

GEN IC REQUEST TEMPLATE FOR
Generic Clearance: Quantitative Data on Tobacco Products and Communications
OMB Control Number 0910-0810

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.

Ensure all instruments, instructions and scripts are submitted with this gen IC request and that all documents 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: Quantitative Data on Tobacco Products and Communications
OMB Control Number 0910-0810
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

Experimental Study Survey

Provide details about how the information will be collected (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 and the basis for the assurance. Cite and describe Privacy Impact Assessment (PIA), # XXXXX.

[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.

[If no incentive is offered, state as such.]

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.

Type of information collection/Category of Respondent/Activity	No. of Respondents	Participation Time (minutes)	Total Burden (hours)
Totals	[enter total]		[enter total]

10. Date(s) to be Conducted

Insert date(s) and locations, if applicable.

11. Requested Approval Date

Insert date.

12. FDA Contacts

Program Office Contact	FDA PRA Contact
Insert name, email Enter program office Enter center	Insert name, email Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations