U.S. Food & Drug Administration

Data To Support Social and Behavioral Research
as Used by FDA

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 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 decisionmaking processes and communications impacting 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 is requesting approval of this generic information collection request.

Among the general provisions of the act, FDA is charged with promoting the public health through regulatory oversight as well as clinical research. Specifically, section 1003 of the Federal Food, Drug, and Cosmetic Act (FFDCA, or 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 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, 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 reported outcomes; and integrating knowledge from research and evaluation into agency programs.

[1] 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 http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm342936.htm.

2. Purpose and Use of the Information

FDA plans to use the data collected under this generic clearance to inform its drug educational, health outcome intervention, 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.

3. Use of Information Technology and Burden Reduction

The information will be collected through one-on-one telephone or in-person 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.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of 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 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 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. Consequence 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 remain at a disadvantage as both potential threats to the public health emerge, and should the agency devote finite resources to public health campaigns that would prove 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 Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of September 19, 2016 (81 FR 64166). No comments were received by FDA in response to the notice.

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

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 (when appropriate[2]); 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.

Only agency-sponsored personnel will have access to individual-level surveys, interviews, or focus group data. All project staff from a contractor conducting the information collection must take required measures to ensure respondent privacy and confidentiality of data. Personally identifiable data shall be limited to information that may be required in the process of respondent enrollment. Personally identifiable information will be accessible to only those contractors who need them and will not be linked to interview data. All personally identifiable data will be destroyed as soon as feasible following interview data collection. Neither FDA employees nor any federal employee of any other agency will have access to personally identifiable information.

[2] In some cases, FDA sponsorship will not be made known to respondents prior to data collection out of concern for the potential introduction of bias to study results. In such cases, FDA sponsorship will be made known after the data are collected.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals preserved. Reports will be used only for research purposes and for the development of communication messages.
Social and behavioral testing efforts described in this proposal are typically considered exempt from the "*Regulations for the Protection of Human Subjects*" in accordance with paragraph (b)(3) of 45 CFR Sec. 46.101. Before data are collected, FDA researchers must obtain either an exemption or an expedited or full approval for all research from FDA's IRB, the Research

** *Involving Human Subjects Committee*:

Where FDA's IRB determines that minors are capable of giving an assent, the IRB shall determine whether adequate provisions are made for soliciting assent. Generally, assent requires securing the signature of a minor to the research in a separate assent form, in addition to the consent form the parent or legal guardian signs. An assent document should contain an explanation of the study, a description of what is required of the subject (e.g., what they will experience (whether they will be in the hospital, whether the child's parents will be with him or her, etc.)), an explanation of any risks and pain associated with the study, an explanation of any anticipated change in the child's appearance, and an explanation of the benefits to the child or others.

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 (http://www.whitehouse.gov/omb/fedreg/1997standards.html). 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 behavior, 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. The agency is 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. 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 can be used for retrieval.

12. Estimates of Annualized Burden Hours and Costs

*12a. Estimated Annualized Hourly Burden*

FDA estimates the total reporting burden for the information collection to be 9,198 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 health-care professionals. Proposed data collection methodologies are described in more detail in the agency's Supporting Statement –Part B.

Table 1. Estimated Annual Reporting Burden

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average burden per response in hours | Total Hours |
|---|---|---|---|---|---|
| Interviews/Surveys | 2,520 | 14.6 | 36,792 | 0.25 (15 mins.) | 9,198 |

*12b. Estimated annual cost burden.*

We estimate no annualized cost to respondents for the information collection. FDA notes, however, the estimated salaries attributable to some of the targeted 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, any amounts and justifications for any incentives associated with the information collection 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.

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% of 25 FTE (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

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) 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 Submissions

There are no exceptions to the certification.