FOOD AND DRUG ADMINISTRATION

Character-Space-Limited Online Prescription Drug Communications

OMB Control No. 0910- NEW

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) (2015)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. § 393(b)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act. Under the FD&C Act and implementing regulations, promotional labeling and advertising about prescription drugs are generally required to be truthful, non-misleading, and to reveal facts material to the presentations made about the product being promoted (*See* FD&C Act §§ 502(a) & (n), 201(n) (21 U.S.C. §§ 352(a) & (n); 321(n)); *see also* 21 C.F.R. 202.1).

Prescription drug regulations require a fair balance of the content and prominence of risk and benefit information in prescription drug product claim promotion. The rise of Internet communications that have character space limitations, such as sponsored link promotion and microblog messaging, has led to questions about how to use these communications for prescription drug promotion while complying with the fair balance requirements. In 2014, FDA released a draft guidance entitled, "Guidance for Industry Internet/Social Media Platforms with Character Space Limitations--Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices," (Ref. 1) which states:

Regardless of character space constraints that may be present on certain Internet/social media platforms, if a firm chooses to make a product benefit claim, the firm should also incorporate risk information within the same character-space-limited communication. The firm should also provide a mechanism to allow direct access to a more complete discussion of the risks associated with its product.

The concept of linking to risk information by providing substantive product risk information on a landing page ("link to the risk information"), rather than presenting substantive risk information together with product benefit information within the character-space-limited communication, has been the subject of legislation and has been discussed as an option by some in industry and media (for example, Refs. 2-5).

Another factor to consider is that when consumers turn to the Internet for information, they are driven by different goals. These goals can affect what information they pay attention to and what kind of information they find (Refs. 6-8). Therefore, we will also

manipulate whether participants are instructed to browse the information or to search for specific information.

2. Purpose and Use of the Information Collection

   The studies are designed to address the question of whether substantive risk information in direct-to-consumer (DTC) character-space-limited prescription drug communications is effective in communicating risks when benefit claims are made, or whether a link to the risk information is sufficient. Within each study, we will manipulate whether or not substantive risk information appears in the character-space-limited communication. Part of FDA's public health mission is to ensure the safe use of prescription drugs; therefore it is important to communicate the risks and benefits of prescription drugs to consumers as clearly and usefully as possible.

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 the Internet, 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 surveys to less than 20 minutes.

4. Efforts to Identify Duplication and Use of Similar Information

   We conducted a literature search to identify duplication and use of similar information. To our knowledge there is no research on the inclusion of risk information in DTC character-space-limited prescription drug communications.

5. Impact on Small Businesses or Other Small Entities

   There will be no impact on small businesses or other small entities. The collection of information involves individuals, not small businesses.

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 November 7, 2016 (81 FR 78163), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. A number of comments were received and were discussed in the agency's 30 day notice that published July 18, 2017 (82 FR 32842). Most comments related to study design while others asked clarifying questions to which FDA provided response. Those comments that did not address any of the information collection topics solicited were not discussed. No comment requested that we revise our burden estimate.

External Reviewers

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

1. David DeAndrea, Ph.D., Assistant Professor, The Ohio State University, deandrea.1@osu.edu
2. Ann Schlosser, Ph.D., Professor, University of Washington, aschloss@uw.edu

9. Explanation of Any Payment or Gift to Respondents

For completing a survey, participants will receive approximately $5.00 in e-Rewards currency which can be exchanged in the Research Now marketplace for a variety of items (airline miles, hotel points, magazines, movie tickets, etc.).

Following OMB's "Guidance on Agency and Statistical Information Collections," we offer the following justification for our use of these incentives.

Data quality: Because providing a market-rate incentive should increase response rates, it should also significantly improve validity and reliability to an extent beyond that possible through other means. Previous research suggests that providing incentives may help reduce sampling bias by increasing rates among individuals who are typically less likely to participate in research (such as those with lower education (Ref. 10). Furthermore, there is some evidence that using incentives can reduce nonresponse bias in some situations by bringing in a more representative set of respondents (Refs. 11-12). This may be particularly effective in reducing nonresponse bias due to topic saliency (Ref. 13).

Past experience: Research Now, the contractor for this study, has conducted hundreds of health-related surveys in the past year. Research Now offers incentives to its panel members for completing surveys, with the amount of incentive for consumer surveys determined by the length of the survey. Their experience indicates that the requested amount is reasonable for a 20 minute survey.

Reduced survey costs: Recruiting with market-rate incentives is cost-effective. Lower participation rates will likely impact the project timeline because participant recruitment will take longer and, therefore, data collection will be slower and more costly.

10. Assurance of Confidentiality Provided to Respondents

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

Researchers will not tie respondents' personally identifiable information (PII) to their answers. All analyses will be done in the aggregate and respondent information will not be appended to the data file used. Further, no identifying information will be included in the data files delivered by the contractor to FDA.

The following procedures will be used to ensure participant confidentiality before, during, and after fielding: (1) data transfer between ResearchNow and the contractor (Forms Marsh Group; FMG) will be conducted via a password-protected, secure File Transfer Protocol (FTP) site; (2) all screening-related information will not be tied to any PII, but identified and matched by the assigned unique ID; (3) data sets and reports will not contain any PII; and (4) respondents will not be tied to their individual responses, and all analyses will be conducted in the aggregate (i.e., any data used in reporting will not be attributed to specific participants).

Any data sets and reports delivered to FDA will not include PII. All identifying information will be kept on a separate password-protected computer and/or in locked cabinets for a period of three years, only accessible by FMG. After three years, FMG will destroy the information by securely shredding documents or permanently deleting electronic information. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

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). These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee, RIHSC).

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Pretest 1 screener	464	1	464	.08 (5 min.)	39
Pretest 2 screener	464	1	464	.08 (5 min.)	39
Study 1 screener	786	1	786	.08 (5 min.)	66
Study 2 screener	786	1	786	.08 (5 min.)	66
Study 3 screener	786	1	786	.08 (5 min.)	66
Study 4 screener	786	1	786	.08 (5 min.)	66
Pretest 1	277	1	277	.33 (20 min.)	93
Pretest 2	277	1	277	.33 (20 min.)	93
Study 1	469	1	469	.33 (20 min.)	157
Study 2	469	1	469	.33 (20 min.)	157
Study 3	469	1	469	.33 (20 min.)	157
Study 4	469	1	469	.33 (20 min.)	157
Total	6,502				1,128

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

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

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

14. Annualized Cost to the Federal Government

    The total estimated cost to the Federal Government for the collection of data is $273,819 ($91,273 per year for 3 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 ($236,379). 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 ($37,440; 4 hours per week for 3 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 of the Supporting Statement 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**
Main study data collected	45 weeks
Final methods report completed	58 weeks
Final results report completed	70 weeks
Manuscript submitted for internal review	88 weeks
Manuscript submitted for peer-review journal publication	98 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.

References

1. Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations--Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices, available at:

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401087.pdf.

2. https://www.congress.gov/bill/114th-congress/house-bill/2479/text.
3. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm.
4. http://www.politico.com/story/2015/06/at-the-fda-drugs-and-tweets-dont-mix-118693.
5. http://www.dtcperspectives.com/is-one-click-in-the-cards/.
6. Detlor, B., S. Sproule, and C. Gupta, "Pre-Purchase Online Information Seeking: Search Versus Browse." Journal of Electronic Commerce Research, vol. 4, pp. 72-84, 2003.
7. Pieters, R. and M. Wedel, "Goal Control of Attention to Advertising: The Yarbus Implication." Journal of Consumer Research, vol. 34, pp. 224-233, 2007.
8. Schlosser, A. E., "Experiencing Products in the Virtual World: The Role of Goal and Imagery in Influencing Attitudes Versus Purchase Intentions." Journal of Consumer Research, vol. 30, pp. 184-198, 2003, http://dx.doi.org/10.1086/376807.
9. FDA (2008). Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products; Final Rule. Federal Register, 73(209), 63886 – 6389. Available at https://www.regulations.gov/document?D=FDA-2003-N-0313-0008
10. Guyll, M., R. Spoth, R., and C. Redmond, "The Effects of Incentives and Research Requirements on Participation Rates for a Community-Based Preventive Intervention Research Study." Journal of Primary Prevention, vol. *24*(1), pp. 25-41, 2003.
11. Castiglioni, L., and K. Pforr, "The effect of Incentives in Reducing Non-Response Bias in a Multi-Actor Survey." Presented at The 2nd Annual European Survey Research Association Conference, Prague, Czech Republic, June, 2007.

12. Singer, E., “Nonresponse Bias in Household Surveys.” Public Opinion Quarterly, vol. 70(5), pp. 637-645, 2006.

Groves, R., M. Couper, S. Presser, E. Singer, R. Tourangeau, G. Acosta, and L. Nelson, “Experiments in Producing Nonresponse Bias.” *Public Opinion Quarterly*, vol. 70(5), pp. 720-736, 2006.