

**Request for Approval under the “Generic Clearance for Quantitative Testing
for the Development of FDA Communications”
(OMB Control Number: 0910-NEW)**

TITLE OF INFORMATION COLLECTION: [Provide the name of the collection that is the subject of the request. (e.g. Experimental Study Testing FDA Web Materials on xxxx)]

1. STATEMENT OF NEED

[Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.]

2. TYPE OF COLLECTION

[Check one box.]

Experiment

Survey

3. PARTICIPANT UNIVERSE AND SAMPLING PLAN

[Describe participants, including justification for their selection, and the sampling frame and sampling method to be used.]

4. INCENTIVE

Is an incentive (e.g., money or reimbursement of expenses, token of (appreciation) provided to participants?) Yes No

[If yes, describe the incentive and provide a justification for the amount.]

5. DATA ANALYSIS PLAN

[Describe how the data will be analyzed and reported and discuss how the data will be used.]

6. BURDEN HOURS

Activity: Provide the type of activity (e.g., screener, pre-test, survey)

No. of Respondents: Provide an estimate of the Number of respondents.

Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey).

BURDEN HOUR COMPUTATION (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

Activity (by category of respondent, if applicable)	No. of Respondents	Participation Time (minutes)	Burden (hours)
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Totals			

7. CERTIFICATION:

In submitting this request, I certify the following to be true:

- a) The collections are voluntary;
- b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
- c) The collections are noncontroversial and not of a sensitive nature;
- d) Personally identifiable information (PII) is collected only to the extent necessary¹ and is not retained; and
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.²

REQUESTED APPROVAL DATE: [insert]

8. NAME OF PRA ANALYST & PROGRAM CONTACT: [insert]

FDA CENTER: [insert]

Please make sure that all instruments, instructions, and scripts are submitted with the request.

¹ For example, collections that collect PII in order to provide remuneration for participants of cognitive interviews will be submitted under this request. All privacy act requirements will be met.

² As defined in OMB and agency Information Quality Guidelines, “influential” means that “an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.”