



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-3585]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Character-Space-Limited Online Prescription Drug Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “Character-Space-Limited Online Prescription Drug Communications.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Character Space-Limited Online Prescription Drug Communications

OMB Control Number 0910-NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act. 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* section 502(a) and (n), 201(n) of the FD&C Act (21 U.S.C. 352(a) and (n), 321(n)); *see also* 21 CFR 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).

The studies are designed to address the question of whether substantive risk information in the character-space-limited 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.

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.

Two pretests will be conducted to test the goal instructions, stimuli, questionnaire, and procedure. In studies 1-4, participants will be randomly assigned to one experimental condition and will view the corresponding study materials (tables 1-4). Across all studies, we will examine two different character-space-limited formats and two medical conditions. For pretest 1 and

study 1, the study materials will be a character-space-limited communication about a fictional weight loss drug, embedded in a Google search page about weight loss. The study 2 materials will be a character-space-limited communication about a fictional drug to treat migraine, embedded in a Google search page about migraine. The study 3 materials will be a character-space-limited communication about a fictional weight loss drug, embedded in a Twitter search page about weight loss. The pretest 2 and study 4 materials will be a character-space-limited communication about a fictional drug to treat migraine, embedded in a Twitter search page about migraine.

All study materials will allow for scrolling and clicking on any links. The study materials will be accessible by participants only. After viewing the study materials, participants will complete a questionnaire that assesses participants' retention of the risk information and their perceptions of the drug's risks and benefits. We will also measure covariates such as demographics and health literacy. The questionnaires are available upon request.

We hypothesize that participants who see substantive risk information in the character-space-limited communication, compared with link-only participants, will have greater retention of the risk included in the communication and higher perceived risk. We will explore whether including substantive risk information in the character-space-limited communication affects the likelihood that participants notice the communication or click the link to the risk information. We hypothesize that participants with a search goal, compared with a browse goal, will have greater retention of the benefit and risk information and higher perceived risk because they will be more likely to notice the character-space-limited communication and to click the link to the risk information. We will test these hypotheses in studies 1-4 to determine whether these effects hold across different medical conditions and different character-space-limited platforms. To test

these hypotheses, we will conduct inferential statistical tests such as logistic regression and analysis of variance.

All participants will be 18 years of age or older. We will exclude individuals who work in healthcare or marketing. Half of the studies will have a sample of participants who self-report needing to lose 30 pounds or more; the other half will have a sample of participants who self-report suffering from migraines. We selected these samples to increase the likelihood that participants will be interested in the fictitious study drugs and therefore motivated to pay attention during the study. The studies will be conducted with an Internet panel. With the sample sizes described in the tables, we will have sufficient power to detect small-sized effects in studies 1-4 (table 5).

Table 1.--Study 1: Google Sponsored Link, Weight Loss

			Motivation			
			General search		Learn about treatments	
			Risk only landing page	Risk and benefit landing page	Risk only landing page	Risk and benefit landing page
Mobile	Risk Location	In character space-limited communication				
		On linked Web page only				
Desktop/Laptop	Risk Location	In character space-limited communication				
		On linked Web page only				

Table 2.--Study 2: Google Sponsored Link, Migraine

			Motivation			
			General search		Learn about treatments	
			Risk only landing page	Risk and benefit landing page	Risk only landing page	Risk and benefit landing page
Mobile	Risk Location	In character space-limited communication				
		On linked Web page only				
Desktop/Laptop	Risk Location	In character space-limited communication				
		On linked Web page only				

Table 3.--Study 3: Twitter, Weight Loss

			Motivation			
			General search		Learn about treatments	
			Risk only landing page	Risk and benefit landing page	Risk only landing page	Risk and benefit landing page
Mobile	Risk Location	In character space-limited communication				
		On linked Web page only				
Desktop/Laptop	Risk Location	In character space-limited communication				
		On linked Web page only				

Table 4.--Study 4: Twitter, Migraine

			Motivation			
			General search		Learn about treatments	
			Risk only landing page	Risk and benefit landing page	Risk only landing page	Risk and benefit landing page
Mobile	Risk Location	In character space-limited communication				
		On linked Web page only				
Desktop/Laptop	Risk Location	In character space-limited communication				
		On linked Web page only				

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

Table 5.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest 1 screener	464	1	1	0.08 (5 minutes)	39
Pretest 2 screener	464	1	1	0.08 (5 minutes)	39
Study 1 screener	786	1	1	0.08 (5 minutes)	66
Study 2 screener	786	1	1	0.08 (5 minutes)	66
Study 3 screener	786	1	1	0.08 (5 minutes)	66
Study 4 screener	786	1	1	0.08 (5 minutes)	66
Pretest 1	277	1	1	0.33 (20 minutes)	93
Pretest 2	277	1	1	0.33 (20 minutes)	93
Study 1	469	1	1	0.33 (20 minutes)	157

Study 2	469	1	1	0.33 (20 minutes)	157
Study 3	469	1	1	0.33 (20 minutes)	157
Study 4	469	1	1	0.33 (20 minutes)	157
Total	6,502				1,156

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

In the Federal Register of November 7, 2016 (81 FR 78163), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. Eleven comments were received. Two comments did not address any of the information collection topics solicited and therefore we do not discuss them in this document (they called for a ban on prescription drug character-space-limited communications). No comments addressed Topic 2--Accuracy of Our Estimate.

Topic 1--Practical Utility

Four comments addressed topic 1 with respect to the practical utility of the study stimuli and real-world application. FDA's goal is always to regulate prescription drug promotion in support of our public health mission. We are not aware of any studies, to date, that specifically assess the general question of whether a link to prescription drug information can effectively convey the risks associated with a drug when benefit claims about that drug are made within character-space-limited communications. This concept has been suggested in various ways by our stakeholders, and we feel that it is important to gain further insight into this potential practice. We appreciate the considerations these comments have put forth; however, we feel that the current objective is important and will maintain it for this project.

One comment stated that a balance of risk and benefit is not needed in a character-space-limited communication. The proposed research is designed to test this question.

One comment encouraged dissemination of our results and requested we indicate a subsequent use for this information collection. We plan to disseminate our results via our Web site and peer-reviewed publication. FDA will use the information from this study to inform its understanding and regulation of prescription drug promotion. Results from studies we conduct are evaluated within the broader context of research and findings from other sources.

Topic 3--Ways to Enhance Quality, Clarity, Utility.

Comments related to study design.

Several comments suggested ways to enhance the study design. Four comments suggested alternate study objectives, such as testing risk icons, testing different kinds of character-space-limited communications, and testing direct-to-consumer promotion in the presence of misinformation about the product. We appreciate these suggestions for future studies. However, we feel the current objectives are important and will maintain them for this project.

Two comments recommended including mobile displays. We agree and will recruit an equal number of participants who are using mobile and non-mobile devices. This will not change the study burden.

One comment suggested manipulating whether the landing page includes only risk information or whether it includes risk and benefit information. We have taken this suggestion and revised the study design. This does not change the study burden.

One comment suggested evaluating participant engagement with the stimuli. We plan to measure engagement variables such as clicking links and scrolling.

One comment suggested that the issue we should be studying is whether consumers know that drugs generally have risks rather than whether consumers know the specific risks associated

with a drug. We believe the purpose of communicating the drug's specific risk information is so consumers can make informed decisions based on both the drug's benefits and risks.

One comment suggested FDA conduct background research before conducting the proposed research. We appreciate these suggestions, and note that FDA has undertaken a content analysis of mobile prescription drug promotion (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm>). For this proposed research, FDA wishes to use its resources more pointedly toward the research questions proposed in this notice.

One comment suggested explicitly telling participants to search for drug risk information. We will use random assignment to instruct participants either to search or browse for information. However, we will not instruct participants to search for risk information, specifically, because we are interested in how individuals respond to character-space-limited communications with and without risk information rather than whether participants can find risk information when they are instructed to search for it.

One comment suggested that the browse/search goal construct was not relevant because approximately half of U.S. Internet users have searched for medical information online and because this construct hasn't been studied in the realm of prescription drug information before. The comment asserts that consumers are unlikely to browse health information online. This comment assumes that only consumers actively searching for prescription drug information will be exposed to communications about these products. We disagree. Consumers who view information about a topic more generally (such as weight loss) may not be actively searching for prescription drug information but may come across it anyway. Our conditions are meant to

simulate a search of “migraine” or “weight loss” that contains prescription drug information, for which consumers either will or will not specifically be looking.

One comment suggested adding a general population sample. We chose to recruit individuals with the medical condition being advertised to increase the likelihood that participants will be engaged with the browse and search tasks. Weight concerns and migraine affect large segments of the population. To reduce burden, we do not plan to add a general population sample.

One comment suggested that we change the “browse2” instruction so that it discusses browsing information in general rather than referring to a topic. We made this change.

Comments Related to Study Stimuli.

Several comments suggested ways to enhance the study stimuli. Four comments suggested testing Twitter cards or photos embedded in tweets that would expand the space available to communicate risk information. Sponsors are permitted to promote their products on platforms using additional multimedia components, and we appreciate these suggestions for future studies. However, the current study aims to address the more general question of whether a link to prescription drug risk information can effectively convey the risks associated with a drug when benefit claims about that drug are made within character-space-limited communications used in prescription drug promotion.

One comment addressed the content surrounding the character-space-limited communication. The other links and tweets will replicate real-world searches, including links to general health information Web sites and links to Web sites for other (non-prescription) treatments. The surrounding content will not differ across condition for experimental control.

One comment suggested using high-visibility techniques to communicate risks. We appreciate this suggestion but we intend to make the prominence of the risk and benefit information comparable in these studies.

One comment suggested formatting the landing page to optimize readability (e.g., easy-to-read font size) and ensuring participants know they can click the links. We will take these suggestions when we create the landing pages and study instructions. Another comment suggested specific tools to use to create our stimuli. We are employing a professional firm to create realistic stimuli.

One comment suggested using “decoy” links/tweets and suggested randomizing the order of the links/tweets to decrease bias. We will have nine other links or tweets, for a total of ten to simulate one search page. To make the stimuli as close to real-world online searches as possible, the sponsored link will always appear at the top of the search results. To keep the stimuli similar across studies, the tweet will also appear at the top of the page. The order will remain constant across conditions in all studies.

One comment suggested changing “Important Risk Information” to “See Important Risk Information” to include a “call to action.” We have made this change.

Comments Related to the Questionnaire.

Several comments had suggestions for how we ask our questions. Two comments suggested changes to our medical condition screening questions. These questions come from the National Health Interview Survey and the National Health and Nutrition Examination Survey. We plan to keep these questions “as is” so we can compare our samples to these national samples. We will change the description of our samples to match these questions.

Two comments suggested adding a “don’t know” option or letting some participants opt out of the first series of questions. We added a “don’t know” option to these questions. We will use cognitive interviews and pretests to assess whether we need to make additional changes, including other minor wording changes suggested in the comments.

Two comments suggested moving, editing, or deleting specific questions (such as perceptions and intentions). We moved the items as suggested, and will flag these items for potential editing or removal based on cognitive interview and pretest results.

One comment suggested screening out participants who had never used Google or Twitter and participants with low health literacy. We added a screening question regarding Internet usage. We do not plan to screen based on literacy, but rather we will examine whether literacy moderates any effects.

One comment suggested defining “serious side effect” for consumers; however, previous FDA research found that consumers were able to understand this concept (Ref. 9).

Topic 4--Ways to Minimize Burden.

One comment addressed topic 4. This comment suggested conducting 20 hour-long qualitative interviews per study rather than conducting pretests. To clarify, we will conduct nine hour-long qualitative interviews to cognitively test the study stimuli and materials. We will use the pretests to test and select the browse and search goal instructions for the main studies and to pilot the main studies.

II. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

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.
<https://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 Yabus 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, <https://dx.doi.org/10.1086/376807>

9. FDA. “Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products; Final Rule.” 73 FR 63886 to 6389. Available at <https://www.regulations.gov/document?D=FDA-2003-N-0313-0008>, 2008.

Dated: July 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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