United States Food and Drug Administration

Generic Clearance: Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910-0847

SUPPORTING STATEMENT

Terms of Clearance**:** None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports research conducted by the Food and Drug Administration (FDA or we). Understanding patients, consumers, and health care professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-making processes and communications affecting various stakeholders. To better understand patients, consumers, and health care professionals' perceptions and behaviors regarding various issues and patient reported outcomes associated with the safety and administration of drug products overseen by the Agency, FDA requests approval of this generic information collection request (ICR).

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 FFDCA (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 seeks to conduct research consisting of focus groups, interviews, and self-administered surveys relating to the formative pretesting of drug communication messages and other materials directed to patients and health care professionals, and designed to help develop communication messages, educational materials, and interventions directed toward promoting and protecting the public health.

The qualitative and quantitative research anticipated by FDA aligns with Agency objectives. Among eight scientific priorities is our goal to *"strengthen social and behavioral science to promote informed decision-making about FDA-regulated products."*[1] Such research plays a large role in meeting this goal by serving to identify gaps in key areas of knowledge and in reaching diverse audiences; assessing knowledge and perceptions about drug-related topics with specific target audiences; evaluating the effectiveness of FDA's risk communications; patient

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1[1] Food and Drug Administration. About Science & Research at FDA. Silver Spring, MD: U.S. Department of Health and Human Services (HHS), May 2022.

reported outcomes; and integrating knowledge from research and evaluation into Agency programs.

2. Purpose and Use of the Information Collection

FDA plans to use the data collected under this generic clearance to inform its drug, educational, health outcome interventions, patient reported outcomes, and regulatory science programs. FDA expects the data to guide the formulation of its educational and public health objectives on drugs and support development of subsequent research efforts. The data will not be used for the purposes of making policy or regulatory decisions. Rather, FDA's public education campaigns and other educational/interventional materials are directed to informing patients and health care professionals regarding matters impacting the public health.

FDA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;
- The collections are noncontroversial;
- Personally identifiable information (PII) is collected only to the extent necessary[2] and is not retained;
- —Information gathered will not be used for substantially informing influential policy decisions;[3] and-

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (e.g., a copy of the interview or moderator guide, screening questionnaire).

This collection has been previously used by the agency to gather information about the public's knowledge of health-related topics and to test messaging on these topics. This collection has also been used to conduct a survey of healthcare facilities, assessing their use of safety measures in the operating room. This collection was also used for a study looking at how dosing errors occur when parents give liquid medicines. This type of information assists FDA in understanding how errors occur and how they might be prevented.

3. Use of Improved Information Technology and Burden Reduction

2 For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.
3As defined in OMB, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

The information will be collected through one-on-one telephone, in-person or online/ virtual interviews, focus groups, individual interviews, or self-administered surveys, depending upon the target audience being questioned, expectations about whether the information will be evaluated in an individual or group context, and the need to present educational and or interventional materials. Because we find that using computer-assisted information technology methods to administer data collection helps minimize burden on respondents, wherever possible, FDA will make use of web-based data collection methods, including data collected through mobile devices. We estimate that 85% of responses will be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of any similar data collection. As each new research study is developed, FDA will review existing literature and databases, including pretesting reports on existing educational and intervention materials. FDA will also consult with outside experts to evaluate available information on similar educational interventions with comparable audiences. Also, on an ongoing basis we engage with other Offices and Centers within FDA, as well as 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 private individuals. However, communication and educational research being considered will frequently include healthcare workers in the target population. When research with this audience is required, FDA works through established medical and professional societies and research contractors to gain access and obtain the necessary participants. Our research efforts will be carefully planned to minimize the burden on healthcare provider practices and any other small entities.

6. Consequences of Collecting the Information Less Frequently

FDA utilizes a variety of communication techniques to convey messages, information, and interventional materials to inform and educate the public about appropriate benefits and risks associated with drug use. To communicate effectively, we rely on current research and must therefore continue to advance our efforts in this area. Without ongoing testing and data collections, FDA would be at a significant disadvantage. For example, both data collection and message testing allow FDA to better understand potential emerging public health threats and medication safety issues, and to develop public health campaigns that will result in effective messaging.

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 August 10, 2022 (87 FR 48665). Three comments were received. The first comment was not relevant to the information collection. The second comment requested that participants be informed that participation is voluntary and can withdraw at any time. Prior to beginning the interview and several times throughout, participants are informed that their participation is voluntary and that they can withdraw at any time. We believe no further clarification to the survey instruments are necessary. The third comment expressed concerns regarding the potential misuse of information from the collection. We have previously outlined the scope and purpose of the information collection, and we do not believe further elaboration is necessary. Further, as outlined in this supporting statement, all information collections must be non-controversial, must not retain PII, and "will not be used for substantially informing influential policy decisions."

9. Explanation of Any Payment or Gift to Respondents

Where appropriate, a cash stipend or other gift may be offered to the research participants as a token of appreciation for a respondent's time and interest in the project, but the use of incentives will not be the default practice. Amounts and justifications for any incentives will be determined on an individual project basis and will be supported by research indicating that incentives are useful for the particular population participating in the information collection. 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 will collect personally identifiable information (PII). The PII collected typically consists of name and contact information. PII is collected on behalf of the FDA by a contractor or vendor who conducts surveys. PII is collected to support social and behavioral research conducted by the FDA. Information collected by the vendor or contractor will be summarized into aggregate form, sent in aggregate to FDA (no PII will be included), and destroyed after the study or interview has been completed. Collected PII is used to notify potential respondents of their selection and includes name and contact information. All information collected will be kept secure by the vendor or contractor. FDA and any vendor or contractor will disclose identifiable information only to the extent authorized by the individual or required by law. Contractors or vendors maintaining information will destroy it in accordance with applicable records retention and other requirements, per contract terms, after the aggregate information has been provided to FDA and the survey has been completed. In keeping with Institutional Review Board (IRB)/Human Subjects Research protocols, the FDA clearance process ensures that study data is appropriately secured (e.g., housed on the contractor's servers, password protected, separate storage areas for each study access controlled).

FDA determined that although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor does not use name or any other personal identifier to retrieve records from the information collected.

11. Justification for Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of a target population that FDA is trying to reach. A portion, therefore, of respondents could consider questions about race, ethnicity, or other demographic characteristics to be sensitive. Where relevant to the information collection, all information collection on race/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 speaks with the demographic population for whom its messages and intervention materials are intended.

Additionally, because these data collections may be concerned with the prevention of drug risks and associated behaviors, some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. While this information is needed to gain a better understanding of the target audience so that the messages, strategies, and materials designed will be appropriate, it may be considered by some respondents to be sensitive. We are mindful that such questions will require some 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.

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 can be used for retrieval.

Information provided by respondents will be kept private and anonymous, except as otherwise required by law. This will be communicated to respondents by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to focus groups or telephone interviews, and consent forms as appropriate. Respondents also will be advised of the following: the nature of the activity; the intended purpose and use of the data collected; FDA sponsorship and the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any individual questions.

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 27,368 hours. Respondents to the collection are primarily private individuals, including those from specific target labor groups such as primary care physicians, medical specialists, and other healthcare professionals. Proposed data collection methodologies are described in more detail in FDA's Supporting Statement – Part B.

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Interviews and Surveys	109,470	1	109,470	0.25 (15 minutes)	27,368

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

12b. Annualized Cost Burden Estimate

For healthcare professionals, surveys or interviews would likely be conducted during business hours as part of the duties assigned. This is typical of many quality improvement projects in healthcare settings. The estimated annualized reporting costs to respondents (physicians, nurses and patients) in this information collection for 27,368 hours is $3,361,404.56. According to the U.S. Department of Labor, Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for the United States (located at https://www.bls.gov/oes/current/oes_nat.htm), the average industry wage rate is $116.44 per hour for physicians, $39.78 per hour for nurses, and $28.01 for patients. We have doubled this wage rate to account for benefits and overhead, yielding an hourly wage rate of $232.88 for physicians, $79.56 for nurses and $56.02 for patients.

[Physicians time (9,123 hours x $232.88 = $2,124,564.24) + nurses time (9,123 hours x $79.56 = $725,825.88) + patients time (9,122 hours x $56.02 = $511,014.44) = $3,361,404.56.]

Table 2.—Estimated Annual Cost Burden

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Physicians	9,123	$232.88	$2,124,564.24
Nurses	9,123	$79.56	$725,825.88
Patients	9,122	$56.02	$511,014.44
	27,368		$3,361,404.56

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

No capital or start-up costs will be incurred by respondents as a result of the information collection request.

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 costs; 25 percent of 25 full-time equivalents (2,610 hours) annually (using a salary cost of $57.13 per hour); and is rounded to the nearest whole number. [$2,180,000 + (57.13 x 2,610)].

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, our burden estimate for this information collection reflects an overall increase of 35,886 responses with a corresponding increase of 8,972 hours. We attribute this adjustment to an increase in funding and need to obtain additional information in specific areas, particularly substance abuse (for example, opioids and stimulants) and COVID-19. In addition, we attribute the increase in the number of respondents (from 7,298 to 109,470) and decrease in the number of responses per respondent from 15 to 1 to an inadvertent administrative error reflected in the 60-day notice. These changes, however, do not impact the estimated total annual responses or burden hours.

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) 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 audience for the messages. 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 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 respondents.

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 of the 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 drug products via social and behavioral research to support FDA communications and regulatory science initiatives, FDA will make results available to a variety of health program planners at Government agencies, voluntary organizations, health professional organizations, and medical institutions. In addition, FDA and contractors 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 Submission

There are no exceptions to the certification.