

UNITED STATES FOOD & DRUG ADMINISTRATION

Accelerated Approval Disclosures on
Direct-to-Consumer Prescription Drug Websites

OMB Control No. 0910- 0872: Reinstatement with change of a currently approved collection.

SUPPORTING STATEMENT Part A – Justification:

1. Circumstances Making the Collection of Information Necessary

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 (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.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides 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 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 our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features, including content and format; and the second topic area, target populations.

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/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research>. The website includes links to the latest Federal Register notices and peer-reviewed publications produced by our office. The website

maintains information on studies we have conducted, dating back to a direct-to-consumer (DTC) survey conducted in 1999.

Pursuant to section 506(c) of the FD&C Act (21 U.S.C. 356(c)) and 21 CFR part 314, subpart H (or 21 CFR part 601, subpart E for biological products), FDA may grant accelerated approval to a drug product under section 505(c) of the FD&C Act or a biological product under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)). This pathway enables faster approval of prescription drugs intended to treat serious or life-threatening illnesses. Accelerated approval may be based on a determination that a drug product has an effect on a surrogate endpoint (for example, a blood test result) that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit (i.e., an intermediate clinical endpoint). In approving a drug under the accelerated approval pathway, the severity, rarity, or prevalence of a condition, and the availability or lack of alternative treatments, are taken into account.

The accelerated approval pathway is limited to certain products intended to treat serious or life-threatening illnesses as there can be “[u]ncertainty about whether clinical benefit will be verified and the possibility of undiscovered risks” (FDA 2014 guidance for industry entitled “Expedited Programs for Serious Conditions--Drugs and Biologics,” available at <https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf>). Sponsors are generally required to conduct post approval studies to verify and describe the predicted clinical benefit, but those confirmatory studies are not complete at the time that the accelerated approval is granted (Ref. 1). In the event that the required post-approval confirmatory studies fail to verify and describe the predicted effect or clinical benefit, a drug’s approval can be withdrawn using expedited procedures.

Under FDA regulations governing physician labeling for prescription drugs, the INDICATIONS AND USAGE section of FDA-approved prescribing information for a drug approved under accelerated approval must include not only the indication (21 CFR 201.57(c)) but also a “*succinct description of the limitations of usefulness of the drug and any uncertainty about anticipated clinical benefits...*” (21 CFR 201.57(c)(2)(i)(B)). In a guidance, FDA recommended that in addition to these required elements, the INDICATIONS AND USAGE section for drugs approved under accelerated approval should generally acknowledge that continued approval for the drug or indication may be contingent on verification and description of clinical benefit in confirmatory trials (FDA 2019 guidance for industry entitled “*Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Pathway*,” available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM390058.pdf>).

Some DTC websites have included disclosures about accelerated approval, and of those, many included similar content to that seen in the INDICATIONS AND USAGE section of approved labeling. A content analysis of DTC websites for accelerated approval products found that 21 percent of the disclosures used language directly from the approved physician

labeling, 79 percent of the disclosures used at least some medical language, but 27 percent of the websites did not include any disclosure that the products attained approval through this pathway (Ref. 2). The same analysis found that 84 percent of accelerated approval disclosures on DTC websites mentioned the approval basis, 68 percent mentioned unknown outcomes, and 47 percent mentioned confirmatory trials (Ref. 2).

OPDP recently conducted a general-population study testing the disclosure of FDA accelerated approval information on a DTC prescription drug website (OMB control number **0910-0872**—Experimental Study of an Accelerated Approval Disclosure). The study tested a control condition with no disclosure; a disclosure based on wording used in physician labeling, including more complex or technical terminology (physician-labeling disclosure); and a consumer-friendly disclosure drafted using simpler language intended to be suited for that audience (consumer-friendly disclosure). The disclosures had three elements: (1) approval basis, (2) unknown outcomes, and (3) confirmatory trials. The physician labeling disclosure was “This indication is based on response rate. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.” The consumer-friendly disclosure was “In a clinical trial, [Drug X] returned blood counts to normal. However, we currently do not know if [Drug X] helps people live longer or feel better. We continue to study [Drug X] in clinical trials to learn more about [Drug X]’s benefits.” We also varied whether the physician-labeling and consumer-friendly disclosures were presented with low or high prominence (varying the size, color, and location of the disclosure). Preliminary results related to the comprehension of the disclosures tested in that study suggest that the consumer-friendly disclosure helped participants understand information related to the drug’s accelerated approval, but that participants’ understanding was low overall.

The purpose of the current project is to replicate and extend our prior research through two studies by: (1) testing the same experimental conditions with a different study population (cancer survivors and cancer caregivers in study 1) and (2) testing additional consumer-friendly disclosures in study 2. Replication is an important part of science and, if confirmation of prior results is seen, can increase confidence in the results from our first study.

With regard to proposed Study 1, public comments for FDA’s previous accelerated approval disclosure study and other similar FDA studies have suggested conducting studies with people who have been diagnosed with the medical condition or who are caregivers to patients diagnosed with the medical condition that the fictitious drug in the study is intended to treat. Specifically, public comments on the previous study suggested enrolling participants who have been diagnosed with cancer (i.e., cancer survivors) or people who have cared for loved ones with cancer (i.e., cancer caregivers). Because a number of oncology products are granted accelerated approval, cancer survivors and cancer caregivers are more likely to seek out or be exposed to promotion for accelerated approval products than the general population. They may also be more familiar with cancer-related terms and concepts than the general population. Study 1 will involve cancer survivors and cancer caregivers, a different population than our prior study.

With regard to study 2, public comments on the original study (Docket No. FDA-2018-N-3138) expressed concern that over-disclosure could dissuade consumers from considering accelerated approval products. One public comment specifically suggested removing the “unknown outcomes” element in the consumer-friendly and physician-labeling disclosures. Based on these comments, in study 2, we propose testing four versions of the consumer-friendly disclosure: the “three element” version of the consumer-friendly disclosure as well as three other consumer-friendly disclosures that vary with respect to which of these three elements they address. This will allow us to evaluate the impact on participants’ comprehension of the disclosure and perception of the fictitious drug when they view a disclosure with only the approval basis, the approval basis plus information about the unknown outcomes, the approval basis plus information about confirmatory trials, and finally the approval basis plus information about both the unknown outcomes and confirmatory trials.

2. Purpose and Use of the Information Collection

Pretesting will be used to refine the study materials and procedures. We propose to test accelerated approval disclosures on a prescription drug website with cancer survivors and caregivers. In Study 1, we will vary the presence, prominence (low or high), and wording (physician-labeling vs. consumer-friendly) of an accelerated approval disclosure. In Study 2, we will vary the information included in a high-prominence consumer-friendly disclosure (approval basis, approval basis + unknown outcomes, approval basis + confirmatory trials, approval basis + unknown outcomes + confirmatory trials). Part of FDA’s public health mission is to ensure the safe use of prescription drugs; therefore, it is important to communicate the benefits and risks of prescription drugs to consumers as clearly and usefully as possible.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. One hundred percent (100%) of participants in the pretests and main studies will self-administer the survey via the Internet, which will record responses and provide appropriate probes when needed. In addition to its use in data collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time basis for each participant, and by keeping surveys to less than 20 minutes.

4. Efforts to Identify Duplication and Use of Similar Information

We conducted a literature search to identify duplication and use of similar information. The available literature yields little information on this topic.

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small businesses or other small entities. The collection of information involves individuals, not small businesses.

6. Consequences of Collecting the Information Less Frequently

The proposed data collection is one-time only. There are no plans for successive data collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of June 11, 2021 (86 FR 31323), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one submission that was PRA-related. Within the submission, FDA received multiple comments that the Agency has addressed below. For brevity, some public comments are paraphrased and therefore may not reflect the exact language used by the commenter. We assure the commenter that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: DTC = direct-to-consumer; HCP = healthcare professional; FDA and “the Agency” = Food and Drug Administration; OPDP = FDA’s Office of Prescription Drug Promotion.

(Comment 1) Comment one expressed concern that this research will duplicate a prior FDA study and lack practical utility. The comment asserts that while the 60-day PRA notice provided a statement of “*preliminary results*” of the prior study, full study materials, results, and conclusions of that prior study have not been published. It requested that the results of the prior study be published before this study is conducted, suggesting that, without publishing the results of the prior study, FDA has not addressed how the new proposed research would address open research issues or limitations of the prior study.

(Response 1) Contrary to the comment’s suggestion, we do not plan to duplicate the prior research, although there often is value in that undertaking. Rather, the present research seeks to replicate the previous study in a new patient population and extend the previous study by testing additional versions of the disclosure. The new research is directly informed by open research issues and limitations raised in the public comments from the previous study. The proposed studies will be conducted in a new cancer survivor and caregiver sample, which differs from the sample in the prior study, which was conducted with a general population sample. As noted above, cancer survivors and cancer caregivers are more likely to seek out or be exposed to promotion for accelerated approval products than the general population. They may also be more familiar with cancer-related terms and concepts than the general population. Replications in different study samples are often proposed. Indeed, at the time of the previously proposed study (0910-0872 Study), public comments suggested conducting the study with cancer survivors who had used oncology products. Also, in response to public comments on the prior study design, we will extend the prior research by testing additional versions of the disclosure. This study therefore has

practical utility to expand our information regarding website disclosures regarding accelerated approval drugs, both by extending to additional versions of the disclosure related to our overall questions, and to determine if results are consistent with those of the earlier study. We intend to publish the results of the current study as well as the prior study.

(Comment 2) Comment two stated that establishing mandates to unduly emphasize a product's accelerated approval status could deter appropriate usage and lead to misconception and confusion among patients. The comment specifically referred to one statement in the disclosure, "we currently do not know if [Drug X] helps people live longer or feel better" to suggest that the disclosure may oversimplify the benefits of the product and thus discourage patients from getting needed treatments. The comment later stated that the availability of FDA prior review of promotional pieces for accelerated approval means there is less need to prescribe specific overarching new rules for disclosures because FDA can consider disclosures on a case-by-case basis.

(Response 2) This notice proposes a data collection for research purposes and does not establish a mandate or propose a new rule. Instead, it proposes research that may inform FDA and stakeholder thinking on accelerated approval product disclosures in DTC promotional materials. The research will specifically investigate patient understanding of and reaction to the disclosure language about a product's accelerated approval status. Study 2 was designed in direct response to public comment on the previously proposed study (0910-0872 Study) raising concerns about over-disclosure. Study 2 will test several conditions based on disclosures found in the marketplace, two of which will not include the statement "we currently do not know if [Drug X] helps people live longer or feel better" (see Table 2).

(Comment 3) Comment three suggested that DTC promotional materials are not the best venue for providing information about prescription drugs, given the role of healthcare professionals (HCPs) in discussing and prescribing treatments. Based on this, the comment suggested modifying the study to focus on prescriber-patient interactions rather than DTC promotion by including a component to evaluate patient understanding of accelerated approval after consultation with a prescriber.

(Response 3) We agree that the prescriber-patient interaction is important. Consumers often wish to participate in shared decision-making with HCPs when selecting prescription drugs and may request specific prescription drugs from their HCPs based on promotions they have seen in the marketplace. Because information consumers receive through DTC prescription drug promotion can impact these requests, it is important to investigate how the information in prescription drug promotional pieces impacts consumer attention, understanding, and perceptions.

(Comment 4) Comment four suggested conducting qualitative interviews or a blended approach of qualitative and quantitative research rather than a quantitative study. In addition, the comment recommended that the interviews include showing the stimuli to participants, asking them questions about the stimuli, and then showing them the stimuli again so they can read the disclosure and have it in front of them while answering questions.

(Response 4) We plan to conduct nine one-hour interviews to cognitively test the stimuli and questionnaire. These interviews will allow for in-depth discussions with participants, and the findings from the interviews will help improve the study materials. In addition, the questionnaire follows the approach the commenter suggested: participants view the stimuli and answer questions, then see the disclosure again for Questions 16 and 17. This will allow us to test what participants remember and understand after visiting a website for an accelerated approval product, as well as their understanding of the disclosure language while it is in front of them. We will use the cognitive interviews and pretesting to determine whether participants will be able to view the stimuli when answering more of the questions in study 2.

(Comment 5) Comment five suggested screening for patients who have a personal experience with Acute Lymphoblastic Leukemia (ALL) (the cancer referred to in the study stimuli) and who have received accelerated approval products from their prescribers.

(Response 5) We will ask participants about the type of cancer and type of treatment(s) they or their loved one had. In this study, we will not ask if they used an accelerated approval product, because participants are unlikely to know this information. In the pretest, we will examine the feasibility of quotas aiming for a broad range of cancer diagnoses in the sample, including blood cancers like ALL. We will also use the pretest to examine the feasibility of restricting recruitment to cancer survivors, and caregivers for cancer survivors, who have received a systemic therapy (e.g., chemotherapy, hormonal therapy, immune therapy, targeted therapy).

(Comment 6) Comment six questioned why caregivers are included in the sample and noted that it is unclear what direct role caregivers have in drug prescribing decisions.

(Response 6) We included caregivers in part because previous public comments have encouraged FDA to include caregivers in DTC research (for example, Docket No. FDA-2019-N-2313). Prior research also supports the inclusion of caregivers in a study on consumer understanding of health information on a DTC prescription drug website. Surveys have found that many people searching for health information online are doing so on behalf of someone else (e.g., Refs. 3, 4). These “*surrogate seekers*” are more likely to be caregivers (Refs. 6, 7). In addition, caregivers are a known audience for DTC prescription drug websites. For instance, to enter some DTC prescription drug websites, people must select whether they are “*a patient or caregiver*” or a “*healthcare provider.*” Other DTC prescription drug websites specifically include information for caregivers.

(Comment 7) Comment seven stated that information on the proposed number of study participants was not observed in the 60-day notice, and suggested a minimum of 200-300 participants, with 400-500 being optimal. The comment also suggested considering quotas for demographic variables such as age and education to allow for subgroup analyses.

(Response 7) The proposed number of participants can be found in Table 3 of this notice. Specifically, we propose 630 participants in study 1 and 400 participants in study 2. We

have not proposed any planned subgroup analyses; however, we will have quotas for age, sex, race, and education to ensure a diverse sample.

(Comment 8) Comment eight suggested that, for study participants to understand the disclosures being tested, they must first be told that the drug received an accelerated approval; accelerated approval is based on an FDA determination that the drug is likely to provide meaningful therapeutic benefits to patients over existing treatments and likely addresses a significant unmet medical need; and the drug is approved based on adequate and well-controlled clinical trial(s) on surrogate or intermediate clinical endpoints that are reasonably likely to predict clinical benefit, but that the drug's effects need to be verified with additional data.

(Response 8) Consumers encountering DTC websites for accelerated approval products would not have this background information, so giving this information to participants would defeat the purpose of testing what perceptions these consumers form from the website disclosures.

(Comment 9) Comment nine suggested testing an alternative disclosure that would include background information about accelerated approval, described in the last comment, along with the disclosures currently proposed to be tested.

(Response 9) We acknowledge that we cannot test all possible disclosure language. We based the disclosures we plan to test on FDA-approved labeling for accelerated approval products and on disclosures found in the marketplace (Ref. 2). We encourage research on alternate disclosures.

(Comment 10) Comment ten stated that Question 9, which asks participants about their understanding of the confirmatory trials concept from the disclosure, is unclear and suggested deleting the question or refining the answer options.

(Response 10) We will delete this question in study 1. As noted in the questionnaire, we plan to test two versions of Question 9 in the study 2 pretests. We will refine or delete this question in study 2 based on findings from the cognitive interviews and pretesting.

(Comment 11) Comment eleven suggested clarifying "*quality of life*" in consumer-friendly terms and defining specific quality of life measures in Question 10.

(Response 11) Question 10 does not refer to a specific quality of life measure. In a recent survey of metastatic breast cancer patients, most participants (89%) reported understanding the term "quality of life" (Ref. 6). We expect participants in this study will also understand the term "quality of life" without further clarification, but we will cognitively test and pretest the question to determine if any clarification is needed.

(Comment 12) Comment twelve stated that Questions 11 and 12, which ask about risk-benefit tradeoffs, are redundant and too general, not sufficient to study over-disclosure, and that these questions typically require consumers and HCPs to arrive at the answer together.

The comment suggested that instead, the study ask whether, based on information on the website, participants intend to ask to take the drug, not ask to take the drug, speak with a doctor about whether the drug is right for them, or none of these.

(Response 12) We disagree that consumers do not form their own perceptions about risk-benefits tradeoffs after seeing DTC promotional materials and prior to any discussion with a HCP. Thus, we plan to ask participants about their perceptions of the risk-benefit tradeoff through Question 11, which is a common and validated item in DTC research. We will delete Question 12 to reduce redundancy (Ref. 7). We will also ask about behavioral intentions. Participants do not necessarily have the type of cancer the fictitious drug is indicated to treat; therefore, it would not make sense to ask them about their intentions to ask about the drug for themselves. Instead, similar to what the comment requests, Question 14 asks whether participants would recommend that a loved one diagnosed with the cancer that the fictitious drug is indicated to treat ask a doctor about taking the drug.

(Comment 13) Comment thirteen recommended deleting Question 13, which asks about the drug side effects, because it is too general and does not test the disclosure.

(Response 13) Question 13 is intended to measure the effect of the disclosure on participants' risk perceptions. We will assess this question in cognitive interviews and pretesting and will refine it if needed.

(Comment 14) Comment fourteen suggested deleting or refining Question 14, which asks participants to select all actions they would suggest a loved one take (i.e., asking a doctor about taking the drug, asking about the drug's risks, its benefits, and its FDA approval). The comment stated that because all options may be applicable, it is unclear how the item would yield meaningful data for this research.

(Response 14) We revised Question 14 from "*select all that apply*" to separate "yes/no" items for each action. We will assess the utility of asking about each of these actions in cognitive interviews and pretesting. At a minimum, we will retain the "taking [Drug X]" item to assess intentions as discussed in a previous comment.

(Comment 15) Comment fifteen suggested that participants are unlikely to have the information to provide yes or no answers to Question 19, which asks participants whether they used any accelerated approval products for their own cancer, and questioned why it is important for a patient to understand the regulatory approval pathway for a drug, as opposed to information about the drug's safety and effectiveness for use in discussion with an HCP.

(Response 15) We agree that participants are unlikely to know whether the product they used was an accelerated approval product and will delete this question in this study.

(Comment 16) Comment sixteen suggested deleting Question 21, which asks how similar the study website was to other DTC websites the participant has seen, because it seems vague and not directly related to the research question.

(Response 16) Question 21 is for pretesting purposes only and is intended to assess the quality of the stimuli. We will keep Question 21 for pretesting but will not ask it in the main studies.

External Reviewers

In addition to public comment, OPDP sent materials and received comments from one individual for external peer review in 2021. This individual is:

Arif Kamal, MD. Associate Professor of Medicine and Associate Professor in Population Health Sciences, Duke University School of Medicine

9. Explanation of Any Payment or Gift to Respondents

Participants will receive points equivalent to approximately \$10 at completion of the study. The incentive amount is determined using a structured incentive scheme that reflects the length of the survey (i.e., 20 minutes) and the percentage (i.e., incidence rate) of the study target population present in the panel. The incentive options allow panelists to redeem from a large range of gift cards, points programs, and partner products or services. Participants are compensated only for surveys that they qualify for and complete.

Following OMB's "*Guidance on Agency and Statistical Information Collections*," (January 2006), we offer the following justification for our use of this remuneration.

Burden on the respondent: As participants often have competing demands for their time and recently even more limited time due to pandemic challenges (e.g., lack of or limited childcare, increase in home or caregiving responsibilities), incentives are used to encourage participation in research. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that recognizes the time burden placed on participants, encourages their cooperation, and conveys appreciation for contributing to this important study. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort that they expend to participate (Refs. 9-10). Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation, as well as to provide enough motivation for them to participate in the study rather than another activity.

Data quality/Improved coverage of specialized respondents, rare groups, or minority populations: This data collection involves recruiting participants with a cancer diagnosis or caregivers of patients with a cancer diagnosis. Previous research suggests that providing incentives may help reduce sampling bias by increasing rates among individuals who are typically less likely to participate in research. Furthermore, there is some evidence that using incentives can reduce nonresponse bias in some situations by bringing in a more representative set of respondents. High nonresponse can risk our ability to achieve the target number of completes for the study. Therefore, it is critical to maximize the number who respond to ensure sufficient power to determine meaningful differences by experimental conditions. An underpowered study increases the chance for Type II error, which may result

in erroneously rejecting hypothesized models (Ref. 11). The use of modest incentives is expected to enhance survey response rates and reduce nonresponse bias. In fact, monetary incentives have been found to increase initial response rates, convert refusals, and reduce subsequent attrition (Refs. 12-14).

Reduced survey costs: If the incentive is not adequate, participants may not agree to participate in the study, or they may agree to participate but then drop out early resulting in an incomplete survey. Low participation may result in inadequate data collection and can cause a difficult and lengthy recruitment process that in turn, can cause delays in launching the research, both of which lead to increased costs.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR does not collect personally identifiable information (PII).

While PII is collected at the subcontractor website (i.e., name, phone number, email address) it is collected so the individual can be compensated for their participation in various surveys. The individuals who provide their PII are voluntarily signing up to participate in surveys from many companies, not just for the FDA. They are considered an existing pool of participants. Information is not collected on behalf of the FDA. This ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). Confidentiality of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The consent form is in Appendix A and the complete list of questions is available in Appendices B (screener) and C (questionnaire).

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Table 1. Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest 1 and 2 screener	3,600	1	3,600	0.08 (5 minutes)	288
Study 1 and 2 screener	20,600	1	20,600	0.08 (5 minutes)	1,648
Pretest 1	100	1	100	0.33 (20 minutes)	33
Main Study 1	630	1	630	0.33 (20 minutes)	208
Pretest 2	80	1	80	.33 (20 minutes)	26
Main Study 2	400	1	400	0.33 (20 minutes)	132
Total	25,410				2,335

These estimates are based on FDA's and the contractor's experience with previous consumer studies.

12b. Annualized Cost Burden Estimate

There are no capital costs or operating and maintenance costs to respondents of the collection of information. As a voluntary collection being administered at FDA's expense, we estimate no annualized cost to respondents.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for the collection of data is \$270,000. This includes the costs paid to the contractors to program the study, draw the sample, collect the data, and create a database of the results. The cost also includes FDA staff time to design and manage the study, to analyze the data, and to draft a report. The contract was awarded as a result of competition. Specific cost information other than the award amount is proprietary to the contractor and is not public information.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for experimental data, such as descriptive statistics, analysis of variance, and regression models, will be used to analyze the data. See Section B for detailed information on the design, hypotheses, and analysis plan. The agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations at trade and academic conferences, publications, articles, and Internet posting.

Table 2. – Project Time Schedule

Task	Estimated Number of Weeks after OMB Approval
Pretest data collected	12 weeks
Main study data collected	48 weeks
Data analysis completed	96 weeks

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

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