Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–05000 Filed 3–12–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2017–0114; Docket Number NIOSH–305]

Final National Occupational Research Agenda for Transportation, Warehousing and Utilities

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final National Occupational Research Agenda for Transportation, Warehousing and Utilities

DATES: The final document was published on March 7, 2018.

ADDRESSES: The document may be obtained at the following link: *https://www.cdc.gov/niosh/nora/sectors/twu/agenda.html*

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H, (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On December 1, 2017, NIOSH published a request for public review in the **Federal Register** [82 FR 56973] of the draft version of the National Occupational Research Agenda for Transportation, Warehousing and Utilities. No comments were received.

Dated: March 8, 2018.

Frank Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–04988 Filed 3–12–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0493]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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: Submit either electronic or written comments on the collection of information by April 12, 2018.

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 ''Utilization of Adequate Provision Among Low to Non-internet Users.'' 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, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

Utilization of Adequate Provision Among Low to Non-Internet Users

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 (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 (§ 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 certain 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 website 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 toll-free 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 toll-free number and print ad as part of adequate provision in direct-to-consumer (DTC) prescription drug broadcast ads. 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 will 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 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 toll-free 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 . . .''; (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. 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. 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.

In the **Federal Register** of June 12, 2017 (82 FR 26934), FDA published a 60-day notice requesting public comment on the proposed collection of information. Comments received along with our responses to the comments are provided below. For brevity, some public comments are paraphrased and therefore may not reflect the exact language used by the commenter. We assure commenters that the entirety of their comments was considered even if

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

not fully captured by our paraphrasing. The following acronyms are used here: FRN = **Federal Register** Notice; DTC = direct-to-consumer; FDA and ''The Agency'' = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

Comment 1a, regulations.gov tracking number 1k1–8y16–3nqx (summarized): The commenter expresses support for FDA's collective research and welcomes the Agency's current proposed survey examining adequate provision.

Response to Comment 1a: We appreciate and thank the commenter for their support.

Comment 1b (verbatim): Throughout the main survey questionnaire, some questions ask about ability to obtain information on prescription drugs after seeing an advertisement on television. These questions presume access to a television. If understanding this process of first seeing an ad on TV then searching for information is the key objective, we suggest in the screening criteria ensuring all respondents have access to a TV and/or watch television on a regular basis.

Response to Comment 1b: We have added a screening question to confirm that participants watch television at least occasionally.

Comment 1c (verbatim): As currently outlined, the sample frame is relatively broad in that it includes those who possibly do not have experience with prescription medications or experience searching for prescription medication information. Respondents without experience in this area could provide speculative responses to many questions, and thus, [the commenter] suggests that they are outside of the scope. To address this, we recommend adding a screening question or questions to include only those who have had at least one medical condition which has required prescription medication within the last 12 months.

Response to Comment 1c: To ensure a motivated sample, we included a question to screen for past or present prescription drug use.

Comment 1d (verbatim): The purpose of the secondary objective of the study pertaining to risk statements is not entirely clear. Since the sample frame is not restricted to those who suffer from a condition which could be helped by the mock drug, responses have the possibility to be speculative and reflect bias of people coming in to the study rather than what is intended. For instance, respondents who happen to be within a population targeted by the major statements are reasonably more likely to report a higher likelihood of experiencing a stated side effect and reporting a higher seriousness of them, biasing experiment responses.

Response to Comment 1d: The secondary objective of the study is designed to assess the impact of opening statements that could be used to introduce risks in DTC prescription drug broadcast ads. This objective complements previously published research and adds value by newly investigating the impact of framing statements among a sample of low to non-internet users. Our approach involves random assignment to experimental conditions which should lead to approximately equal numbers of diagnosed versus undiagnosed individuals in each of the conditions, lessening any concern about bias. Nonetheless, please understand that this secondary objective is intended to provide a *preliminary* assessment of the stated research questions for development purposes. Procedurally, this objective will involve only a brief presentation of a short audio broadcast followed by three questions, allowing us to gather this valuable information with very low burden to participants who are already engaged in our larger survey regarding adequate provision.

Comment 1e (verbatim): Additionally, information gained from the experimental manipulations (E–1 through E–3) will only be applicable to hearing the opening and major statement presented over the phone, rather than versus being read through print or online. Interpretations and understanding of this info could differ between the media. While this could possibly be a useful supplement to current knowledge, the learnings will likely not be directly applicable to the other media. If comparison of interpretation between the media is the goal of this section, [the commenter] suggests a stand-alone study would better address that goal rather than an addendum to this one.

Response to Comment 1e: We appreciate this limitation of our preliminary assessment and intend to take it into consideration when interpreting results.

Comment 1f (verbatim): Screener: The current screener terminates cell phone users who have not browsed the internet in the past month (S I). It is not readily apparent why this group should not participate in the survey. We would suggest that the termination criteria be removed from this question as it may make incremental improvement to response rates.

Response to Comment 1f: The screener only excludes cell phone users (T1 = 2) who choose ''don't know'' (− 98) or refuse the question (− 99) (S1 < 0).

Comment 1g (verbatim): As is, it is unclear what an independent variable for the questionnaire is intended to be. One possibility [the commenter] suggests is including a question aimed at understanding the overall preference for source of information, which would serve as the independent variable in the study or could be combined with the ability and access questions to make a composite variable. *(e.g.,* ''What is your preferred medium in which to receive prescription drug information: Print ads for the drug; the manufacturer's phone number or website; or asking your healthcare provider?'')

Response to Comment 1g: Please refer to the instruction set preceding question 3. Our questionnaire attempts to learn about patient preferences through questions about participant likelihood to seek information via the various available sources, as well as past use, ability, and willingness, among other constructs. We believe these constructs to provide adequate assessment of consumer preference to obtain additional information via the various available sources. Moreover, we note that another commenter (see Comment 3n) takes the position that we should not inquire about patient preferences. We have considered both of the perspectives when deciding upon potential revisions.

Comment 1h (verbatim): Throughout the survey, [the commenter] suggests defining each point on the 5 point scales used to avoid confusion by respondents. In our consumer research efforts, we customarily use 5 point scales that are defined at each point, such as 'Excellent, Very Good, Good, Poor, and Very Poor'.

Response to Comment 1h: We concur that defining each point on 5 point scales helps mitigate confusion and have revised the questionnaire to define each point of scales.

Comment 1i (verbatim): It seems inappropriate to use a Likert scale to answer ''Q1: Access to sources of information'', as it would seem access could be defined more narrowly—No access, some access, or complete access. We suggest using the pre-test to examine this question in particular to ensure either that the current scale is interpreted correctly or determine an appropriate re-wording. Additionally, it could be helpful to include the more specific options as distinct answer choices (*e.g.* an option for internet at a public library and a separate option for internet at a coffee shop) in order to provide more granular information which could be useful to the FDA as

well as industry as a whole. We suggest using the pre-test to produce a full list of options as well as any appropriate re-wordings.

Response to Comment 1i: We agree that defining access more narrowly may be sufficient for this question and so we have adopted this approach in our revised survey. We will also evaluate responses to this narrowed scale in our analysis of pretest data. We also appreciate the value of assessing locations of access; however, we consider such questions to be of lesser relevance to our key objectives, and we have sought to limit the duration of the survey to less than 15 minutes. Consequently, we do not adopt this recommendation.

Comment 1j (verbatim): Throughout the survey, we suggest adding in ''Talked with your doctor'' as an answer choice among the options for sources of information. Physicians are a major source of product information and ''talking with a doctor'' are what drug advertisements generally suggest to consumers, so inclusion of this option is appropriate.

Response to Comment 1j: We agree that health care providers are one important source for adequate provision. Nonetheless, the current investigation is designed to assess the utility of the various options for disseminating additional product risk information, and speaking with a health care provider is not under reevaluation. Consequently, we ask participants to respond under the premise that they are seeking information prior to approaching a health care professional.

Comment 1k (verbatim): As currently worded, question 13 has the possibility to lead the respondent by stating that ''Some people change their approach . . .'' The current wording could bias respondents to be overly critical. [The commenter] would suggest either changing the question or adding in a new question prior to the current Q 13 to ascertain a rating of the level of privacy offered by each information source. This new question would provide the respondents current perceptions of privacy, something which the survey omits. For example, a newly worded question could be as follows: ''On a 5-point scale, in which 1 is Very Low Privacy and 5 is Very High Privacy, what is the level of privacy offered by each of the following information sources when getting full prescription-drug product information?'' The current question 13 could then follow this question.

Response to Comment 1k: Our intention with this question (and its wording) is to facilitate comparisons between baseline likelihood to use the various sources of adequate provision (see Q3) and likelihood to use the various options in cases where privacy is a concern. By stating ''Some people change their approach . . . '' we hoped to give participants permission to respond differently than they had in the earlier question, if they felt a change in their response was appropriate. Nonetheless, we recognize that this language could be leading and so we have eliminated it from our revised questionnaire. We are hopeful that the revised question will still allow us to draw the intended comparisons.

Comment 1l (verbatim): In addition to our concerns regarding the goal of the experiment questions (E 1–E2), the purpose in the variations of the major statements is unclear. The objectives state that varying opening statements (E I) are the secondary focus of this research, not major statements. We suggest choosing an appropriate major statement in the pre-tests and then using that in the broader fielding of the study.

Response to Comment 1l: The purpose of varying the major statements was to add to the generalizability of our findings. The revised version of our survey adopts this commenter's recommendation and includes only one version of the major statement.

Comment 1m (verbatim): We suggest adding a ''Don't know'' option for EI–E3 as respondents might not be able to assess how long lasting, serious, or likely the side effects would be. The current range of answer choices may force inaccurate or speculative responses; a ''Don't Know'' answer would be a legitimate choice and informative for the study. Our standard practice is to provide a ''Don't Know'' option whenever it could be a valid answer.

Response to Comment 1m: The items used in this section were developed through scale validation research and thus we prefer to retain them in their original form. Nonetheless, we have added labels to each point on the scales in response to Comment 1h, and the midpoint (''neutral'') of these scales may be treated similarly to a ''Don't Know'' option.

Comment 2a, regulations.gov tracking number 1k1–8xz6–t7bj (verbatim): The practical utility of this study is unclear. Currently, industry is broadly executing on making labeling available via both IN [internet] and non-IN based options to a diverse audience. Historically, there were many options available to enable patients to locate drug-related labeling, even before the IN became available. When added to the three options mentioned above, the IN provides patients with a fourth option, one that is increasingly at a patient's fingertip via tablet, cell phone, or laptop. Hence, it is unclear how results from this study will enhance consumer access to information or be applied to modify current practices.

Response to Comment 2a: As stated in the 60-day FRN (82 FR 26934), our intention is to assess the utility of the various sources of adequate provision among a sample of low to non-internet users. For example, it may not be necessary to include both a print ad reference and toll free number reference. We have received inquiries along these lines from stakeholders. Additionally, we may find that low to non-internet users would be willing to use the internet themselves or with the help of a friend or family member if non-internet options were unavailable. This research will provide insights to inform our approach to the adequate provision requirement.

Comment 2b (verbatim): The sampling frame focuses on those ''not likely to have IN access'' as defined by FDA and includes older adults, with less than a high school education, who make less than $30,000/year, and live in rural areas; it also includes bilingual Spanish speakers. Yet it is not clear how persons not likely to have IN access would be able to inform FDA about how they would behave if they had access to the IN and other options were not available. Rather than speculate about how their behavior might change if faced with IN access and no other options, it would be better to design a study that focuses on understanding the effectiveness of non-IN options to provide information in general.

Response to Comment 2b: To be clear, we intend to sample from the above referenced populations separately, as opposed to sampling from one population with all these attributes.

As indicated in the 60-day FRN (82 FR 26934), we do intend to assess the effectiveness of non-internet options. However, as a secondary objective, it seems to us worthwhile to also consider how low to non-internet users may respond if non-internet options were unavailable. As another commenter indicates (see Comment 3b), internet use is widespread and technological sources of adequate provision may suffice (when combined with recommendation to speak to a health care professional). We hope to shed light on this question through our research.

Comment 2c (verbatim): Questions 1–5 and 13: The current choices do not assess the respondent's willingness or ability to visit their healthcare provider

to obtain the approved package labeling. This option should be added.

Response to Comment 2c: Please refer to Comment 1j and our associated response.

Comment 2d (verbatim): Question 15: Given the length of the package labeling making it impractical to receive the information verbally, it would be likely that callers would prefer an option, *Mail the prescription drug product information to me,* even when faced with privacy concerns.

Response to Comment 2d: This response option has been added to our revised questionnaire.

Comment 2e (verbatim): Instructions for Experimental Manipulations, E1/E2: E2 includes three different versions of the major statements. If 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-IN users, and risk perceptions will be assessed as influenced by opening statements that could be used to introduce risks, it is unclear why the major statements (E2: A, B, C) differ when assessing whether or not opening statements (E1: 1, 2, 3) influence risk perceptions.

Response to Comment 2e: Please refer to Comment 1l and our associated response.

Comment 3a, regulations.gov tracking number 1k1–8y13–m7td: FDA is conducting too much research without ''articulating a clear, overarching research agenda or adequate rationales on how the proposed research related to the goal of further protecting public health.'' ''The Agency should publish a comprehensive list of its prescription drug advertising and promotion studies from the past five years and articulate a clear vision for its research priorities for the near future.''

Response to Comment 3a: OPDP's mission is to protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated, so that patients and health care providers can make informed decisions about treatment options. OPDP's research program supports this mission by providing scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.* The website includes links to the latest FRNs and peer-reviewed publications produced by our office. The website maintains information on all studies we have conducted, dating back to a DTC survey conducted in 1999.

Comment 3b; the commenter provided a summary of their comments followed by a more detailed description of the same comments. For brevity, only the summary of comments (verbatim) is provided below. Full comments may be accessed at regulations.gov via tracking number 1k1–8y13–m7td.

First, FDA's proposed research appears to offer limited practical utility in several ways:

- The Agency proposes research based on an outdated, 18-year-old guidance document that fails to recognize adequately the societal and technological changes of the last two decades, including the many options now available to satisfy the adequate provision requirement.
- FDA regulations require adequate, not complete, provision. Given the prevalence of the internet and smartphones across all U.S. demographic groups, we believe that biopharmaceutical manufacturers can satisfy adequate provision simply through information dissemination at health care provider offices or pharmacies, a 1–800 number, and/or the internet.
- FDA fails to recognize existing research that demonstrates the pervasiveness of the internet and smartphones in the United States. This research limits any potential utility of the proposed study. The Agency's proposal mainly relies on data from six to 16 years ago. The smartphone is dramatically increasing internet connectivity for traditionally low to non-internet use demographic groups. Further, FDA does not acknowledge that older adults (with or without internet access) tend to rely on others, including family and health care personnel, for drug information.

Response to Comment 3b: FDA recognizes that a large proportion of the U.S. population utilizes the internet. It is specifically for this reason that we are conducting research to inform our current guidance recommendations. Nonetheless, as indicated in the 60-day FRN (82 FR 26934), certain segments of the U.S. population are unlikely to use the internet. For example, 41 percent of individuals aged 65 and older do not use the internet, yet are the largest consumers of prescription drugs. As the commenter states, some individuals from this demographic rely on others to obtain drug information, but this perspective does not take into account the desire for privacy in obtaining such information, or the availability of these other individuals. The proposed research will provide empirical assessment of how vulnerable populations such as older adults may be impacted by changes to regulatory policy.

The assertion that the requirement for ''adequate'' provision can be fulfilled by disseminating information through ''health care provider offices or pharmacies, a 1–800 number, and/or the internet'' may be correct, and FDA invites the commenter to submit data supportive of this perspective. FDA maintains a science-based approach to its regulatory decisionmaking, and as such, the current research is designed to inform our thinking in this area.

We disagree with the assertion that our proposal relied mainly on data from 6 to 16 years ago. A more careful review of the FRN will show that our key citations range from 2013 to the present. By necessity, we also cite the relevant 1999 guidance, as well as a few other references which speak to general patterns of human behavior.

Comment 3c (summarized): The commenter recommends removal of the second proposed study concerning opening statements to frame risk information on the grounds that (a) questions regarding adequate provision may impact responding in the second

proposed study and (b) a low to non-internet user sample is not sufficiently diverse.

Response to Comment 3c: Please refer to Comment 1d and our associated response.

Comment 3d (summarized): The commenter provides several recommendations pertaining to subject enrollment. The first comment on this topic ''recommends that FDA ensure that the subject sample includes representative portions of alleged subpopulations of low to non-internet users, including older adults, low socioeconomic status individuals, people with less than a high school education, and individuals living in rural areas.''

Response to Comment 3d: To obtain a nationally representative sample of the target population of adult low to non-internet users who are also prescription drug users, the research team will use a sample sourced from a dual frame. This approach involves using a random digit dialing sample that has been pre-identified as being a non-internet household (or having at least one non-internet using member). The demographics within this frame of low to non-internet users fall within the expected range of subpopulations with respect to older adults, low socioeconomic status, and people with less than a high school education or some college. The sample is designed to represent the adult U.S. population (including Hawaii and Alaska) and will include rural areas. This sample solution is ideal because it relies on a dual-frame probability-sample, yet has the advantage of already knowing who are likely to be low to non-internet users.

Comment 3e (summarized): In the second comment pertaining to subject enrollment, the commenter recommends that participants reached via smartphone not be included in the sample.

Response to Comment 3e: We agree that smartphone use is increasing internet access for traditionally low to non-internet use demographics and appreciate the importance of confirming our sample are low to non-internet users. Notwithstanding, we are screening based on self-reported internet browsing, such that individuals who report browsing the internet three or more times in the past month—regardless of medium—will not be asked to participate in the survey. Further, the current approach supports that only households which have been pre-identified as having at least one non-internet using member will be screened for participation, adding an additional layer of assurance that only low to non-internet users will be asked to participate in the questionnaire.

Comment 3f (summarized): In the third comment pertaining to subject enrollment, the commenter recommends collecting data in-person because data collection via phone may impact responses regarding the 1–800 number.

Response to Comment 3f: We acknowledge that in-person data collection would add value to the proposed research but cost implications bar us from pursuing it. We will consider implications of our protocol for survey administration when interpreting results.

Comment 3g (summarized): In the final comment pertaining to subject enrollment, the commenter indicates agreement with the proposed approach to screen for past and present prescription drug use in order to ensure a motivated sample.

Response to Comment 3g: We appreciate the support for this planned approach.

Comment 3h: Remaining comments pertain to the draft study questionnaire. The first comment on this topic suggests that certain items may lead participants to respond in certain ways. Examples (abbreviated for brevity) include:

- The instructions for Q3 of the Main Study Survey state: ''Prescription drugs advertised on television provide only limited product information. For example, not all of the product's risks and side effects are described. Imagine you wanted to obtain additional product information before seeing your health care provider.'' As previously mentioned, while research ''reveal[s] consumers engage in some prescription drug information seeking . . . most takes place *after* visiting a doctor, not before'' (emphasis added [by commenter]). The question prompt does not reflect common practice and may lead to a misleading answer. Both the prompt and question itself should be revised to reflect that subjects may look specifically to their healthcare provider for this information.
- Further, the Main Study Survey introduces questions about privacy by stating: ''Next, I will ask about privacy concerns you might have when getting full prescription-drug product information.'' Such phrasing suggests that a subject should have ''concerns'' in this context. Q12 asks subjects to ''rate the extent to which you *value* privacy . . . '' (emphasis added [by commenter]). Such language suggests subjects should indeed ''value'' privacy.
- The prompt for Q13 is also leading by introducing the question with: ''Some people change their approach to getting information about prescription drugs when privacy is a concern.''

Response to Comment 3h: As the commenter indicates in the first comment, there is evidence to suggest that consumers seek information both before and after visiting with a health care professional. Moreover, the ubiquity of DTC prescription drug advertising suggests that pharmaceutical companies are well aware of the advantages of introducing products to consumers prior to the consumer-health care provider interaction. The proposed research is concerned with how low to non-internet users access full product information prior to approaching a health care professional. As such, we need to provide this context to participants before they can respond regarding their interest and experiences within this context. We disagree that our presentation here is leading as the commenter describes, and consequently, we retain our current approach with these questions.

Likewise, in response to the second comment, we cannot inquire about privacy concerns without referencing privacy concerns. Nonetheless, we have revised Q12 to read ''How much value do you place on privacy . . .''

In response to the third comment, please see Comment 1k and our associated response.

Comment 3i (summarized): The second comment pertaining to the study questionnaire concerned definitions and terms. The commenter states, ''The questionnaires do not define certain key terms (*e.g.,* side effect, risk, serious, reference, full product information, partial information). Subjects may interpret these terms based on different standards. For example, for Q16 of the Main Study Survey, FDA may wish to provide context for what could constitute ''complete prescription-drug product information. FDA should consider providing user-friendly definitions or terms throughout the questionnaires.''

Response to Comment 3i: We appreciate the importance of ensuring uniform interpretation of terms. In cognitive interviews preceding this work, we assessed whether individuals interpret key terms similarly and made revisions where necessary. We have also considered the additional time (burden) that would be required to complete the survey if every term were defined in the pretest and main study. We have targeted to keep the current information collection to under 15 minutes per respondent. With these factors in mind, we have chosen not to provide additional definitions.

Comment 3j (summarized): The third comment pertaining to the study questionnaire concerned the sliding scale format of certain questions: ''FDA should consider replacing the sliding scale format (especially for Q1–Q3 of the Main Study Survey) with a binary or ''Yes-No-Neutral'' scheme. The sliding-scale format is at times confusing in form, inappropriately frames certain questions, and could potentially introduce error.''

Response to Comment 3j: Please see Comment 1i and our associated response.

Comment 3k: The final comments pertaining to the questionnaire were characterized by the commenter as miscellany. The first comment read, ''As previously mentioned in Section II.A, E1–E3 of the Main Study Survey should be eliminated. (reference omitted) Similarly, we would also recommend that elimination of ''Other Questions of Interest'' (Q16–Q20) of the Main Study Survey, which appear to have limited applicability to the study of adequate provision.''

Response to Comment 3k: In regards to E1–E3, please see Comment 1d and our associated response. In regards to Q16–Q20, all these items provide potentially valuable information relevant to the topic of interest, and therefore we prefer to retain them.

Comment 3l: The next comment characterized as miscellany read: ''The Study Screener introduction should not state that the survey is being conducted ''on behalf of the Food and Drug Administration'' and that study results ''will be used in the consideration of important policy decisions.'' These statements could potentially influence subjects' responses to study questions. Instead, this information might be provided at the conclusion of the study.''

Response to Comment 3l: Such statements are intended to communicate the legitimacy of the study to potential participants, and thus validate participation. Upon further consideration, we concur that these statements may potentially influence responses, and we have removed them.

Comment 3m: The next comment characterized as miscellany read: ''The Main Study Survey should include a similar question to Q5, inquiring about if a toll-free number was not available.''

Response to Comment 3m: We acknowledge the potential value of this question, but given the key objectives of the research, and concerns about participant burden, we decline to adopt this recommendation. We have targeted to keep the current information collection to under 15 minutes per respondent.

Comment 3n: Continuing under the miscellany category: ''There are several questions of the Main Study Survey (*e.g.,* questions associated with Instructions_2) that inquire about a subject's preferences regarding the provision of product labeling. We do not understand the utility of these questions. Again, FDA's regulation concerns adequate, not preferred, provision.''

Response to Comment 3n: In deciding upon potential revisions, we have considered both this commenter's views and those of another commenter (see Comment 1g) which recommend utilizing consumer preferences as an independent variable. We agree with the first commenter that consumer preferences are crucial for understanding the issues at hand as articulated in the 60-day FRN (82 FR 26934). Consequently, we have retained these questions.

Comment 3o: The next miscellany comment read: ''Certain questions, like Q4 and Q5 of the Main Study Survey, should include the option of asking a health care provider. Such a choice is part of FDA's adequate provision recommendation in the Guidance Document.''

Response to Comment 3o: Please see Comment 1j and our associated response.

Comment 3p: The next miscellany comment read: ''The ordering of the questions (web page, toll-free number, print ad) of the Main Study Survey could potentially introduce bias. FDA may want to randomize the ordering of questions (*e.g.,* Q6–Q11) to eliminate such bias.''

Response to Comment 3p: We accept this recommendation and will randomize the ordering of questions Q6 to Q11 pertaining to web page, toll-free number, and print ad.

Comment 3q: The final comment characterized as miscellany read: ''Q15 of the Main Study Survey should include an option of mailing information to the customer.''

Response to Comment 3q: Please see Comment 2d and our associated response.

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	.05 (3 minutes)	3.15
Pretest Survey	25	1	25	.25 (15 minutes)	6.25
Main Study Screener	4,990	1	4,990	.05 (3 minutes)	249.5
Main Study Survey	1,996	1	1,996	.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

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 website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Department of Health and Human Services, Food and Drug Administration (1999). ''Guidance for Industry: Consumer-Directed Broadcast Advertisements.'' Available at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125039.htm.*

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3. U.S. Department of Commerce, U.S. Census Bureau (2013). ''Computer and internet Use in the United States: Population Characteristics.'' Available at *https://www.census.gov/prod/2013pubs/p20-569.pdf.*

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6. O'Donoghue, A.C., H.W. Sullivan, K.J. Aikin, et al. (2014). ''Important Safety Information or Important Risk Information? A Question of Framing in Prescription Drug Advertisements.'' *Therapeutic Innovation and Regulatory Science,* 48: pp. 305–307. doi: 10.1177/2168479013510306
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12. Groves, R.M. (2006). ''Nonresponse Rates and Nonresponse Bias in Household Surveys.'' *Public Opinion Quarterly,* 70: pp. 646–675.
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Dated: March 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04996 Filed 3–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1837]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Transfer of a Premarket Notification

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 April 12, 2018.

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 ''Transfer of a Premarket Notification.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Transfer of a Premarket Notification

OMB Control Number 0910-New

The draft guidance ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers'' is intended to provide information on how to notify FDA of the transfer of a 510(k) clearance from one person to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date. The proposed information collection seeks to provide information to notify FDA of the transfer of a premarket notification (510(k)) clearance.

The respondents to this collection of information are 510(k) holders and parties claiming to be 510(k) holders.

In the **Federal Register** of December 22, 2014 (79 FR 76331), FDA published a 60-day notice requesting public comment on the proposed collection of information. While FDA received comments on the draft guidance document, none were related to the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Voluntary reporting of transfer of 510(k) clearance on FDA's Unified Registration and Listing System (FURLS) (outside of annual listing reporting requirement)	4,080	1	4,080	0.25	1,020
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132
Total					9,152

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

FDA estimates that 78 percent of 510(k)s are listed outside of the annual registration cycle based on numbers in the FURLS database from fiscal year 2009 through fiscal year 2014. Fiscal year 2008 was left out of this cohort as it was the first year that registrants were required to report the 510(k) number on their listings and, therefore, an unusually high number of listings were created. An average of 5,231 510(k)s have been listed each year since 2008.