

United States Food and Drug Administration

Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery

OMB Control No. 0910-0697

SUPPORTING STATEMENT

Terms of Clearance: 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 submission 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; and (4) submit no more than five Generic Submission Templates with each request.

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

Executive Order 12862, “Setting Customer Service Standards” directs Federal Agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously 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. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

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 directly to the improvement of program management.

2. Purpose and Use of the Information Collection

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 be 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.

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, a standardized form will be submitted to OMB along with supporting documentation (e.g., a copy of the moderator guide, a comment card or questionnaire). The submission will have automatic approval, unless OMB identifies issues within 5 business days.

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.”

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

The FDA has established a manager/managing entity to serve for this generic clearance and will conduct an independent review of each information collection to ensure compliance with the terms of this clearance prior to submitting each collection to OMB.

3. Use of Improved Information Technology and Burden Reduction

Consideration will be given to collecting information electronically or using online collaboration tools to reduce burden. However, the applicability of such tools to in-person interviews and/or discussions is at present relatively unlikely, since the quality and level of detail in qualitative data collection would be difficult to obtain via virtual data collection methods. Therefore, due to the nature of qualitative research, approximately 5 percent of these information collections will be completed electronically.

4. Efforts to Identify Duplication and Use of Similar Information

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

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 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 4/3/2020 (85 FR 18989). Although two comments were received, they were 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

FDA as a rule will not provide payment or other forms of remuneration to respondents of its various forms of collecting feedback. Focus groups and cognitive laboratory studies are the exceptions.

In the case of in-person cognitive laboratory and usability studies, the FDA may provide stipends of up to \$40. In the case of in-person focus groups, the FDA may provide stipends of up to \$75. If respondents participate in these kinds of studies remotely, via phone, or Internet 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 focus groups, 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

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.

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 focus group, 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 collected in the focus group discussion. All personally identifiable data will be destroyed following data collection 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 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 Investigational Review Board (IRB), the Research Involving Human Subjects Committee.

Minors (or children) are persons who have not attained the legal age for consent to treatments or 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 (in what setting the interview or focus group 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 topic, and an explanation of the benefits to the child or others.

11. Justification for Sensitive Questions

As mentioned in Section 10, some studies require the inclusion of people who match selected characteristics of the target audience that FDA is trying to reach. This may require asking a question about race/ethnicity, income, education and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that FDA speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information is voluntary and will be treated as private and

anonymous. All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (https://www.whitehouse.gov/omb/fedreg_1997standards).

Because FDA communications may be concerned with the prevention of premature mortality, some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. The probability of sensitive questions occurring depends upon the topic of the communication. This information is needed to gain a better understanding of the target audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature, while not as personal as those about sexual behavior or religious beliefs, still 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, when respondents are more comfortable with the interview situation and are more at ease with the interviewer/moderator. As noted in Section 10, participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable.

Raw data from data collections that include sensitive information (for example, screening questionnaires and audio tapes) are not retained once the data have been extracted and aggregated. The information is never a part of a system of records containing permanent identifiers that can be used for retrieval.

12. Estimates of Annualized Burden Hours and Costs

A variety of instruments and platforms will be used to collect information from respondents. The annual respondent burden hours requested (8,491) are based on the number of collections we expect to conduct over the requested time frame for this clearance.

12a. Annualized Hour Burden Estimate

Table 1 --Estimated Annual Reporting Burden					
Type of Survey	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Focus groups	800	1	800	1.75	1,400
Customer comment cards/forms	1,325	1	1,325	.25 (15 minutes)	331.25
Small discussion groups	800	1	800	1.75	1,400
Customer satisfaction surveys	12,000	1	12,000	.33 (20 minutes)	3,960

	Table 1 --Estimated Annual Reporting Burden				
Usability Studies	800	1	800	1.75	1,400
TOTAL					8,491.25

12b. Annualized Cost Burden Estimate

The annualized cost burden for respondents is estimated for all occupations and for the health professions, as the primary occupational group likely to be involved in studies undertaken under this generic clearance. Studies conducted under this generic clearance will provide annualized respondent cost burden for the study population of interest. These wage rates were obtained from the U.S. Department of Labor, Bureau of Labor Statistics May 2018 National Occupational Employment and Wage Estimates for the United States located at https://www.bls.gov/oes/current/oes_nat.htm#00-0000.

	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
All occupations	4,245	\$24.98	\$106,040.10
Physicians	2,223	\$101.43	225,478.89
Allied Health Professions	2,223	\$39.42	\$87,630.66
Total			\$419,149.65

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

No costs are anticipated.

14. Annualized Cost to Federal Government

FDA incurs costs to set up small discussion and focus groups, including potentially hiring a contractor to provide a facilitator/moderator, rent meeting space, travel to conduct the groups, and provide respondents with minimum payment cost in the form of a token stipend. For these expenses, FDA spends approximately \$250,000 annually.

For customer satisfaction surveys and other interview surveys, FDA incurs costs to hire a contractor to select respondents, draw up the questionnaire, cognitively test the questionnaire, and conduct and analyze the survey, for which FDA spends approximately \$7,500 per question per survey. For a 20-question survey, the average cost is expected to be \$150,000.

Therefore, FDA's total annualized estimated cost to the Federal government is \$400,000.

15. Explanation for Program Changes or Adjustments

The burden for this collection of information has increased by 800 responses from 14,925 to 15,725 responses due to an inadvertent omission of responses of usability studies for this collection. This addition to responses will correct the number of responses for this collection. The burden hours in OMB's inventory will remain the same.

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.

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

There are no exceptions to the certification.