

United States Food and Drug Administration

Qualitative Feedback on FDA Service Delivery

OMB Control No. 0910-0697--EXTENSION

SUPPORTING STATEMENT

Previous terms continue: OMB approves this collection for a period of three years. To request approval of information collections under this generic approval, the agency must do the following: 1) Unless an agency is using multiple modes of collection (e.g., paper forms and electronic submissions), provide a Generic Clearance Submission Template for each Instrument; 2) If the agency is using multiple modes of collection (e.g., paper forms and electronic submissions), the same Generic Clearance Submission Template may be used for both instruments; 3) each Generic Clearance Submission Template must be uploaded as a Supplementary document using a naming convention that allows the public to identify the associated instrument; 4) submit no more than five Generic Submission Templates with each request.

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

This collection of information is necessary to enable FDA to garner customer and stakeholder feedback using a variety of methods in an efficient, timely manner, in an effort to improve service delivery. Service delivery might include public health communications, website content, recalls, market withdrawals, and safety alerts. The information collected from our customers and stakeholders will help ensure that users have a satisfying experience with FDA's programs and communications. 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 allow for ongoing, collaborative, and actionable communications between FDA and its customers and stakeholders. It also allows feedback to contribute directly to the improvement of program management.

2. Purpose and Use of the Information Collection

Improving agency programs requires ongoing assessment of service delivery. 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.

The types of collections that this generic clearance covers include, but are not limited to:

- Customer comment cards/complaint forms
- Small discussion groups
- Focus Groups of customers, potential customers, delivery partners, or other stakeholders
- Qualitative customer satisfaction surveys (e.g., post-transaction surveys; opt-out web surveys)
- Moderated, un-moderated, in-person, and/or remote-usability studies.

Respondents to this collection of information cover a broad range of customers and stakeholders who have specific characteristics related to certain products or services regulated by FDA. These stakeholders include members of the general public, healthcare professionals, industry, and others who have experience with a product under FDA's jurisdiction.

3. Use of Improved Information Technology and Burden Reduction

Information technology will be used to collect and process information for these surveys. Surveys will be simple with short questions. Data collection methods and procedures may vary and the specifics of these will be provided with each gen IC. FDA expects to use a variety of

¹ For example, collections that collect PII in order 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.

² As 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."

methods for these collections such as commercial survey-specific software to automate its collection and analysis of feedback. Telephone scripts and interviews may also be used.

4. Efforts to Identify Duplication and Use of Similar Information

Research conducted is not anticipated to duplicate any other evaluation being completed by FDA or other federal agencies.

5. Impact on Small Businesses or Other Small Entities

These proposed data collection activities will focus primarily on participants in their roles as stakeholders and customers of the agency. 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 these types of 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 for this collection of information. 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 May 25, 2023 (88 FR 33889). No comments were received.

9. Explanation of Any Payment 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.

A stipend of \$40 will be the standard for groups that are harder to reach. However, for some surveys, focus groups, and interviews, we will provide a justification in the individual gen IC for a proposed higher incentive rate.

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 gather information from our customers which will help FDA understand consumers attitudes and emotions in response to topics and concepts, and as a result will help develop communication message and campaigns. 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 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

For the vast majority of focus groups, no questions will be asked that are of a personal or sensitive nature. Some products regulated by FDA are for conditions that are considered personal and potentially embarrassing. In addition, certain populations may be asked questions regarding questionable behavior of regulated products (e.g., tobacco). Therefore, there may be instances in which a particular topic of interest touches upon issues that could be considered sensitive. In these cases, extra care will be taken to ensure that any questions are absolutely necessary to the purpose of the information collection, are asked in a sensitive and respectful way, and that participants’ right to refuse response is protected.

12a. Estimates of Annualized Burden Hours and Costs

A variety of instruments and platforms will be used to collect information from respondents.

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Focus groups	3,000	1	3,000	1.75	5,250
Customer comment cards/forms	1,500	1	1,500	.25	375
Small	800	1	800	1.75	1,400

discussion groups					
Customer satisfaction surveys	20,000	1	20,000	.33	6,600
Usability studies	1,100	1	1,100	1	1,100
TOTAL	26,400				14,725

12b. Annualized Cost Burden Estimate

We project that the general public will complete the majority of data collections. The average salary for these groups is indicated in the table below. The total estimated hours multiplied by the average hourly wage rate as indicated by the U.S. Bureau of Labor Statistics is multiplied to arrive at the total respondent cost. We have doubled the wage rate to account for benefits and overhead.

Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General public	8,075	\$66.00	\$532,950
Healthcare professionals	6,650	\$266.00	1,768,900
Total			\$2,301,850

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 Federal Government

FDA may incur costs to hire a contractor to select respondents, draft the questionnaire, cognitively test the questionnaire, and conduct and analyze the survey for which we estimate \$8,000 per survey resulting in a total of \$160,000 for 20 surveys.

Assuming a cost of \$325,348 per one full-time equivalent (salary plus overhead, full-time 40-hour week) divided by the total number of hours worked (2,080 hours) per year, the fully loaded wage rate is \$156 per hour. An FTE may devote 30% (624 hours) of their time preparing, reviewing, and monitoring a project resulting in \$97,344 (624 hours x \$156/hour) spent annually. An FTE supervisory may spend 25% (520 hours) of their time reviewing and monitoring a project resulting in \$81,120 (520 hours x \$156/hour) spent annually. We estimate a total of \$178,464 is spent on government salaries.

Therefore, the total cost to Federal government is approximately \$338,464.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we increased the number of respondents for focus groups, customer comment cards/forms, customer satisfaction surveys, and usability studies. This adjustment results in an overall burden increase of 6,234 hours.

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 or other public release.

Although FDA does not intend to publish its findings, FDA 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.

It is not appropriate to treat focus group data as quantifiable. FDA will disseminate focus group findings only when appropriate and will include specific discussion of the limitations of focus group results with regard to being non-quantitative. Information quality encompasses (1) utility, the usefulness of the information to its intended users, including the public; (2) objectivity, whether information is being presented in an accurate, clear, complete, and unbiased manner; and (3) integrity, the information is protected from unauthorized access or revision. FDA uses a number of mechanisms to ensure the quality of the information we disseminate. FDA reviews the quality of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance, and dissemination.

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

FDA is requesting no exemption from display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.