Prevention and the Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0493]

Agency Information Collection Activities; Proposed Collection; Comment Request; Utilization of Adequate Provision Among Low to Non-Internet Users

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 ''Utilization of Adequate Provision among Low to Non-Internet Users.''

DATES: Submit either electronic or written comments on the collection of information by August 11, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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–2017–N–0493 for ''Utilization of Adequate Provision among Low to Non-Internet Users.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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: *For copies of the questionnaire:* Office of Prescription Drug Promotion Research Team, *DTCresearch@fda.hhs.gov. For questions on the PRA:* JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

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. 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.

Utilization of Adequate Provision Among Low to Non-Internet Users; OMB Control Number 0910–NEW

I. Background

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.

Prescription drug advertising regulations require that broadcast advertisements containing product claims present the product's major side effects and contraindications in either audio or audio and visual parts of the advertisement (21 CFR 202.1(e)(1)); this is often called the major statement. The regulations also require that broadcast advertisements contain a brief summary of all necessary information related to side effects and contraindications or that ''adequate provision'' be made for dissemination of the approved package labeling in connection with the broadcast (21 CFR 202.1(e)(1)). The requirement for adequate provision is generally fulfilled when a firm gives consumers the option of obtaining FDA-required labeling or other information via a toll-free telephone number, through print advertisements or product brochures, through information disseminated at health care provider offices or pharmacies, and through the Internet (Ref. 1). The purpose of including all four elements is to ensure that most of a potentially diverse audience can access the information.

Internet accessibility is increasing, but many members of sensitive demographic groups (*e.g.,* older adults, low socioeconomic status individuals) nonetheless report that the Internet is inaccessible to them either as a resource or due to limited knowledge, and so a Web site alone may not adequately serve all potential audiences (Refs. 2 and 3). Similarly, some consumers may prefer to consult sources other than a health care provider to conduct initial research, for privacy reasons or otherwise (Refs. 1, 4, and 5). In light of these considerations, the 1–800 number and print ad may provide special value to consumers who are low to non-Internet users and/or those who value privacy when conducting initial research on a medication, though not necessarily unique value relative to one another. As such, a primary purpose of this research is to examine the value of including both the 1–800 number and print ad as part of adequate provision in direct-to-consumer (DTC) prescription drug broadcast ads. Secondarily, we will also investigate the ability and willingness of low to non-Internet users to make use of Internet resources if other options were unavailable. These questions will be assessed using a survey methodology administered via telephone.

In addition, building on concurrent FDA research regarding drug risk information,[1] we will assess risk perceptions as influenced by opening statements that could be used to introduce risks in DTC prescription drug broadcast ads. Opening statements may be used to frame risk information that follows. As such, consumers may interpret the likelihood, magnitude, and duration of risks differently depending on how those risks are introduced (Refs. 6–9). The intended outcome of this component of the research is to evaluate the influence of these opening statements within a sample of low to non-Internet users. This research question will be addressed using a 1×3 between-subjects experimental design embedded in the previously mentioned survey. This particular component of the research will serve as an exploratory test intended to inform FDA's future research efforts.

Sampling Frame. Given that older adults (*i.e.,* those aged 65 and older) are among the largest consumers of prescription drugs (Ref. 10) and that approximately 41 percent of older adults do not use the Internet (Ref. 2), investigating use of adequate provision in this population is especially important. Also of concern, 34 percent of those with less than a high school education do not use the Internet, 23 percent of individuals with household incomes lower than $30,000 per year do not use the Internet, and 22 percent of individuals living in rural areas do not use the Internet (Ref. 2). These estimates capture non-Internet users, and so consideration of low-Internet users warrants additional concern. Consistent with these citations, the present research will utilize a nationally representative sample of low to non-Internet users from these and other relevant demographic groups.

Data collection will utilize a random digit dialing (RDD) sample that has been pre-identified as being a non-Internet household, or having at least one non-Internet using member. This sample solution is ideal because it relies on a dual-frame (landline and cell phone) probability-sample, yet has the advantage of prior knowledge of those who are likely to be low to non-Internet users (re-screening will verify this). The Social Science Research Solutions (SSRS) Omnibus, within which this survey will be embedded, utilizes a sample designed to represent the entire adult U.S. population, including Hawaii and Alaska, and including bilingual (Spanish-speaking) respondents. As reflected in the overall population of low to non-Internet users, we intend to collect a small sample of Spanish-speaking individuals, which comprise a subsample of the regular landline and cell phone RDD sampling frames. We may also screen for past and present prescription drug use in order to ensure a motivated sample.

Survey Protocol. This survey will be conducted by telephone on landline and cell phones, with an expected 50 to 60 percent of interviews conducted on cell phones. Interviewing for the pretest and main study will be conducted via SSRS's computer-assisted telephone interviewing (CATI) system. We expect to achieve a roughly 40 percent survey completion rate from the pre-identified respondents to be sampled in this study, given an 8-week field period and a maximum of 10 attempts to reach respondents. The original SSRS Omnibus from which this sample is derived receives an approximately 8 to 12 percent response rate. These are not uncommon response rates for high-quality surveys and have been found to yield accurate estimates (Refs. 11 and 12).

As communicated earlier, the primary focus of interview questions concern the ability and willingness of low to non-Internet users to utilize the various components of adequate provision, particularly the 1–800 number and print ad components. In addition to these questions, experimental manipulations will be embedded in the survey as an exploratory test to assess the impact of opening statements that could be used to introduce risks in DTC prescription drug broadcast ads, which is a related concept. To form the experimental manipulations, participants will be presented with a statement of major risks and side effects (''the major statement'') drawn from a real prescription drug product, but modified to include only serious and actionable risks. Preceding this description of major risks will be one of three opening statements: (1) ''[Drug] can cause severe, life threatening reactions. These include

[1] *https://www.federalregister.gov/documents/2015/01/13/2015-00269/agency-information-collection-activities-submission-for-office-of-management-and-budget-review.*

. . .''; (2) ''[Drug] can cause serious reactions. These include . . .''; or (3) ''[Drug] can cause reactions. These include . . .'' All risk statements will conclude with the following language: ''This is not a full list of risks and side effects. Talk to your doctor and read the patient labeling for more information.'' Participants will be randomly assigned to experimental condition, and all manipulations will be pre-recorded to allow for consistent administration. Following exposure to these manipulations, participants will respond to several questions designed to assess risk perceptions.

Before the main study, we will execute a pretest with a sample of 25 participants from the same sampling frame as outlined in this document. The pretest questionnaire will take approximately 15 minutes to complete. The goal of the pretest will be to assess the questionnaire's format and the general protocol to ensure that the main study is ready for execution. To test the protocol among the target groups, we will seek to recruit a mix of participants based on demographic and other characteristics of interest. We do not plan to use incentives for the pretest or main study portions of this survey. However, upon request, cell phone respondents may be offered $5 to cover the cost of their cell phone minutes.

Questionnaire development is an iterative process and so the main study questionnaire will include any changes from pretesting, as well as other outcomes, such as OMB and public comments, or cognitive interviewing. Like pretesting, the main study questionnaire should take approximately 15 minutes to complete. Based on a power analyses, the main study sample will include approximately 1,996 participants. This sample size will allow us to draw statistical comparisons between the various demographic groups in the sample.

Measurement and Planned Analyses. Consistent with the larger purpose of the study, survey questions will examine access, technical ability, and willingness to use adequate provision options; preference for and experience using adequate provision options; privacy concerns; and potentially other secondary questions of interest. In addition, to assess the impact of the experimental manipulations, survey questions will assess perceived risk likelihood, perceived risk magnitude, and perceived risk duration. Demographic information will also be collected. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. A copy of the draft questionnaire is available upon request.

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

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest Screener	63	1	63	0.05 (3 minutes)	3.15
Pretest Survey	25	1	25	0.25 (15 minutes).	6.25
Main Study Screener	4,990	1	4,990	0.05 (3 minutes)	249.5
Main Study Survey	1,996	1	1,996	0.25 (15 minutes).	499
Total Hours					757.9

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

II. References

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12. Groves, R. M. (2006). ''Nonresponse Rates and Nonresponse Bias in Household Surveys.'' *Public Opinion Quarterly,* 70: pp. 646–675.

Dated: June 5, 2017.

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