

GEN IC REQUEST TEMPLATE
Qualitative Feedback on FDA Service Delivery
OMB Control Number 0910-0697

BEFORE SUBMISSION

Ensure that your gen IC meets the requirements of the umbrella generic. This generic facilitates FDA's ability to conduct customer satisfaction surveys and gain important feedback from all FDA-regulated industries. Feedback from these collections is intended to 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.

All documents submitted with this gen IC should indicate FDA sponsorship and display the current OMB approval expiration date.

HOW TO USE THIS TEMPLATE

This template utilizes fill-in enabled text form fields. Simply click on the shaded text and enter your narrative.

United States Food and Drug Administration
Qualitative Feedback on FDA Service Delivery
OMB Control Number 0910-0697
Gen IC Request for Approval

Title of Gen IC: (Insert center) Provide the name of the collection of information that is the subject of the request.

1. Statement of Need

Provide a brief description of the purpose of this collection.

2. Intended Use of the Information

Indicate how the information will be used.

3. Description of Respondents

Describe participants/respondents.

4. How the Information is Collected

[Provide details about how the information will be collected (e.g., focus group, customer comment card/form, small discussion group, customer satisfaction survey, usability study.)

Who (e.g., contractor) will conduct the information collection and on what platform (e.g., social media, telephone, web-based).

5. Confidentiality of Respondents

Describe any assurance of confidentiality provided to respondents.

[You may provide this statement on your survey instrument]: “Your participation / nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.”

6. Amount and Justification for Proposed Incentive

This generic allows for an incentive of up to \$40 for in-person interviews or hard to reach respondents. Please provide justification if an incentive is requested.

7. Questions of a Sensitive Nature

Describe and provide justification.

8. Description of Statistical Methods

Describe sample size and method of selection.

9. Burden

Replace the content of the example table below with the estimated burden for this gen IC.

Participation time may be in the format of hours or minutes (use a decimal) and indicated in the heading.

Burden Hour Computation: Number of Respondents multiplied by participation time = total burden hours. ***Data in all fields of the table must be entered, including totals.***

Be sure not to double count respondents. In the example below the Number of Respondents is 200 because focus group respondents have been counted as part of the focus group screener respondents. (The focus group respondents are part of the screener group.) Round up to whole numbers for the total burden hours; do not use decimals. ***Delete this italicized instruction prior to submission.***

Type of information collection/Category of Respondent	No. of Respondents	Participation Time (choose hours or minutes and modify this heading accordingly)	Total Burden (hours)
Focus group screener respondents	200	1 hour	200
Focus group respondents	120	1 hour	120
Totals	200	2 hours	320

10. Date(s) to be Conducted

Insert date(s) and locations, if applicable.

11. Requested Approval Date

Insert date if shorter than 10 day turn-around time as noted in the SSA. Otherwise use the month and year, only, allowing for a 30 day review time at APRA.

12. FDA Contacts

Program Office Contact	FDA PRA Contact
Insert name, email Enter program office Center for Drug Evaluation and Research	Insert name, email Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations