National Direct-to-Consumer Advertising Survey

OMB Control No. 0910- NEW

Supporting Statement Part A

1. Circumstances Making the Collection of Information Necessary

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the Food and Drug Administration (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.

FDA last surveyed patients about their experiences with and attitudes toward DTC advertising in 2002 (Ref. 1). Numerous changes have affected the DTC landscape since 2002, including declines in print readership, the rise in online prescription drug promotion, and self-imposed industry guidelines for DTC advertising (Ref. 2). These changes may have affected consumers' exposure to different kinds of DTC advertising and its influence on their attitudes and behaviors.

2. Purpose and Use of the Information Collection

The purpose of this survey is to collect updated insights on consumer experiences with and attitudes towards DTC promotion of prescription drugs. This study will build on previous research by recruiting a wider range of respondents, weighting the data to make it nationally representative, and asking a wider range of questions about DTC promotion, including in online formats.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. We plan to use an address-based mixed-mode methodology that will direct one randomly-chosen member of sampled households to complete a 20-minute online survey, with non-respondents receiving a paper questionnaire. 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 surveys to less than 20 minutes.

4. Efforts to Identify Duplication and Use of Similar Information

FDA last surveyed patients about their attitudes toward DTC advertising in 2002 (Ref. 1). Although recent surveys have included a few questions about DTC advertising (e.g., Refs. 3, 4), there are few, if any, recent nationally representative surveys devoted to DTC advertising (Ref. 5). Changes in the DTC landscape outlined above call for a new nationally representative survey specifically on DTC advertising.

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 February 29, 2016 (81 FR 10257). Nine comments were received. Five comments did not address any of the information collection topics solicited and therefore we do not discuss them in this document (four called for a ban on direct-to-consumer prescription drug advertising and one discussed FDA's response to public comments in general). No comments addressed Topic (2) -- accuracy of our estimate.

Topic (1) – practical utility. One comment suggested that we increase the practical utility of the survey by (1) including teenagers 14-18 years of age and (2) skewing the survey to include a disproportionate number of Americans over 50 years of age. Another comment suggested we use a quota to ensure that limited literacy respondents are included. One of our main goals is to survey a nationally representative sample of U.S. adults about their experiences with and attitudes towards DTC promotion of prescription drugs. Note that we have designed other studies that specifically examine adolescent and older adults' responses to prescription drug advertising (FDA-2013-N-1151-0004, "*Experimental Study of Direct-to-Consumer Promotion Directed at Adolescents*;" FDA-2015-N-2163-000, "*Hearing, Aging, and Direct-to-Consumer Television Advertisements*"). We will measure health literacy within the survey.

One comment suggested that respondents should watch a prescription drug television ad and then answer questions about benefit and risk recall. Although this design is beyond what we can accomplish within a nationally representative survey, we have conducted studies that use this design (for examples, see http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm).

Topic (3) – ways to enhance quality, clarity, utility. Four comments suggested changes to the survey to enhance its quality, clarity, and utility. First, three comments suggested changing our terminology throughout the survey for clarity. As suggested, we changed "television" to "TV," "advertisement" to "ad," used "health care provider" throughout the survey, and specified that by Internet we mean Internet accessed by computer, phone, or tablet. We changed "small print" to

"additional information." We did not change "prescription drug" to "medicine." Respondents in cognitive interviews understood the term "prescription drug," and we are concerned that "medicine" is too broad. We also chose not to highlight or bold "prescription drug" as cognitive interview respondents understood the purpose of the survey and we do not want to overuse highlighting.

Second, two comments suggested deleting survey questions. Two comments questioned the utility of a series of questions about the safety and efficacy of certain products. We agree that these questions are not as central to the survey topic and have deleted them. They also recommended deleting a series of questions about FDA approval of DTC promotion. These questions will highlight claims within the ad to determine whether consumers believe that advertising in general as well as specific claims are approved by FDA. Therefore, we have chosen to keep these questions on the survey. One comment recommended deleting a question perceived to be too negative whereas another comment recommended adding positive answer choices to balance the question; we chose the latter option.

Third, four comments suggested additional topics for survey questions. In response we added questions about whether prescription drug advertising has caused respondents to talk with their healthcare provider about symptoms or side effects they've experienced, or to look for information about a prescription drug they thought might be helpful for a friend of family member. We also added a question about the respondents' primary language. Finally, we now ask whether respondents have seen prescription drug promotion on streaming services and whether they have looked for information on medical association websites.

One comment suggested adding places where consumers could see or hear advertisements (e.g., "on television at the doctor's office," "in a pharmacy") to a question that asks about the type of medium where they saw or heard an ad (e.g., "TV," "print"). We chose not to take this suggestion because the question concerns medium, not location. We are also concerned about measurement error. For instance, some doctor's offices have magazines with DTC print ads, TVs playing broadcast television, or TVs playing videos. This also relies on having gone to a doctor or pharmacist in the last three months.

One comment suggested adding additional response options to a question about where consumers might attain more information about prescription drugs. Because this question is focused on adequate provision in DTC television ads, we chose not to add any additional response options beyond those specific to adequate provision (i.e., branded website, manufacturer's toll-free number, print ad, and health care provider).

We note that the survey contains a series of questions about various new media, including social media, websites, and online videos. It also asks about respondents' attitudes about how benefits and risks are presented, whether they have seen information about the medical condition in TV ads, and whether they've looked for information on government websites. We chose not to ask whether they've looked for information on manufacturer websites because we don't want respondents to confuse it with the option, "a prescription drug website."

Finally, three comments had suggestions for how we ask our questions. One comment recommended reducing or eliminating the number of open-ended questions. The main survey has only two questions with an open-ended option (allowing respondents to specify another response). If pilot testing reveals potential closed-ended response options for these two questions we will add them to the main survey. One comment suggested changing our scale for how we measure exposure to prescription drug promotion. We changed this scale from qualitative frequency to a yes/no scale. Similarly, one comment asked us to consider how we measure how much of an ad respondents saw or read because there may be many variables that affect this. We have chosen not to change this scale but will consider this point when interpreting the data. One comment suggested that we randomize response order for the paper-based surveys. We plan to create multiple versions of the paper-based scale to account for household sampling and viewing of the ad, so we are concerned that creating different versions to account for response option randomization will be too complex for a survey of this scale. However, we agree that response option order is important to take into account when interpreting results.

Topic (4) – ways to minimize burden. One comment suggested we conduct the survey with an online consumer survey panel to reduce time and costs and increase response rates. Although we agree that online survey panels can be an efficient way to collect data, this survey is designed to be nationally representative. Following OMB's advice, therefore, we will use the Internet as one mode of data collection but will not rely on an online survey panel for sampling (https://www.whitehouse.gov/sites/default/files/omb/inforeg/pmc_survey_guidance_2006.pdf).

External Reviewers

In addition to public comment, FDA sent materials and received comments from two individuals for external peer review in 2016. These individuals are:

1. Dr. Fred Conrad, Research Professor, University of Michigan, fconrad@umich.edu

2. Dr. Joel Weissman, Associate Professor, Harvard Medical School, jweissman@partners.org

9. Explanation of Any Payment or Gift to Respondents

We plan to recruit using two $1 bills ($2 total per sampled respondent) mailed in advance with the initial invitation letter as a gesture to encourage response and maintain data quality. In the second contact attempt, we will conduct an experiment to test whether a short statement mentioning the previously paid incentive increases survey response, thereby testing whether social exchange can be extended past the initial contact attempt. Half the sample will be provided language that reminds them they received a cash incentive in the previous letter; the remaining half will be reminded they received a letter but will not be specifically reminded about the incentive.

Incentives are a commonly used technique to encourage participation and decrease non-response. Scientific studies have consistently shown the inclusion of an incentive increases response rates,

and that prepaid incentives are more effective than incentives that are contingent upon completion of the survey (e.g., Refs. 5, 6). Shettle and Mooney (Ref. 7) concluded that incentives in government surveys provide a "decided cost advantage" in improving response rates, without negatively impacting non-response bias, data quality, or respondent good will. Indeed, studies point to incentives improving data quality in terms of greater response completeness, accuracy and reduced question item nonresponse, and more comments to open-ended questions (Refs. 8, 9, 10). Recent studies on the use of incentives (Refs. 11, 12) demonstrate their continued effectiveness in increasing survey response, particularly pre-paid cash incentives. Mercer, et al. (11) found that, "pre-paid incentives offered in mail surveys had the largest per dollar impact on response" when compared with promised incentives and non-mail modes. Medway and Tourangeau (Ref. 13) found that offering an incentive led to a significant reduction in item nonresponse.

While studies have shown that the marginal returns diminish as the pre-paid incentive amount increases (Refs. 8, 14, 15), there is still no agreement on an "optimal" incentive amount. A $2 incentive amount was chosen based on past studies. For example, Shaw et al. (Ref. 14) found that a $2 incentive with multiple mailings, when compared with a $5 incentive, was effective in improving response rates in a cost-efficient fashion. Another study by Millar and Dillman (Ref. 16) found that a token cash incentive of $2 was effective in improving response rates in a mixed mode survey. Based on these and similar findings (Ref. 17), we believe this amount is reasonable for broad demographic recruitment, both in increasing response rate and timeliness of response.

10. Assurance of Confidentiality Provided to Respondents

All participants will be provided with an assurance of privacy to the extent allowable by law (see Appendix A).

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.

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 better secure confidential data. 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 8 weeks. An additional backup is generated every fourth week and retained for 1 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 8 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.

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 (Research Involving Human Subjects Committee, RIHSC) 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. 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
Pilot Study					
Survey invitation letter	100	1	100	.08 (5 min.)	8
Reminder postcard	100	1	100	.03 (2 min.)	3
Non-response letter	82	1	82	.08 (5 min.)	7
Non-response questionnaire letter	81	1	81	.08 (5 min.)	7
Second postcard	60	1	60	.03 (2 min.)	2

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Survey	35	1	35	.33 (20 min.)	12
Main Study					
Survey invitation letter	5,042	1	5,042	.08 (5 min.)	403
Reminder postcard	5,042	1	5,042	.03 (2 min.)	151
Non-response letter	4,173	1	4,173	.08 (5 min.)	334
Non-response questionnaire letter	4,073	1	4,073	.08 (5 min.)	326
Second postcard	3,063	1	3,063	.03 (2 min.)	92
Survey	1,765	1	1,765	.33 (20 min.)	582
Total					1927

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

We estimate a 35 percent response rate, based on recent work on similar studies (Ref. 18). Prior to the main study, a pilot study will be conducted to test the data collection process. We estimate 35 respondents will complete the pilot study and 1,765 will complete the main study (see table 1).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for the collection of data is $562,415 ($281,207.50 per year for two years). This includes the costs paid to the contractors to program the study, draw the sample, collect the data, and create a database of the results ($531,215.00). 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 data, and to draft a report ($31,200; five hours per week for two 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 survey data, such as descriptive statistics, t-tests, chi-square tests, and regression models will be used to analyze the data. See Section B below for detailed information. FDA 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
Pilot study data collected	9 weeks
Main study data collected	25 weeks
Final methods report completed	35 weeks
Final results report completed	47 weeks
Manuscript submitted for internal review	60 weeks
Manuscript submitted for peer-review journal publication	70 weeks

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

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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