

United States Food and Drug Administration

Customer/Partner Customer Satisfaction Service Surveys

OMB Control No. 0910-0360

SUPPORTING STATEMENT

Terms of Clearance: (1) In accordance with 5 CFR 1320, this request is approved for 3 years under the following conditions: (1) FDA shall submit memos for individuals surveys (e.g., statement of need, intended use of information, description of respondents, information collection procedures, justification for incentives and estimated burden; (2) OMB will respond with clearance or questions within 10 working days; and (3) OMB and FDA will jointly evaluate the generic clearance upon resubmission in 3 years. Upon resubmission, FDA will provide a summary of each collection approved under the generic clearance (e.g., use of information). The scope of this collection is limited to surveys.

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

Executive Order 12862 directs Federal agencies to provide the best possible service to the public. In order to ensure that our programs are effective and meet our customers' needs, The Food and Drug Administration (FDA) seeks to obtain extension of OMB approval for this generic clearance to collect qualitative feedback on our service delivery that provides useful insights on perceptions and opinions. This generic does not include statistical surveys and the results will not yield quantitative results that can be generalized to the population of study.

FDA is requesting OMB approval of the extension of this generic ICR in an effort to fulfill Executive Order 12862 which directs agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want their level of satisfaction with existing services." FDA provides a wide range of services to the public and to the regulated industries. To fulfill this directive FDA is requesting a generic approval to conduct:

- customer service surveys of any regulated entities such as food processors, cosmetic, drug, biologic, medical device and tobacco manufacturers, consumers, health professionals, and State and local governments;
- web-based, remote-user feedback surveys to assess and improve the quality of information services that FDA provides through its website.

FDA plans to seek ideas from respondents on (1) their current level of satisfaction with the services and information provided by FDA and (2) their recommendations on how to improve services and information provided by FDA. FDA will provide OMB a copy of each survey instrument for review and approval normally received within 10 business days and inclusion in the public docket.

This collection of information is necessary to enable FDA to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with FDA's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between FDA and its customers and stakeholders. It will also allow feedback to contribute to the improvement of program management.

2. Purpose and Use of the Information Collection

FDA will collect and use information gathered through this vehicle to identify strengths and weaknesses in current service provisions, including FDA's website, and to make improvements that are practical and feasible. Information from these customer service surveys and website usability surveys will be used in an effort to improve or maintain a high quality of service to affected publics. FDA's website provides a variety of services to the general public, health professionals, drug and biologics companies, consumer advocates, students, medical professionals, and journalists. Website usability will be surveyed on a regular basis on different parts of FDA's website. Information gathered from surveying website users will enable the agency to provide an effective, efficient, and satisfying experience. Timeliness, appropriateness, accuracy of information, courtesy, or problem resolution will be assessed in individual programs.

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only, and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement. Customer satisfaction surveys approved under the generic clearance will only be used to obtain information for general service improvement, not for publication or for the purpose of informing significant policy or resource allocation decisions. In addition, individual collections will concern subject matter and methods that are not controversial. FDA website usability data will be collected to ensure that we have the valuable data needed to routinely revise content and reorganize important online health and consumer information in a way that is most easily understood and useful to by the website visitors.

Improving agency programs requires ongoing assessment of service delivery, by which we mean systematic review of the operation of a program compared to a set of explicit or implicit standards, as a means of contributing to the continuous improvement of the program. FDA will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback. The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public.

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 respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary¹ and is not retained;
- Information gathered will only be used internally for general service improvement and program management purposes and is not intended for release outside FDA (if released, procedures outlined in Question 16 will be followed);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions²; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Respondents to this collection of information cover a broad range of stakeholders who have specific characteristics related to certain products or services regulated by FDA.

3. Use of Improved Information Technology and Burden Reduction

As appropriate, automated information technology will be used to collect and process information for these surveys to reduce the burden on the public. FDA estimates that approximately 75% of the respondents will use electronic means to fulfill the agency's requirement or request. Surveys will be simple with short questions. Data collection methods and procedures may vary and the specifics of these will be provided with each collection request. FDA expects to use a variety of methodologies for these collections such as commercial survey-specific software to automate its collection and analysis of feedback. Telephone scripts and personal interviews may also be used.

4. Efforts to Identify Duplication and Use of Similar Information

No similar data are gathered or maintained by FDA or are available from other sources known to FDA.

¹All privacy act requirements will be met.

²As defined in OMB and agency Information Quality Guidelines, "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."

5. Impact on Small Businesses or Other Small Entities

Small business or other small entities may be involved in these efforts but FDA will minimize the burden on them of information collections approved under this clearance by sampling appropriately, asking for readily available information, and using short, easy-to-complete information collection instruments.

6. Consequences of Collecting the Information Less Frequently

If this information is not collected, vital feedback regarding customers' satisfaction or dissatisfaction with various aspects of FDA program services, including FDA's website, will be unavailable. Without feedback about its service delivery, FDA will not have timely information to adjust its services to meet customer needs.

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

There are no special circumstances. The information collected will be voluntary and will not be used for statistical purposes.

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 1/21/2020 (85 FR 3389). No comments were received.

FDA programs will use routine contacts with customers and partners and other qualitative information collection activities to identify areas of interest and concern to customers and partners. FDA will utilize in-house statistical staff and the staff of contractors in developing survey plans. As needed, FDA may also utilize the statistical resources of the National Center for Health Statistics, which has a questionnaire design laboratory. As appropriate, centers will establish panels of outside experts to help in design and implementation of the surveys.

9. Explanation of Any Payments or Gift to Respondents

FDA, as a rule, will not provide payment or other forms of remuneration to respondents of its various forms of collecting feedback on customer satisfaction.

In the case of in-person interview requiring travel, any proposed stipend needs to be justified to OMB. Normally, a stipend of \$40 will be provided. If such information collections include hard-to-reach groups and FDA plans to offer non-standard stipends, FDA will provide OMB with additional justifications in the request for clearance of these specific activities. If OMB guidance for the stipend level is adjusted upward, the stipends may also be increased accordingly.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII) or information of a personal nature. PII collected is contact information. This ICR is collecting information from our customers and stakeholders which will help ensure that users have an effective, efficient, and satisfying experience with FDA's programs. FDA determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

Information provided by respondents will be kept secure to the extent provided by law 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 telephone interviews, and consent forms. Respondents also will be advised of the following: the nature of the activity; the purpose and use of the data collected; FDA sponsorship (when appropriate³); 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 particular questions.

Only personnel from a contractor conducting the information collection will have access to individual-level survey or interview data. All project staff from a contractor conducting the information collection must take required measures to ensure the security and anonymity 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 at the completion of the study. Neither FDA employees nor any federal employee of any other Agency will have access to this information.

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. To prepare for further security and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals. Reports will be used only for research purposes and for the development of communication messages.

Communications testing efforts 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 a full approval for all research from FDA's IRB, the Research Involving Human Subjects Committee.

Minors (or children) are persons who have not attained the legal age for consent to treatments or

³ 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.

procedures described in the study are covered under the applicable law of the jurisdiction in which the research will be conducted. 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 the interview will take place, whether the child's parents will be with him or her, etc.)), an explanation of any risks or mental anguish associated with the study, and an explanation of the benefits to the child or others.

11. Justification for Sensitive Questions

No questions will be asked that are of a personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

The total annual estimated burden imposed by this collection of information is 13,750 hours annually.

Table 1.—Estimated Annual Reporting Burden¹

Type of Survey	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Mail, telephone, Web-based	55,000	1	55,000	0.25	13,750

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

12b. Annualized Cost Burden Estimate

There are no costs to the respondents.

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

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

Staff or Contractor	Total Burden	Hourly Wage Rate	Total Respondent

	per Study		Cost
Contractor instrument preparation, conduction, analysis (GS-12/GS-13 FTE)	20	\$48.12	\$906.20
FTE survey preparation, conduction, analysis (GS-13)	20	\$52.27	\$984.40
FTE manager survey review (GS-14)	5	\$61.77	\$290.85
Total			\$2,181.45

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The amount of burden hours has not changed.

16. Plans for Tabulation and Publication and Project Time Schedule

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. Findings will be used for general service improvement, but are not for publication, other public release, or for the purpose of informing significant policy or resource allocation decisions.

Although FDA does not intend to publish its findings, it may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). FDA will disseminate the findings when appropriate, strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public," and will include specific discussion of the limitation of the qualitative results discussed above.

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

The agency is not requesting an exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.