direct-to-Consumer Advertising of Prescription Drugs: Impact on Consumers,'' at the 32d Association for Marketing and Healthcare Research Annual Meeting and Conference, February 27-March 1, 2013, Big Sky, MT.
7. Pashupati K. ''Beavers, Bubbles, Bees, and Moths: An Examination of Animated Spokescharacters in DTC Prescription Drug Advertisements and Web sites,'' *Journal of Advertising Research,* 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,'' *Journal of Consumer Psychology,* 2010;20(2):138–145.
9. Callcott MF, Phillips BJ., ''Observations: Elves Make Good Cookies: Creating Likeable Spokescharacter Advertising,'' *Journal of Advertising Research,* 1996;36(5):73–79.
10. Garretson JA, Niedrich RW., ''Spokes-Characters: Creating Character Trust and Positive Brand Attitudes,'' *Journal of Advertising,* 2004;33(2):25–36.
11. Delbaere M, McQuarrie EF, Phillips BJ, ''*Personification in Advertising: Using a Visual Metaphor to Trigger Anthropomorphism,'' Journal of Advertising,* 2011;40(1):121–130.
12. Hart PM, Jones SR, Royne MB, ''The Human Lens: How Anthropomorphic Reasoning Varies by Product Complexity and Enhances Personal Value,'' *Journal of Marketing Management,* 2013;29(1–2):105–121.
13. Moyer-Guse E, Mahood C, Brookes S., ''Entertainment-Education in the Context of Humor: Effects on Safer Sex Intentions and Risk Perceptions,'' *Health Communication,* 2011;26(8):765–774.
14. Lang A., ''The Limited Capacity Model of Motivated Mediated Message Processing,'' *The Sage Handbook of Mass Media Effects,* New York: Sage;2009:193–204.
15. Garretson JA, Burton S., ''The Role of Spokescharacters as Advertisement and Package Cues in Integrated Marketing Campaigns,'' *Journal of Marketing,* 2005;69(4):118–132.
16. Lang A., ''Using the Limited Capacity Model of Motivated Mediated Message Processing to Design Effective Cancer Communication Messages,'' *Journal of Communication,* 2006;56:557–580.

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04569 Filed 3–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0110]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On August 31, 2015, the Agency submitted a proposed collection of information entitled ''Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency 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. OMB has now approved the information collection and has assigned OMB control number 0910–0437. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04576 Filed 3–1–16; 8:45 am]

BILLING CODE 4164–01–P