

United States Food and Drug Administration

Data to Support Cross-Center Collaboration for Social Behavioral Sciences Associated with  
Disease Prevention and Treatment and the Safety, Efficacy, and Usage of FDA regulated  
Products

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

**Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection is intended to support research conducted by, or on behalf of, the Food and Drug Administration (FDA or we). Understanding consumers, patients, caregivers, academic/scientific experts and public health professionals' perceptions and behaviors plays an important role in improving FDA's decision-making processes and communications impacting various stakeholders. To better understand consumers, patient, caregivers, academic/scientific experts and public health professionals' perceptions and behaviors regarding various issues and outcomes associated the disease prevention, treatment, and the safety, efficacy, and usage of products overseen by the agency, FDA is requesting approval of this generic information collection request.

Among the general provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA, or the Act), FDA is charged with promoting the public health through regulatory oversight as well as clinical research. Specifically, section 1003 of the Act (21 U.S.C. 393(d)(2)(C) and (D)) provides that the Commissioner of Food and Drugs shall be responsible for “*research relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out this chapter; [and]conducting educational and public information programs relating to the responsibilities of the [FDA].*” Accordingly, FDA is seeking to conduct qualitative and quantitative research studies. These studies may consist of small groups, focus groups/town halls, individual in-depth interviews, and surveys relating to the evaluation of disease prevention and treatment and the safety, efficacy, and usage of FDA-regulated products and communication messages and strategies, and other materials directed to consumers, patients, caregivers, and public health professionals (e.g., evaluate the effectiveness of communication messages, educational materials, and interventions directed toward promoting and protecting human and animal health).

The qualitative and quantitative research anticipated by FDA aligns with agency objectives. For example, among eight scientific priorities is the goal to “*strengthen social and behavioral science to promote informed decision-making about FDA-regulated products.*”<sup>1</sup> Such research helps the agency meet this goal by:

---

<sup>1</sup> Food and Drug Administration. About Science & Research at FDA. Silver Spring, MD: U.S. Department of Health and Human Services (HHS), July 2013. Accessed from <https://www.fda.gov/media/81109/download>

- identifying gaps in the target audience’s knowledge regarding FDA-regulated products, and outcomes associated the disease prevention, treatment;
- reaching diverse audiences;
- assessing target audiences’ knowledge, perceptions and behaviors about FDA-regulated products;
- evaluating the effectiveness of FDA’s communications;
- exploring ways to incorporate patient input into decision-making;
- leveraging real-world data;
- evaluating outcomes; and
- integrating the knowledge gained from the research into agency communications, activities, interventions and programs.

## 2. Purpose and Use of the Information

FDA plans to use the data collected under this generic clearance to inform its FDA-regulated products educational, interventions, outcomes, and regulatory science programs, materials and resources and disease prevention and treatment. FDA expects the data to guide the formulation of the agency’s educational and public health objectives on FDA-regulated products and support development of subsequent research efforts. The data will not be used to make policy or regulatory decisions. Rather, these data will: (1) inform FDA’s public education campaigns and other educational/interventional materials directed to informing consumers, patients, caregivers, and public health professionals about human and animal health issues; and (2) provide information on the safety, efficacy and usage of FDA-regulated products.

## 3. Use of Information Technology and Burden Reduction

The information will be collected through focus groups, individual in-depth interviews, and surveys and experimental studies depending upon the target participants, expectations about whether the information will be evaluated in an individual or group context, and the need to present (for example) FDA educational and/or interventional materials. Because online methods for collecting data can minimize the burden on respondents, when possible, FDA will make use of web-based data collection methods, including data collected through mobile devices.

## 4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of a similar data collection generic clearance. As each new research study is developed, FDA will review existing literature and databases to identify duplicative studies (e.g., pretesting reports on existing educational and intervention materials). Also, on an ongoing basis, FDA engages with other agencies within the Department of Health and Human Services to determine whether existing research may be coordinated to avoid duplicative data collection.

## 5. Impact on Small Businesses or Other Small Entities

FDA expects most respondents will be general population individuals. However, FDA’s communication and educational research frequently requires involvement by public health

professionals (e.g., physicians, dentists, pharmacists, veterinarians, dietitians, nurses). Particularly when research with this audience is required, FDA works through contractors and cooperative agreement grantees and food and cosmetics, medical, veterinary, academic institutions, other federal agencies and other professional societies to obtain the necessary participants. In doing so, we will carefully plan these efforts to minimize the burden on small healthcare provider practices and any other small entities.

#### 6. Consequence of Collecting the Information Less Frequently

FDA uses a variety of techniques to evaluate knowledge of and attitudes toward FDA functions and programs; to convey messages, information, and interventional materials to inform and educate the public about appropriate benefits and risks associated with the use of regulated products; or implement other programs to improve the public health. To perform these duties effectively, we rely on research studies to obtain the needed evidence and advance our efforts in this area. Without ongoing data collections, FDA would be at a disadvantage whenever public health concerns emerge. In addition, without these data collections, the agency may devote finite resources to developing and disseminating public health information and campaigns or implementing programs that may ultimately be ineffective.

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

The information collection complies with the guidelines found in 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of 7/7/2020 (85 FR 40655). Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

#### 9. Explanation of Any Payment or Gift to Respondents

When appropriate, a cash stipend or other gift may be offered to the research participants as a token of appreciation for their time and effort in the project. Amounts and justifications for any payment or gift will be determined on an individual project basis and will be supported by research indicating that payments or gifts are useful for the target audience. This information will be included in the statement provided to OMB for each information collection to be conducted under this generic authorization.

#### 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 collects personally identifiable information (PII). The PII submitted is name, telephone number, age, race/ethnicity, and geographical location. Personally identifiable information shall be limited to data that may be required in the process of respondent enrollment. Information is collected for individual interviews, small group, and focus group methodologies. Personally identifiable information will be accessible only to those who have a business need and will not be linked to interview data or the individual. Neither FDA employees nor any federal employee of any other agency will have access to personally identifiable information. Through appropriate instruction, FDA minimized the PII collected to protect the privacy of the individuals.

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)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

#### 11. Justification for Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of a target audience that FDA is trying to reach. Therefore, a portion of respondents could consider questions about race, ethnicity, sex, gender, or other demographic characteristics to be sensitive. When relevant to the study, all information collection on race or ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997. Respondents will be informed that this is being done to make sure that FDA addresses the demographic population for whom its messages, intervention materials and research are intended.

Additionally, because these data collections may be concerned with preventing drug misuse, drug abuse, and other risky behaviors exhibited by consumers of FDA-regulated products, some projects may involve asking questions about (or discussing) how one perceives his or her personal risk for serious illness. While this information is needed to gain a better understanding of the target audience so that the research, messages, strategies, and materials designed will be appropriate, some respondents may consider these questions to be sensitive. The agency is mindful that such questions will require sensitivity in how they are worded and approached. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, as respondents have grown more comfortable with the interview and more at ease with the interviewer/moderator. As noted in Question 10, participants will be informed prior to their participation about the nature of the research and the voluntary nature of their participation.

Finally, raw data from data collections that may include sensitive information (for example, screening questionnaires) will not be retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that could be used to identify participants.

## 12. Estimates of Annualized Burden Hours and Costs

### 12a. Annualized Hour Burden Estimate

FDA estimates the total reporting burden for the information collection to be 9,198 hours. Respondents to the collection are primarily general population individuals, as well as consumers of certain products, patients and their caregivers, academic/scientific experts, individuals from specific target labor groups such as physicians, medical specialists, pharmacists, dentists, nurses, veterinarians, dietitians and other public health professionals. Proposed data collection methodologies are described in more detail in the agency's Supporting Statement –Part B.

| Table 1. Estimated Annual Reporting Burden <sup>1</sup> |                    |                                 |                        |                             |             |
|---|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Activity  | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average burden per response | Total Hours |
| Interviews/ Surveys/ Focus Groups                       | 2,520              | 14.6                            | 36,792                 | 0.25 (15 mins.)             | 9,198       |

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

### 12b. Annualized Cost Burden Estimate

We estimate no annualized cost to respondents for the information collection. FDA notes, however, the estimated salaries of some of the target labor groups identified above as a possible deterrent to the willingness of these respondents to voluntarily participate in the information collection. Accordingly, and as discussed more fully in Question 9 of this supporting statement, amounts and justifications for any payments or gifts associated with the information collection will be determined on an individual project basis and will be supported by research indicating that payments or gifts are useful for the target audience.

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

Respondents will not incur any costs for participating in the information collection.

## 14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal Government is \$2,329,109. This figure includes an annual cap of \$2,180,000 in contractor or cooperative agreement grantee costs, 25% of 5 full-time employees (FTEs) (522 hours per FTE) annually (using a salary cost of \$57.13 per hour) and is rounded to the nearest whole number. [ $\$2,180,000 + (57.13 \times (522 \times 5))$ ].

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The process for developing the analytical plan for social and behavioral research is similar to that used in any formal evaluation. The staff will discuss the objectives with the individuals (e.g., contractors, cooperative agreement grantees) responsible for developing the materials, determine the analytic questions to be addressed, and then prepare the procedures, instruments, and data analysis plan. The analyses conducted for each project will be determined by the objectives, the messages being tested, or the questions being asked, and the target audience. Specifics of the analyses cannot be determined until the messages to be tested are prepared.

Techniques include primarily qualitative analyses (for example, content analysis for individual in-depth interviews), although some results, such as those from self-administered surveys, are summarized quantitatively using descriptive statistics. In cases where quantitative data is collected, descriptive statistics—including percentages, cross tabulations, and averages—will be calculated and presented, along with demographic descriptions of study participants. Information collected from study participants may be subjected to subgroup analyses to uncover potential differences among key groups (defined by gender, age, race/ethnicity, etc.). Statistical analyses may be conducted using cross-tabulation procedures with categorical variables (e.g., chi-square) and between-group procedures with continuous variables (e.g., ANOVA and t tests). Parametric statistical tests will be used in the case of sufficient sample sizes, normal distributions, and continuous or interval data; non-parametric procedures will be used otherwise. All analyses will be done in the context of understanding the limitations of the sampling and data collection methods.

While the primary purpose of this data collection is to gather information on FDA-regulated products via social and behavioral research to support the agency's communications and regulatory science initiatives, FDA will make results available to a variety of health program planners at government agencies, voluntary organizations, public health professional organizations, and medical and veterinary institutions. In addition, FDA, contractors and cooperative agreement grantees may present the findings at relevant professional association meetings or publish results in professional journals. In any findings presented at professional association meetings or in professional journals, FDA will state the limitations of the data based on the sampling and data collection methods used.

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

The OMB expiration date will be displayed on the collection instruments.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.