United States Food and Drug Administration

Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part 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 FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (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.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first two topic areas, advertising features and target populations.

Because we recognize that the strength of data and the confidence in the robust nature of the findings is improved by utilizing the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm. The website includes links to the latest *Federal Register* notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a survey on direct-to-consumer (DTC) advertisements conducted in 1999.

Advertisers have used celebrity endorsers for years, and DTC pharmaceutical promotion is no different. As researchers studied the influence of celebrity endorsers, they theorized that a correspondence bias occurs in which people believe that endorsers truly believe what they are saying. LaTour and Smith (Ref. 1) examined whether a pharmacist, physician, celebrity, or consumer would be most persuasive in advertisements for four different types of OTC products. They found that endorsements by expert physicians and pharmacists were the most likely to lead to purchase intentions, followed by endorsements by consumers, and lastly, by celebrities. The type of OTC product did not affect the persuasiveness of an endorsement.

Bhutada and Rollins (Ref. 2) recently completed a study examining the role of endorser type (i.e., celebrity vs. expert vs. non-celebrity), and endorser and consumer gender in product DTC ads. They found, like LaTour and Smith (Ref. 1), that expert endorsers were thought of as higher in credibility and generally resulted in the same amount of attention as celebrities. The authors did not find that endorsement by experts resulted in greater consumer intention to pursue the drug product.

We propose to extend previous research by examining four types of endorsers in two separate studies (celebrity, physician, patient, non-celebrity influencer[1]) and examining whether the presence of a disclosure of their payment status influences participant reactions. We propose to also test two different types of disclosure language—one direct and more consumer-friendly, and one less direct.

2. Purpose and Use of the Information Collection

The purpose of this project is to investigate how consumers understand the messages in DTC promotional pieces when they feature one of several different types of endorsers and a disclosure about payment for endorsement. 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 in a truthful and non-misleading way. This study will inform FDA of the impact of endorsers and payment disclosures on these communications.

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 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 20 minutes in both the pretests and main study.

[1]A "non-celebrity influencer" is a person who has gained a following on a blog, a Twitter feed, or other social media outlet.

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 particular issues we propose to study. Specifically, we know of no studies that examine payment disclosures and no published literature on the role of non-celebrity influencers in the DTC context.

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 the *Federal Register* of January 28, 2020 (85 FR 4994), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six submissions that were PRA-related. One submission (https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=FDA-2019-N-5900&refD=FDA-2019-N-5900-0001) was a brief statement of support for the research and is not addressed further. Within the remaining five submissions, FDA received multiple comments that the Agency has addressed below. For brevity, some public comments are paraphrased and therefore may not reflect the exact language used by the commenter. We assure commenters that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: DTC = direct-to-consumer; FDA and "The Agency" = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion; FTC = Federal Trade Commission.

(Comment 1) One comment suggested that the proposed research, at least in part, is duplicative of information otherwise reasonably available to FDA. The comment pointed out that the Notice cites three scientific references, and it does not address the other literature that exists on the subject of endorsers in advertising. The comment recommended that FDA assemble and review the relevant literature on endorsement to ensure the research questions have not already been answered.

(Response) A literature review was conducted as part of this project that identified relevant literature. We identified a significant gap in the literature regarding the impact of

social media influencers in prescription drug DTC advertisements, as well as a lack of information about the impact of explicit payment disclosure. The research questions outlined in our proposed research were designed to address this gap.

(Comment 2) One comment suggested that, although the studies contain clear variables, they appear to lack clearly defined primary outcomes and prespecified hypotheses for testing. The comment also noted that the studies do not appear to be designed to account for Type I error; thus, the results may be uninterpretable. The comment recommended that FDA propose a primary endpoint for each study and power each study to test it.

(Response) Specific hypotheses have been developed for each of these outcome variables. We will adjust for multiple comparisons using the Bonferroni correction.

(Comment 3) One comment suggested that it is unclear how FDA came up with the proposed sample sizes for the two related studies. For example, the chart for pretest 1 contains the following notation: "(0.80 power, 0.10 alpha, small effect size f=.2)" but it is unclear what f=.2 means in this context. The comment requested that FDA explain what statistical model it used to estimate the study size and how it determined that the relevant effect size is .2.

(Response) f = .2 is a common standard used to calculate small effect size in experimental studies (Ref. 4). We used G*Power to estimate study size (Ref. 5).

(Comment 4) One comment suggested that the proposed research is unnecessary to the proper performance of FDA's functions because the FTC takes the lead on regulating endorsement. The comment stated that FDA has not addressed the extensive framework and guidance available from the FTC on this topic. The comment further stated that, although use of an endorser might conceivably inform an assessment of whether advertising or promotion is false or misleading, it is not clear how FDA views this new research on endorser status as fitting into its core regulatory jurisdiction or activities.

(Response) FDA and the FTC have a long history of working collaboratively to protect American consumers. While FTC does regulate endorsement in many types of commercial advertisements, FDA has authority to regulate prescription drug advertising with respect to the safety and effectiveness of such drugs. In line with FDA's responsibility to ensure that prescription drug advertising and other promotional communications are truthful and non-misleading, the present research will provide data on how elements related to endorsement presentations in prescription drug promotion impact audience perception and comprehension. Collecting this data is critical to FDA's science-based approach to assessing prescription drug promotion to determine whether it communicates information about prescription drugs to consumers in a truthful, non-misleading way. We note that as part of the process of developing the present research, FDA carefully evaluated the FTC guidance on endorser issues.

(Comment 5) One comment recommended that alignment and input should be obtained from the FTC regarding the design of the study and usability of the results.

(Response) We evaluated the current FTC guidance on endorsement disclosure when developing this study and all relevant elements of its design, including our hypotheses, test stimuli, etc.

(Comment 6) One comment suggested that the research may be skewed by the influence of a particular celebrity. The comment recommended that the study be amended so it is not subject to bias by the influence of one particular well-known celebrity.

(Response) Familiarity with an endorser has shown to be an important factor in attention to DTC advertisements, but the evidence is less strong that familiarity uniquely affects other outcomes such as behavioral intention (see, for example, Refs. 2 and 6). The celebrity used in Study 1 will have high levels of public recognition, so we anticipate few participants will be filtered out due to low levels of familiarity with endorser. It is true that the individual characteristics of the celebrity may drive responses. This is an unavoidable limitation of the study design, and we will be transparent when reporting results. Nevertheless, the celebrity we have chosen, similar to other endorsers, is not known to evoke negative associations.

(Comment 7) One comment recommended that FDA use #ad instead of #sp. The comment noted that FTC has stated that #ad is an effective disclosure of sponsorship.

(Response) Our review of current practices shows that vendors continue to indicate endorsement by #sp online. An indirect disclosure such as #sp serves as a useful comparator to a direct disclosure such as “Paid ad…”, helping us answer the research question of whether direct and indirect acknowledgements of endorsement vary in their influence on attitudes and perceptions.

(Comment 8) One comment recommended that FDA incorporate some type of control into each study.

(Response) We have designed these studies to include a control. The control, in both studies, is a duplicate version of the promotion featuring endorsement by a patient, as opposed to a celebrity or influencer, without inclusion of a payment disclosure.

(Comment 9) One comment suggested that FDA should ensure that the hypothetical products used in the proposed surveys do not too closely resemble real products. For example, the conditions of use and the risk of the hypothetical products should not mirror FDA-approved labeling language for any marketed products. In addition, FDA should only present hypothetical drug advertisements for diseases with many treatment options from multiple sponsors. Otherwise, the comment states that FDA’s research could inadvertently harm one particular sponsor.

(Response) The prescription drugs used in this study, while based on existing prescription treatments, are fictitious with names and branding that do not mirror any marketed products. Although we have created the pieces to be as realistic as possible, FDA does

not intend to single out any real product on the basis of our fictional promotion. We specifically use fictitious products and materials to avoid the confound of prior knowledge of actual products. Moreover, it is the endorser type and messaging around the endorsement disclosure that are being investigated. The fictional drug is not a study variable and therefore held constant.

(Comment 10) One comment suggested that the route of drug administration may influence the participants' responses, as oral administration and inhaled medication is preferable compared to injections. Therefore, the comment suggested that the study use fictitious drugs with routes of administration that are similar to top advertised DTC prescription drugs.

(Response) This is outside the scope of study objectives. The goal of the studies is to understand the effect of endorsement and payment disclosure on perceived risks and benefits of DTC promotion. Because the same drug is being presented in each experimental condition, the effects of mode of administration are being held constant in each study; therefore, any observed effects are not related to the route of administration chosen.

(Comment 11) One comment suggested that in order to increase internal validity, the location of the disclosures in the promotional pieces should be consistent across endorser and/or disclosure type.

(Response) FDA will ensure that for each study, disclosures will appear in the same area of the promotional piece, using similar font and style treatment.

(Comment 12) One comment suggested that acne and endometriosis drugs are not representative of the top advertised prescription drugs and that the current proposed study design, therefore, may not represent the most advertised DTC drugs in the market.

(Response) The purpose of the studies is to understand the effect of endorsement and payment disclosure on perceived risks and benefits of DTC promotion. The value of our approach is random assignment to experimental conditions and control of extraneous variables. Choice of drug is not a study variable and therefore held constant. Although the type of drug may play a role in the perceptions of risks and benefits, the value of our study is the comparisons between experimental conditions.

(Comment 13) Two comments suggested that participants' unfamiliarity with the proposed conditions may bias their responses, so it may be more useful to only include patients with the condition as participants in each study.

(Response) The study population is those who are exposed to prescription drug advertisements. For Study 1, we chose a high incidence condition (acne) so that it would be relatable to a large segment of the population. Regardless of whether or not the condition is personally salient, the public is still exposed to these advertisements.

For Study 2, we chose a condition that is important to the influencer in the study--and this information would be known to many of her followers, who are the research audience for Study 2. Engagement and e-Word of Mouth have been shown to be important behavioral outcomes from social media promotion (Ref. 3). Thus, in a real-world setting, audience members may choose to comment on or share the advertised content with family or friends, regardless of whether or not they have the health condition themselves.

For both studies, we ask about personal experience and involvement with the health condition, and we will assess whether these variables have any effects.

(Comment 14) One comment suggested ensuring that neutral language is used when recruiting for Study 1's general population, so as not to select for participants that are more susceptible to the celebrity's influence. For example, the comment suggested that the study ask participants if they "recognize" the celebrity vs. if they are a "fan" of the celebrity.

(Response) In screeners for both studies, we ask if participants are "familiar" with celebrities/influencers, thus maintaining neutral language.

(Comment 15) Two comments suggested participants' familiarity with the endorser may bias responses and limit participant demographics. One comment suggested that recruiting participants from the follower list of an Instagram influencer, as proposed in Study 2, may skew the average age of the participants to be younger, especially if the influencer chosen for this study is a "handheld name" versus a "household name." The comment also suggested that the participants may have a female skew. Another comment suggested that the current inclusion criteria should be expanded to also include followers of influencers with similar content, recognition, and follower demographics as the endorser being tested, which will increase external validity by encompassing viewers that would likely see the post through suggestions via Instagram's algorithm.

(Response) Familiarity with an endorser has been shown to be an important factor in attention given to DTC advertisements (Ref. 2), and that is one driver of an influencer's value as an endorser. By including endorser type as an experimental condition, we seek to isolate these effects. Thus, the biases inherent in these relationships is a necessary aspect of this topic area.

The study design is a between-subjects design. Because participants are only exposed to one promotional piece, the specific effects from behavioral bias can be isolated.

We agree with the commenter that Study 2 will have a younger, female skew. This is consistent with Instagram's audience more generally (Ref. 7). Advertisers who use Instagram influencers as endorsers will access the same audience (i.e., Instagram followers) as in our study. To minimize confounds, we will limit the sample to the influencer's followers, who are likely to be the most influenced by her. Future research can be conducted on whether our findings extrapolate to men and older audiences.

(Comment 16) One comment suggested that to account for the potential bias in these studies, it would be useful to include questions relating to participant demographics in the surveys, such as age, gender, and attitude toward the celebrity or influencer, if they are not already included.

(Response) The survey includes questions about participant demographics and attitude toward endorser.

(Comment 17) One comment suggested that in order to prevent bias, the study should exclude consumers who work in healthcare or marketing settings, primary care providers that spend less than 50 percent of their time on patient care, and Department of Health and Human Service employees.

(Response) The studies in this research do not include physician participants. Consumers will be excluded if they work for a pharmaceutical company, an advertising agency, a market research firm, or the U.S. Department of Health and Human Services. They will also be screened out if they are not familiar with the celebrity/influencer, and, for Study B, if they are biologically male, as men cannot have endometriosis.

(Comment 18) One comment suggested that the questionnaire is too long and recommended deleting questions or rewording.

(Response) We have had individuals unfamiliar with the study test the survey for length, and we found it takes less than 20 minutes to complete. Moreover, we will also conduct pretesting to check timing and make adjustments, if necessary, based on the data from those pretests.

(Comment 19) One comment suggested we should consistently use balanced Likert scales with a neutral midpoint.

(Response) This is a matter of debate in the literature and has never been resolved. Many of our measures derive from previously validated scales, and we prefer to maintain the scales on which they were validated. However, where appropriate, we do use 5-point Likert scales with a neutral midpoint.

(Comment 20) One comment recommended rewording Q17 (in both study questionnaires) to state “What do you remember about the safety information presented?”

(Response) Q17 is a validated (OMB control number 0910-0861) closed-ended item asking how much risk information was read (with a thumbnail image highlighting the important safety information). In order to increase quality of response, we will keep the closed-ended item. Moreover, open-ended questions take longer to answer, and we want to maintain an appropriate length of time to complete the survey.

(Comment 21) One comment suggested that the adjectives that the respondent is asked to rank in Q18a-Q18e (Study 1) are redundant with only nuanced differences that may not

be distinguishable to respondents, and therefore suggested these items be deleted. If they are retained, the comment suggested labeling answer choice #3 with "Neither unimportant nor important."

(Response) These items were adapted from Zaichowsky's Disease State Involvement scale (Ref. 8). The original validated items used a 7-point scale without a labeled midpoint. To be consistent with most of the items and with previous comments, we reduced the scale to 5 points. However, we did not include a labeled midpoint because it could result in under-response for values 2 and 4. This response applies to Q20 (Study B) as well, where we want to ensure that individuals taking Study B on their mobile devices are not overwhelmed.

(Comment 22) One comment suggested that Q20 and Q21 (Study A) may be redundant, and since Q20 uses more consumer-friendly language to seek respondent opinion on effectiveness of drug, the comment recommended removing Q21. This comment also applies to Q22 and Q23 of Study 2.

(Response) We will remove Q21 (Study 1) and Q23 (Study 2).

(Comment 23) One comment recommended that Q22 (Study 1) be framed differently to help understand how endorsers influence the understanding of safety and risk and that the answer choice should have an option for respondents who do not know.

(Response) We decline to make the recommended change because this is a validated item that FDA has used in past survey experiments to measure perceived risk likelihood.

(Comment 24) One comment questioned the utility of asking whether an endorser is "Attractive," "Classy," and "Elegant" (Q30, Study 1); whether a drug name and endorser name "go together" (Q31, Study 1); and how a subject feels about the life and values of the endorser (Q32, Study 1). The comment recommended that FDA consider deleting these questions.

(Response) In the marketing literature on celebrity endorsements, these three elements are well established as important moderators in attitude toward advertisement and behavioral intention. "Attractive, "Classy," and "Elegant" are elements in a 15-item scale validated by Ohanian (1990) to measure endorser credibility (Ref. 9). The literature refers to "whether a drug name and endorser go together" as "product match-up" (Ref. 10), and high match-up was recently shown to be predictive of behavioral intention for e-cigarettes (Ref. 11). The level of identification that consumers have with a celebrity endorser has been shown to influence how consumers attend to and process information in an advertisement (Refs. 12 and 13). Thus, we will maintain these questions.

(Comment 25) One comment suggested that, if the research is intended to assess the influence of endorsers or their payment status, Q15-Q17 in both surveys and Q20-Q27 for Study A and Q22-Q29 for Study B appear to be outside of the scope. With these questions, subjects would be asked to assess the risks and benefits of a drug based on an

advertisement. The comment recommended that FDA delete these questions or revise them so they are focused instead on payment or endorsement.

(Response) As part of the examination of the effect of the endorser, one purpose of the study is to understand the effect of endorsement and payment disclosure in DTC promotion on perceived risks and benefits of a prescription drug. The questions mentioned in this comment measure these dependent variables--consumer perceptions of risk and benefit information presented in the promotion. We will maintain these questions in order to assess if endorsement and the payment disclosure have any effects on perceptions of risk and benefit information.

(Comment 26) One comment suggested that the structure of Q28 (Study 1) and Q30 (Study B) should be consistent with other questions in this survey. It recommended changing each question to include "What is the likelihood" (e.g., What is the likelihood that you would ask your doctor to prescribe) and presenting answer choices in a 5-point Likert scale.

(Response) We will assess how this item functions in pretesting and make any change that is warranted.

(Comment 27) One comment suggested moving Q28a (Study 1) and Q30a (Study 2) up in the survey, after Q13, as this question could function as a priming question after initial viewing of ad.

(Response) Because this item is part of a validated scale (Ref. 14), we will maintain it at its current location in both surveys.

(Comment 28) One comment suggested that Q31 (Study 1) and Q33 (Study 2) construct and answer choices should align with other similarly constructed questions and answer choices in this section of the survey.

(Response) This is a validated item (Ref. 15) to measure endorser-product match-up. Therefore, we will maintain the current format.

(Comment 29) One comment suggested that Q33 (Study 1) and Q35 (Study 2) could cause respondent confusion regarding what is meant by "background," which could lead to uninterpretable results. It recommended explicitly stating what is meant by "background" (e.g., "I prefer a product recommended by an endorser because of his/her experience with this illness").

(Response) This is a validated item (Ref. 16) that measures identification with endorser; thus, we will maintain its original form in both studies.

(Comment 30) One comment mentioned that Q43-Q45 (Study 1) and Q45-Q47 (Study 2) probe the level of influence that endorsers have over respondents and suggested adding a question asking if the respondent has followed the advice of an endorser.

(Response) Q36-Q48 (Study 1) and Q45-47 (Study 2) are validated items in the celebrity-persona parasocial-involvement scale (Ref. 17); thus, we will maintain the integrity of the scale and not add another question in this series.

(Comment 31) One comment suggested that the debriefing statements in both questionnaires may serve the respondent better if placed earlier in the document as a disclaimer and suggested placing the disclaimer language prior to showing the promotional piece.

(Response) To maximize the attention participants give to this survey task, we do not wish to inform them of the information in the debriefing statement until they have completed the survey.

(Comment 32) One comment suggested that Q18 and Q19 (Study 2) are redundant, although respondents may not define a paid endorser post as advertising, and that the items seem irrelevant. It recommended removing Q18 from the questionnaire.

(Response) Previous experimental studies on social media promotion have found that participants did not consistently notice a payment disclosure or interpret a sponsored post as advertising (Ref. 1). These issues are central to the question of whether consumers process payment disclosures. Moreover, participants in cognitive testing distinguished between the two items.

(Comment 33) One comment noticed that Q20 in Study 2 is similar to Q18 in Study 1; however, answer choices are not provided in a similar construct. The comment recommended utilizing a 5-point Likert scale to measure the outcome.

(Response) We simplified the response scale for Study 2 items, where possible, to account for anticipated higher usage of mobile devices. Because we prefer a larger number of response options in general, we plan to maintain the 5-point Likert scale for Study A, but use the 3-point scale in Study 2 to account for mobile devices.

(Comment 34) One comment suggested that Q24 (Study 2) could be framed differently to help understand how endorsers influence the understanding of safety and risk. The comment recommended asking “Do you recall the risk associated with the medication?” and suggested that the answer choice should have an option for respondents who do not know.

(Response) Q24 and Q25 from Study 2 are closed-ended questions that ask about recall of drug benefits and risks. To be balanced, the question stem and response options should be parallel between the two items. Moreover, we cannot add additional open-ended questions to the survey without increasing participant fatigue. Thus, we will maintain the closed-ended nature of the question. We recognize that this will be a difficult question for participants, and therefore we prefer not to provide an option for “don’t know.”

External Reviewers

In addition to public comment, OPDP solicited peer-review comments from researchers in fields relevant to the communication of DTC prescription drug information. We received responses and incorporated the thoughts of the following individual:

Nathaniel J Evans Ph. D.
Assistant Professor

Department of Advertising & Public Relations
Grady College of Journalism & Mass Communication
University of Georgia

9. Explanation of Any Payment or Gift to Respondents

We plan to recruit using $1 in LifePoints for the Study 1 pretest, Study 1 main study, and Study 2 pretest. The use of the internet and web-based panels to complete cross-sectional surveys has increased in recent years (Ref. 17). Two meta-analyses conducted by Goritz (Ref. 18), uncovered important findings about the use of incentives in web survey research. The first meta-analysis, examining 32 experiments (N = 212,810 total respondents) about the impact of incentives on response, found incentives motivated respondents to begin a web survey (Ref. 18). The second meta-analysis, examining 26 experiments (N = 7,073 total respondents) on the impact incentives have on respondent retention, found that once respondents accessed a web survey, they were more likely to complete it if an incentive was offered (Ref. 18). In addition, research about government surveys conducted by Shettle and Mooney (Ref. 19) found incentives provide a "decided cost advantage" in improving response rates, without negatively affecting non-response bias, data quality, or respondent good will.

There is still no agreement on an "optimal" incentive amount. However, OMB has previously approved modest incentives for several FDA studies similar to this one. For example, OMB approved a $6.25 incentive for the Animation in Direct-to-Consumer Advertising, which included a 25-minute online survey using a non-probability panel (OMB No. 0910-0826). OMB has also approved $5 incentives for 20 minute online surveys using non-probability panels for the following projects: Disclosures in Professional and Consumer Prescription Drug Promotion (OMB No. 0910-0860), Character-Space-Limited Online Prescription Drug Communications (OMB No. 0910-0846), and Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion (OMB No. 0910-0849).

We have chosen a $1 incentive amount for the 20-minute survey in Study 1 based on the incentive amount requested for a study similar to ours that recently received OMB approval (OMB No. 0910-0881). This incentive amount is below previously OMB-approved incentive amounts and is reasonable for broad demographic recruitment, both in increasing response rate and timeliness of response.

For the Study 2 main study, we propose using a lump-sum lottery incentive. Though the literature generally has found strong effectiveness for pre-paid cash incentives over gifts or lottery incentives in mail surveys, the effectiveness of lotteries, or sweepstakes, in online surveys has been more mixed. Goritz and Luthe (Ref. 20) found that a lottery, especially when paid out in a large lump sum, was effective at increasing response rate in online survey panels. However, a meta-analysis by Singer and Ye (Ref. 17) found that, in five online surveys where there had a been a control, a lottery incentive only increased response rate in two of them. Subsequent work has suggested that lottery-based incentives on online surveys are more effective when survey invitations are highly salient to the prospective respondents (Ref. 21). Our outreach approach, which prominently mentions the incentive and engages an influencer to reach out to her followers on a topic for which she is passionate and has talked about in the past, leverages such salience. Due to the nature of the recruitment method, a lottery incentive also protects the study against fraudulent data generated from survey bots from a publicly available link (Ref. 22).

10. Assurance of Confidentiality Provided to Respondents

All information that can identify individual respondents will be kept by the independent contractor in a form that is separate from the data provided to FDA. For all data, alphanumeric codes will be used instead of names as identifiers. These identification codes (rather than names) are used on any documents or files that contain study data or participant responses.

The following documents will result from the survey:

- Electronic survey data.

- Crosswalk of respondent email addresses to respondent key, which will be used to select the sweepstakes winner from the completed surveys. This crosswalk will only exist for the Study 2 main study, because respondent email addresses will not be collected for the Study 1 pretest, Study 1 main study, or the Study 2 pretest.

Electronic files will be kept on the contractor's network, accessible only to project staff and under password protection. Access to UNIX or network-based data files is controlled through the use of Access Control Lists or directory- and file-access rights based on user account ID and the associated user group designation, which is maintained by the system administrator. Upon initiating a project, a project-specific directory is created for use by that project on network-resident disk storage media. Access rights to the data and applications stored within the directory are granted only to users specifically authorized to access the project directory.

Access control on the PC is achieved by sound file management procedures by each user. Staff are instructed on the proper use of PCs for the storage, transfer, and use of sensitive information and the tools available, such as encryption, to secure confidential data better. All of the contractor's employees have taken and signed the Westat Confidentiality Pledge that assures confidentiality of survey data.

The contractor's Computer Operations staff make a full disk backup of all host and server-based storage once a week. The weekly backups are retained at an off-site location for eight weeks. An additional backup is generated every fourth week and retained for one year.

The contractor also makes a daily incremental backup for host and server-based storage. All disk files that have been created or modified since the previous incremental backup are copied. The incremental backups are retained for eight weeks.

Backup tapes are stored in a specialized high-security, off-site facility under stringent environmental and other data protection controls until they are scheduled to be recycled. Logs of all backup tapes are maintained by a tape management system. To minimize the risk of exposure of confidential information, all tapes are erased before being released to the scratch pool.

The current contract runs through September 11, 2022. We project a data destruction date 3 years after the conclusion of the project, September 2025.

Confidentiality of the personally identifiable information submitted is protected from disclosure by part 20 of the agency's regulations (21 CFR part 20). These methods will be approved by FDA's Institutional Review Board and Westat's Institutional Review Board prior to collecting any information. 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).

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

For both the pretests and main study, the questionnaire is expected to last no more than 20 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[1]

	No. of respondents	No. of responses per respondent	Total annual respondents	Average burden per response	Total hours
Study 1 Screener	933	1	933	.08 (5 min)	74.64
Study 1 Pretest	249	1	249	.33 (20 min)	82.17
Study 1 Main test	405	1	405	.33 (20 min)	133.65
Study 2 Screener	1,417	1	1,417	.08 (5 min)	113.36
Study 2 Pretest	266	1	266	.33 (20 min)	87.78
Study 2 Main test	432	1	432	.33 (20 min)	142.56
Total					634.16

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

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 contracted cost to the Federal Government for the collection of data is $447,205 ($111,801 per year for four years). This includes the costs paid to the contractors to develop 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 ($58,000; 4 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 Part 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	20 weeks
Main study data collected	60 weeks
Final methods report completed	70 weeks
Final results report completed	90 weeks
Manuscript submitted for internal review	110 weeks
Manuscript submitted for peer-review journal publication	130 weeks

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

1. LaTour, C. & M. Smith (1986). "A Study of Expert Endorsement of OTC Pharmaceutical Products." *Journal of Pharmaceutical Marketing & Management,* 1(2), pp. 117-128.

2. Bhutada, N.S., and B.L. Rollins (2015). "Disease-Specific Direct-to-Consumer Advertising of Pharmaceuticals: An Examination of Endorser Type and Gender Effects on Consumers' Attitudes and Behaviors. *Research in Social Administrative Pharmacy,* 11(6), pp. 891–900.

3. Cohen, J. (1988), "*Statistical Power Analysis for the Behavioral Sciences*." Routledge. ISBN 978-1-134-74270-7.

4. Faul, F., Erdfelder, E., Lang, A.G., and A. Buchner (2007). "G*Power 3: A Flexible Statistical Power Analysis Program for the Social, Behavioral, and Biomedical Sciences." *Behavior Research Methods*, 39, pp. 175-191.

5. Woods, C.B., S. Baxter, E. King, K. Palazzi, C. Oldmeadow, and E.L. James (2017). "Celebrity? Doctor? Celebrity doctor? Which Spokesperson is Most Effective for Cancer Prevention?" In E. Kendal & B. Diug (Eds.) *Teaching Medicine and Medical Ethics Using Popular Culture* (pp. 71–98). Palgrave Studies in Science and Popular Culture. Cham, Switzerland: Palgrave Macmillan. doi:10.1007/978-3-319-65451-5_5.

6. Boerman, S.C., L.M. Willemsen, and E.P. Van Der Aa (2017). "This post is sponsored" Effects of Sponsorship Disclosure on Persuasion Knowledge and Electronic Word of Mouth in the Context of Facebook." *Journal of Interactive Marketing,* 38, pp. 82–92.

7. https://www.statista.com/statistics/398166/us-instagram-user-age-distribution/

8. Zaichkowsky, J.L. (1994). "The Personal Involvement Inventory: Reduction, Revision, and Application to Advertising." *Journal of Advertising*, 23(4), pp. 59–70.

9. Ohanian, R. (1990). "Construction and Validation of a Scale to Measure Celebrity Endorsers' Perceived Expertise, Trustworthiness, and Attractiveness." *Journal of Advertising*, 19(3), pp. 39–52.

10. Kamins, M.A. and K. Gupta (1994). "Congruence Between Spokesperson and Product Type: A Matchup Hypothesis Perspective." *Psychology & Marketing*, 11(6), pp. 569–586.

11. Phua, J., J.S.E. Lin, and D.J. Lim (2018). “Understanding Consumer Engagement with Celebrity-Endorsed E-Cigarette Advertising on Instagram.” *Computers in Human Behavior*, 84, pp. 93–102.

12. Brown, W.J. and M.C. Bocarnea (2007). “Celebrity-Persona Interaction Scale. In R.A. Reynolds, R. Woods, & J.D. Baker (Eds.) *Handbook of Research on Electronic Surveys and Measurements* (pp. 302–305). Hershey, PA: Idea Group Reference.

13. Brown, W.J. and M.A.C. De Matviuk (2010). “Sports Celebrities and Public Health: Diego Maradona's Influence on Drug Use Prevention.” *Journal of Health Communication*, 15(4), pp. 358–373.

14. Huh, J. D.E. DeLorme, and L.N. Reid (2005). “Factors Affecting Trust in On-Line Prescription Drug Information and Impact of Trust on Behavior Following Exposure to DTC Advertising.” *Journal of Health Communication*, 10(8), pp. 711–731.

15. Till, B.D. and M. Busler (2000). “The Match-Up Hypothesis: Physical Attractiveness, Expertise, and the Role of Fit on Brand Attitude, Purchase Intent and Brand Beliefs.” *Journal of Advertising*, 29(3), pp. 1–13.

16. Biswas, D. A. Biswas, and N. Das (2006). “The Differential Effects of Celebrity and Expert Endorsements on Consumer Risk Perceptions: The Role of Consumer Knowledge, Perceived Congruency, and Product Technology Orientation.” *Journal of Advertising*, 35(2), pp. 17–31.

17. Singer, E. & C. Ye (2013). “The Use and Effects of Incentives in Surveys.” *The ANNALS of the American Academy of Political and Social Science* 645(1), pp. 112-141. https://journals.sagepub.com/doi/10.1177/0002716212458082

18. Goritz, A.S. (2006). “Incentives in Web Studies: Methodological Issues and a Review.” *International Journal of Internet Science*, 1(1), pp. 58-70.

19. Shettle, C. & G. Mooney (1999). “Evaluation of Using Monetary Incentives in a Government Survey.” Mathematics Policy Research, National Science Foundation. *Journal of Official Statistics*, 15(2), pp. 23-250.

20. Goritz, A.S. & S.C. Luthe (2013). “Lotteries and Study Results in Market Research Online Panels.” *International Journal of Market Research* 55(5), pp. 611-626. https://journals.sagepub.com/doi/10.2501/IJMR-2013-016

21. Zhang, C., Lonn, S. & S.D. Teasley (2017). “Understanding the Impact of Lottery Incentives on Web Survey Participation and Response Quality: A Leverage-Salience Theory Perspective. *Field Methods* 29(1), pp. 42-60. https://journals.sagepub.com/doi/10.1177/0002716212458082

22. Pew Research Center. (2020). “Assessing the Risks to Online Polls from Bogus Respondents.” Retrieved from https://www.pewresearch.org/methods/wpcontent/uploads/sites/10/2020/02/PM_02.18.20_dataquality_FULL.REPORT.pdf