GEN IC REQUEST TEMPLATE
Generic Clearance for Quantitative Testing for the Development of FDA Communications (CFSAN)
OMB Control Number 0910-0876

TERMS OF CLEARANCE

FDA will submit individual collections under this generic clearance to OMB. Individual collections will also undergo review by FDA's Research Involving Human Subjects Committee (RIHSC), senior leadership in the Center for Food Safety and Applied Nutrition, and Paperwork Reduction Act (PRA) specialists. FDA will prepare a report during the OMB collection renewal summarizing the number of hours used, as well as the nature and results of the activities completed under this clearance.

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 of [will be updated with current OMB 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: Collections for Quick Turnaround Testing of Communication Effectiveness (CFSAN)
OMB Control Number 0910-0876
Gen IC Request for Approval

The Food and Drug Administration (FDA) sometimes needs to communicate with U.S. consumers and other stakeholders about issues of immediate and important public health significance such as foodborne illness outbreaks, food recalls, or other situations requiring expedited FDA food, dietary supplement, cosmetics, or animal food or feed communications. To better protect the public health, the agency needs quick turn-around information collected from consumers and other stakeholders to help ensure its messaging has reached the target audience, has been understood and, if needed, to update its communications during these events. This quick-turnaround generic collection gathers quantitative and qualitative information (i.e., surveys, focus groups, and in-depth interviews) to test communications or educational messages when there is an urgent public health need, assists FDA to communicate effectively about topics of public health and safety, and conveys sometimes complex concepts.

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., interviews, survey) and who (e.g., contractor) will facilitate.]

5. Privacy of Respondents and Protection of Data

   [Describe any assurance of respondent/participant privacy and data security plan.]

   [You may provide this statement on your survey instrument or moderation/interview guide]:

   "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."

   Have you ensured that the following language or similar is included in your study materials? [include cleared language] [ ] YES [ ] NO

6. Amount and Justification for Proposed Incentive

   Is an incentive (e.g., stipend, reimbursement of expenses, token of appreciation) provided to participants? If yes, describe the incentive and provide a justification for the amount. If no, answer no and delete this instruction.

7. Questions of a Sensitive Nature

   [Describe and provide justification.]

8. Description of Statistical Methods

   [Describe sample size and method of selection.]

9. Burden Hour Computation

[See example below and complete the table with the estimated burden for this gen IC. Participation time may be in the format of hours or minutes and indicated in the heading. Burden Hour Computation: Number of responses multiplied by estimated participation time in minutes = total burden hours. Data in all fields of the table must be entered. Round up to whole numbers for the total burden hours; do not use decimals. Delete this instruction prior to submission.]

Survey Type	Number of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours or minutes)	Total Hours
In-depth Interviews, Cognitive Interviews Screener					
In-depth Interviews, Cognitive Interviews					
In-depth Interviews Screener					
In-depth Interviews					
Survey Cognitive Interviews Screener					
Survey Cognitive Interviews					
Pre-test survey screener					
Pre-test survey					
Self-administered surveys - Study Screener					
Self-Administered Surveys					

Focus Group/Small Group, Cognitive Groups Screener					
Focus Group/Small Group, Cognitive Groups					
Focus Group/Small Group Participant Screening					
Focus Group/Small Group Discussion					
Totals	ENTER TOTAL				ENTER TOTAL

10. Dates(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.] Center for Drug Evaluation and Research	[Insert name, email.] Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations