

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus Groups About Drug Products .....	1,440	1	1,440	1.75	2,520

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

Dated: November 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–26794 Filed 11–4–16; 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; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, “Character-Space-Limited Online Prescription Drug Communications.” The objective of this research is to test 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.

**DATES:** Submit either electronic or written comments on the collection of information by January 6, 2017.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

*www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2016–N–3585 for “Character-Space-Limited Online Prescription Drug Communications.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the

public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*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 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(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.

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 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 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 below, 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

	Goal	
	Browse	Search
Risk Location:		
In character-space-limited communication .....	.....	.....
On landing page only .....	.....	.....

TABLE 2—STUDY 2: GOOGLE SPONSORED LINK, MIGRAINE

	Goal	
	Browse	Search
Risk Location:		
In character-space-limited communication .....	.....	.....
On landing page only .....	.....	.....

TABLE 3—STUDY 3: TWITTER, WEIGHT LOSS

	Goal	
	Browse	Search
Risk Location:		
In character-space-limited communication .....	.....	.....
On landing page only .....	.....	.....

TABLE 4—STUDY 4: TWITTER, MIGRAINE

	Goal	
	Browse	Search
Risk Location:		
In character-space-limited communication .....	.....	.....
On landing page only .....	.....	.....

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

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest 1 screener .....	464	1	1	.08 (5 min.) .....	39
Pretest 2 screener .....	464	1	1	.08 (5 min.) .....	39
Study 1 screener .....	786	1	1	.08 (5 min.) .....	66
Study 2 screener .....	786	1	1	.08 (5 min.) .....	66
Study 3 screener .....	786	1	1	.08 (5 min.) .....	66
Study 4 screener .....	786	1	1	.08 (5 min.) .....	66
Pretest 1 .....	277	1	1	.33 (20 min.) .....	93
Pretest 2 .....	277	1	1	.33 (20 min.) .....	93
Study 1 .....	469	1	1	.33 (20 min.) .....	157
Study 2 .....	469	1	1	.33 (20 min.) .....	157
Study 3 .....	469	1	1	.33 (20 min.) .....	157
Study 4 .....	469	1	1	.33 (20 min.) .....	157
<b>Total .....</b>	<b>6,502</b>	.....	.....	.....	<b>1,156</b>

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

**II. References**

The following references are on display in the Division of Dockets Management (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 <http://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/guidance/complianceregulatoryinformation/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 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, <http://dx.doi.org/10.1086/376807>.

Dated: October 31, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–26793 Filed 11–4–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–0086]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Potential Tobacco Product Violations Reporting Form

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained

in FDA's Tobacco Product Violations Reporting Form.

**DATES:** Submit either electronic or written comments on the collection of information by January 6, 2017.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

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- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA–2014–N–0086 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Potential Tobacco Product Violations Reporting Form." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management

between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.