GEN IC REQUEST TEMPLATE FOR
Rapid Response Surveys
OMB Control Number 0910-0500

Ensure that your Gen IC meets the requirements of the umbrella generic. This generic facilitates FDA's ability to obtain data on safety information to support quick-turnaround decision-making about potential safety problems or risk management solutions. This information is collected from health professionals, hospitals, and other user facilities, consumers, sponsors and manufacturers of biologics, drugs and medical products, distributors, and importers when FDA must quickly determine whether a problem with a medical product impacts the public health.

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
Generic Clearance: Customer Satisfaction Surveys
OMB Control Number 0910-0500
Gen IC Request for Approval

Title of Gen IC: 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 and if this is part of a larger study or effort.

3. Description of Respondents

   Describe participants/respondents.

4. How the Information is Collected

   Describe the method of collection (e.g., web-based, telephone, social media) and who (e.g., contractor) will conduct.

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. Proposed Incentive

   What is the amount, if any, of the incentive offered? Provide a detailed justification as to why this group of respondents for this information collection will receive a stipend, reimbursement of expenses, token of appreciation.

7. Questions of a Sensitive Nature

   Describe and provide justification.

8. 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 100 because respondents have been counted as part of the screener respondents. Round up to whole numbers for the total burden hours; do not use decimals. ***Delete this italicized instruction prior to submission.***

Example:

Type of information collection/Category of Respondent	**No. of Respondents**	**Participation Time (minutes)**	**Total Burden (hours)**
Screener: patients and prescribers	100	2	200
Patient interview	40	20	13
Prescriber interview	10	20	3
Totals	100	---	216

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.

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