GEN IC REQUEST TEMPLATE

Data to Support Drug Product Communications (CDER)
OMB Control Number 0910-0695

BEFORE SUBMISSION

Ensure that your Gen IC meets the requirements of the umbrella generic. This generic facilitates FDA's ability to assess the need for communications on specific topics and to assist in the development and modification of communication messages.

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
Testing Communications on Drug Products (CDER)
OMB Control Number 0910-0695
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

   Provide details about how the information will be collected (e.g., individual in-depth interviews, focus group, intercept interviews, self-admnistered survey, omnibus survey) and who (e.g., contractor) will facilitate.

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

   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. 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.***

Respondent Type/Category	Number of Respondents	Participation Time (choose hours or minutes)	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, phone number.] Center for Drug Evaluation and Research	[PRA Staff will insert name, phone number and center.] Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations