person for this jurisdiction; the jurisdictions Web site address and if the jurisdiction is willing to serve as an auditor for another jurisdiction. Part 2 requires information about enrollment, whether this jurisdiction is a new enrollee and the date of enrollment; indication whether this jurisdiction would like to be removed from the jurisdiction listing; indication of updated findings to the self-assessment or verification audit. Part 3 requires information about self-assessment findings and verification audit findings; dates when self-assessment was completed; which standards have been met as determined by the self-assessment; which standards have been met as verified by a verification audit including the completion dates. Part 4 requires permission to publish information on FDA's Web site by checking the appropriate box(es) to indicate what information FDA may publish on the Web site.

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

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Submission of "Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report".	3,958	500	1	500	*0.1	50
Request for documentation of successful completion of staff training.	Conference for Food Protection Training Plan and Log.	500	3	1,500	*0.1	150
Total						200

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

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards. As explained previously, FDA estimates that no more than 500 regulatory jurisdictions will participate in the Program Standards in any given year. FDA estimates a total of 6 minutes annually for each enrolled jurisdiction to complete the form. FDA bases its estimate on the small number of data elements on the form and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3958 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour (or 6 minutes) per response for a total of 50 hours. In addition, FDA estimates that, annually, 500 regulatory jurisdictions will submit three requests for documentation of successful completion of staff training using the CFP Training Plan and Log for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour (or 6 minutes) per response for a total of 150 hours. The total reporting burden for this information collection is 200 hours.

Thus, the total hourly burden for this information collection is 47,345 hours (47,145 recordkeeping hours and 200 reporting hours).

Dated: July 12, 2017.

Anna K. Abram,

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

[FR Doc. 2017–14994 Filed 7–17–17; 8:45 am]

BILLING CODE 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 August 17, 2017.

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 *oira_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.				

TABLE 1—STUDY 1: GOOGLE SPONSORED LINK, WEIGHT LOSS—Continued

			Motivation			
			General search		Learn about treatments	
			Risk only landing page	Risk and benefit landing page	Risk only landing page	Risk and benefit landing page
		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 BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest 1 screener	464	1	1	0.08 (5 minutes)	39

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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 specifics 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 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, *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.

[FR Doc. 2017–15002 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P