

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

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**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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<b>Totals</b>			

**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 necessary<sup>1</sup> and is not retained; and
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.<sup>2</sup>

**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.**

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<sup>1</sup> 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.

<sup>2</sup> 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.”