United States Food and Drug Administration

Disease Awareness and Prescription Drug Promotion on Television

OMB Control No. 0910-NEW

SUPPORTING STATEMENT **Part A. Justification**

1. Circumstances Making the Collection of Information Necessary

Regulatory Background. 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.

Rationale. The FDA's Center for Drug Evaluation and Research (CDER), Office of Prescription Drug Promotion (OPDP) is responsible for ensuring that prescription drug promotional materials are truthful, balanced, and accurately communicated. This project is being proposed as part of the research program of OPDP. 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 we believe are most central to our mission, focusing 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 research data through analytical methodology development and investigation of sampling and response issues. This study falls under the topic of both target populations and advertising features.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through 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 DTC survey conducted in 1999.

The present research concerns disease awareness and prescription drug promotion communications on television. When pharmaceutical companies market a new drug, they

often also release disease awareness communications about the medical condition the new drug is intended to treat.[1, 2] FDA is interested in whether and to what extent this practice may result in consumers confusing or otherwise misinterpreting the different information and claims presented in disease awareness communications and prescription drug promotion. Prior research has documented that in both print[3] and online[4] contexts, consumers tend to conflate the information presented in prescription drug promotional materials with information presented in disease awareness communications. Specifically, the results of these studies suggest consumers incorrectly ascribe benefits to a prescription drug as a result of being exposed to information in a disease awareness communication that broadly describes the symptoms and negative consequences of the disease. There are ways in which this effect can be attenuated. For example, prior research has indicated that greater visual distinctiveness between the two ad types can ameliorate such confusion.[5] The present research seeks to extend previous studies of print and online promotion to the context of television promotion, and broadly examine the extent to which perceptual similarity between the two communication types, as well as their temporal proximity and exposure frequency may lead to viewer confusion and the nature of that confusion.

2. Purpose and Use of the Information Collection

FDA is interested in whether and to what extent certain promotional practices result in consumers confusing or otherwise misinterpreting the different information and claims presented in disease awareness communications and prescription drug promotion. The results from this research will be used by FDA to inform its understanding of DTC promotion, inform regulatory policy, and may also help to identify areas for further research.

3. Use of Improved Information Technology and Burden Reduction

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1Bulik, B.S. (March 11, 2018). Unbranded pharma ads—what are they good for? Actually quite a bit, marketing panelists say. Available at https://www.fiercepharma.com/marketing/unbranded-pharma-ad-what-are-they-good-for-actually-quite-a-bit-marketer-panelists-say?mkt_tok=eyJpIjoiWkRnelpUSmlORFpoWkdNMSIsInQiOiJPaENIUERpT0tnUmt6Y1BPMk9LTnpreUI3bUtPOVRzRnh1RzNuWUtYQmp0cWJhcW05UFhlcllwTzI3V0RJSndjVkZLR3NGUHBLamJOZmJSK2FZeWtIVXczeFRFcmtEV0NFaVdCSjArUmx4dUlRVHZpUzFFOWlVY0dNb1RzOU9XayJ9&mrkid=20932234. Accessed on April 12th, 2019.

2Bulik, B.S. (December 21, 2016). Avanir shelves Danny Glover PBA awareness ad in favor of branded Nuedexta effort. Available at https://www.fiercepharma.com/marketing/avanir-launches-nuedexta-brand-campaign-retires-danny-glover-pba-disease-awareness-ad. Accessed on April 12, 2019.

3Aikin, K. J., Sullivan, H. W., & Betts, K. R. (2016). Disease information in direct-to-consumer prescription drug print ads. *Journal of Health Communication, 21*, 228–239.

4Sullivan, H. W., O'Donoghue, A. C., Rupert, D. J., Willoughby, J. F., Amoozegar, J. B., & Aikin, K. J. (2016). Are disease awareness links on prescription drug websites misleading? A randomized study. *Journal of Health Communication, 21*, 1198–1207.

5See Aikin, Sullivan & Betts (2016).

Automated information technology will be used in the collection of information for this study. The contracted research firm will collect data through Internet administration. Participants will self-administer the survey instrument via a computer, which will record responses and provide appropriate probes when needed. FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's request. 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 respondent, and by keeping study procedures to 90 minutes or less.

4. Efforts to Identify Duplication and Use of Similar Information

   We conducted a literature search to identify duplication and use of similar information. We conducted a review of the scientific literature by locating relevant articles through keyword searches using popular databases such as PubMed and PsycInfo. We also identified relevant articles from the reference list of articles found through keyword searches. We did not find duplicative experimental work on the present topic.

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 for public comment in the *FEDERAL REGISTER* of October 17, 2018 (83 FR 52472). FDA received six comments that were PRA related. Within those submissions, FDA received multiple comments which the Agency has addressed.

   (Comment) Four comments suggested that FDA provide copies of stimuli in the Federal Register for public comment. Relatedly, one comment requested a copy of the participant consent documents.

   (Response) We have described the purpose of the study, the design, the population of interest, and have provided the questionnaire to numerous individuals upon request. Our full stimuli are under development during the PRA process. We do not make draft stimuli

public during this time because of concerns that this may contaminate our participant pool and compromise the research. The consent form is available as part of the information collection submission to the Office of Management and Budget.

(Comment) Three comments expressed support for FDA's determination to take an evidence-informed approach to its regulation of sponsor communications.

(Response) We appreciate this support.

(Comment) Three comments suggested that selecting asthma sufferers as the target population limits the applicability of the results, or that asthma sufferers' prior knowledge regarding asthma may bias their responses.

(Response) Researching each medical condition, or general population sample, requires significant resources. We are committed to conducting this research using our available resources while ensuring the integrity of the research by collecting data on a high prevalence condition (i.e., > 20% incidence rate) for which participants might be thought of as sufficiently representative of the average consumer, thus allowing us to draw conclusions about broad perceptual and cognitive processing outcomes.

(Comment) Three comments suggested that use of mock advertisements, products, and environments do not represent what happens in the real world.

(Response) In response to *Federal Register* notices for prior research under our research program, commenters have suggested the opposite, which is that use of real materials (i.e., existing drug ads) could have confounding results due to consumer familiarity with medicines and drug classes used to treat their existing condition. We sought to address this concern by utilizing realistic mock materials. Additionally, utilizing mock materials allows for precise manipulation of the stimuli fitting with our research questions and is the most common practice in the field.

(Comment) Two comments expressed concern about use of "conflation" as a dependent variable.

(Response) The present research seeks to extend previous studies of print and online promotion to the context of television promotion and as such utilizes many of the same dependent measures, including the key dependent measure of "conflation." Conflation as defined in this notice reflects the key outcome of interest given the research questions posed and therefore has been retained.

(Comment) Two comments suggested that the open-ended response questions are open to interpretation and data variability and encouraged FDA to revise these to close-ended questions.

(Response) The purpose of the open-ended items is to measure unaided participant recall of claims made in the prescription drug promotion. These responses will be content coded

using an inductive approach and numeric codes will be assigned to the open-ended responses. Quantifying open-ended responses provides structure and reduces the interpretation associated with a qualitative coding scheme. After sanitizing open-ended comments (removing obscenities, proper names, and any case-specific information), two reviewers will read the responses and develop a coding scheme to establish theme descriptions, numeric codes, and coding rules. Two coders will receive training and will code 25% of the responses. After achieving high inter-coder reliability (e.g., κappa = .75), the remaining responses will be divided between the coders. Open-ended coding will then be merged with the data set for analysis. Additionally, we have tested these response options in cognitive interviewing and found them to be effective for their intended purpose. We have also received positive feedback on these measures from our consultations with expert peer reviewers. These measures have therefore been retained.

(Comment) Two comments suggested adding a control condition to Study 2 whereby participants only see the prescription drug product ad before completing the survey.

(Response) For Study 2, the primary questions are related to both frequency of exposure and delay. A control condition which features no disease awareness communications makes the delay factor redundant, and comparisons can be made between no exposure and repeated exposure. Therefore, a control condition for Study 2 is unnecessary given the current design.

(Comment) Two comments suggested that studies 1 and 2 are highly similar and thus only one study needs to be conducted. One of these comments suggested dropping Study 2 and utilizing the resources that would have been allotted to instead create different iterations of temporal separation for Study 1.

(Response) Studies 1 and 2 include overlap in their independent and dependent variables. However, they are unique in that Study 1 will explore outcomes within a single period of television programming, whereas Study 2 will examine outcomes over time mirroring the practice of "seeding the market," in which pharmaceutical companies release disease awareness communications before releasing product promotion communications. Both studies offer significant and unique value to FDA and therefore both studies have been retained.

(Comment) One comment suggested separating recall of the ad from recall of the product into separate questions.

(Response) The question reads, "Do you recall seeing a commercial for [Drug X], a prescription product for asthma?" This question is intended to assess recall of the commercial for [Drug X] and is not intended to assess recall for this fictitious product beyond this commercial. We hope this clarification is helpful for understanding why we intend to retain the present version of this question.

(Comment) One comment suggested that pretesting be conducted to ensure that stimuli reflect the intended manipulations.

(Response) FDA intends to conduct both cognitive interviewing and pretesting to ensure the stimuli reflect the intended manipulations.

(Comment) One comment suggests that the proposed research overlooks the positive aspects of disease awareness campaigns, and to address this, steps can be taken such as adding questions about behavioral intentions to the questionnaire.

(Response) FDA acknowledges that there are positive aspects of disease awareness campaigns. This research is intended to evaluate specific research questions as outlined in the 60-day *Federal Register* notice and therefore dependent measures align with these research questions. As an overall strategy to reduce participant burden, we do not intend to ask questions that do not inform these research questions.

(Comment) One comment suggested relocating non-terminating screening questions to the end of the questionnaire to reduce participant fatigue.

(Response) The purpose of including the screening items at the beginning of the questionnaire is to ensure a diverse sample using predetermined quotas, and for required statistical analyses following completion of the data collection. Retaining the screening items at the beginning of the questionnaire will allow for comparisons between non-respondents and respondents.

(Comment) One comment suggested adding a "Don't know" response option wherever applicable.

(Response) We understand the value of providing such responses for items of a factual nature. The drawback to providing such response options to these questions, however, is that we may lose information by allowing respondents to choose an easy response instead of giving the item some thought. Research has demonstrated that providing "no opinion" options likely results in the loss of data without any corresponding increase in the quality of the data. Thus, we prefer not to add these options to the survey.

(Comment) One comment suggested that FDA develop a clear, over-arching research agenda and provide a comprehensive list of its prescription drug promotion studies.

(Response) The 60-day *Federal Register* notice for this study describes OPDP's research agenda, how this study fits into that agenda, and provides the web address of OPDP's research page which 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 DTC survey conducted in 1999.

(Comment) One comment suggested that the current research duplicates prior work conducted in online and print contexts.

(Response) The present research seeks to extend previous studies of print and online promotion to the context of television promotion. In previous *Federal Register* notices under our research program, we have been advised by commenters that findings for one form of advertising should not be assumed to broadly apply to other forms of advertising. Additionally, we note that the present research includes unique elements beyond advertising format that have not previously been studied. An example of this is assessment of "seeding the market" in Study 2 whereby sponsors initially release a disease awareness ad for a period of time, followed by release of a product promotion ad.

(Comment) One comment suggested that the time commitment required for participation may result in a self-selected sample of individuals with more time available (e.g., students).

(Response) Participants will be recruited through online panels, which include a diverse range of participants in regard to age, race/ethnicity, income, education, and employment. We also have proposed the use of soft quotas to further ensure that we will recruit a diverse sample. Finally, we were able to recruit a diverse sample for cognitive interviewing and although a smaller sample size than will be recruited for the pretests and main studies, the sample was not overrepresented in any demographic categories.

(Comment) One comment suggested that the calculated burden is appropriate, but requested additional detail about other requirements that may add to burden in addition to the time in the study itself.

(Response) Data collection will occur online, so the burden estimate reflects time spent answering the screener, stimuli viewing, survey completion, thus reflecting overall study time and requirements.

(Comment) One comment identified errors in the questionnaire.

(Response) Thank you for noting these errors. All identified errors have been fixed.

(Comment) One comment suggested adding intermediate response values to questions that omitted them (e.g., 1 = no improvement, to 6 = substantial improvement).

(Response) These questions were developed through scale validation research. We did not encounter any confusion on the part of respondents during cognitive testing of the questionnaire. We will retain these questions in their original form.

(Comment) One comment suggested that because "prescription drug information" has become a political topic in recent years, the introduction to the questionnaire should be revised to avoid saying that "[w]e will use your feedback to…improve prescription drug information for people like you. The concern is that this information may bias responses depending on participant views of "prescription drug information."

(Response) The proposed research concerns prescription drug information and so we need to provide this context to participants to orient them to the questions that follow. Moreover, institutional review boards typically require transparency about the topic of the research. We have therefore retained this language in our study materials.

(Comment) One comment noted that "[p]erceptions of promotion effectiveness" is described as both a dependent variable and a covariate, and to avoid distortion in the model, recommends selection of a different covariate.

(Response) Perception of promotion effectiveness is described as a dependent variable, differing from perceived ad effectiveness, which measures perception of the disease awareness communications. The purpose of including perceived ad effectiveness as a covariate is that perception of the disease awareness communications may directly affect conflation, which could require statistical adjustment.

(Comment) One comment suggested expanding the participant exclusion criteria to include individuals studying health fields and product marketing (beyond pharmaceuticals).

(Response) We currently exclude individuals who work for a pharmaceutical company, an advertising agency, a market research company, or the Department of Health and Human Services. These criteria exclude individuals working in advertising or market research beyond pharmaceuticals, but do not necessarily exclude students studying these fields. To ensure a diverse sample, we generally aim to limit our exclusion criteria. However, please note that random assignment to experimental condition should ensure that these individuals are approximately evenly distributed across conditions.

(Comment) One comment requested information about how learning effects would be controlled for given the multiple exposures.

(Response) For Study 2, learning effects are accounted for by the exposure frequency manipulation. Participants are randomly assigned to see the disease awareness ad once, three times, or six times. For Study 1, all participants see the ads the same number of times, except participants randomly assigned to the control condition who do not see the disease awareness ad.

External Reviewers

In addition to the comments above, the following experts reviewed the study design,

methodology, and questionnaires:

1. Janelle Applequist, Ph.D., Assistant Professor, University of South Florida, The Zimmerman School of Advertising & Mass Communications
2. Ilwoo Ju, Ph.D., Assistant Professor, Saint Louis University, Department of Communication

9. Explanation of Any Payment or Gift to Respondents

Participants will receive an incentive as a token of appreciation after completing the survey. As participants often have competing demands for their time, incentives are used to encourage participation in research. When applied in a reasonable manner, incentives are not coercive but rather serve as an approach that acknowledges respondents for their participation. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend in a research study. In this particular research study, we are asking participants to provide feedback on concepts that require a high level of engagement.

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation, as well as to provide sufficient motivation for them to participate in the study. If the incentive is not adequate, participants may agree to take the survey and then drop out early. An additional consideration for use of incentives is the potential increased cost due to low participation. Low participation can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the research, which leads to increased costs. Incentive details are listed below:

•For Study 1, participants can earn up to $20. To ensure that participants stay engaged throughout the hour-long television program, we propose a graduated payment schedule that rewards participants for passing attention checks. Participants will earn points for the equivalent dollar amount.

•For Study 2, participants can earn up to $37. As a safeguard against participant dropout between sessions, we propose a payment schedule that rewards participants for each session in which they view disease awareness ads. For the purposes of this study, participants will earn Swagbucks, virtual currency that can be redeemed to purchase gift cards. Swagbucks have a 100 to 1 redemption value. For example, 50 Swagbucks are equivalent to $0.50.

10. Assurance of Confidentiality Provided to Respondents

No personally identifiable information will be sent to FDA. The Internet panel providers

will maintain all information that can identify individual respondents in a form 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, as detailed in the survey consent form. The experimental instructions will include information explaining this to respondents. 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 Internet panel employees and contractors are required to take yearly security awareness and ethic training based on these standards.

All electronic data will be maintained 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).

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The questionnaire is available upon request.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Study 1 Pretest screener	385	1	385	0.08 (~5 min.)	31
Study 2 Pretest screener	329	1	329	0.08 (~5 min.)	26
Study 1 screener	3,007	1	3,007	0.08 (~5 min.)	241
Study 2 screener	2,643	1	2,643	0.08 (~5 min.)	211
Study 1 Pretest	270	1	270	1.33 (~1 hr 20 min.)	359
Study 2 Pretest	158	1	158	0.53 (~32 min.)	84
Study 1	2,105	1	2,105	1.33 (~1hr 20 min.)	2,800
Study 2	1,269	1	1,269	0.53 (32 min.)	673
Total					4,425

[1]There 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 estimated cost to the Federal Government for the research is $568,507.73. This includes the costs paid to the contractor to assist with study design, questionnaire, and stimuli development, recruit a sample, collect and analyze data, write reports of work completed, and present findings. The task order 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.

15. Explanation for Programs 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 posting on FDA's website.

Table 2.--Estimated Project Timetable

Task	**Estimated Completion Date**
RIHSC review	April, 2019
30-day FRN publication	June 27, 2019
OMB Review of PRA package	June, 2019
Pretesting	October, 2019
Main Study Data Collection	February, 2020

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.