## 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)** |
|  |  |  |  |
|  |  |  |  |
| **Totals** |  |  |  |

7. CERTIFICATION:

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

1. The collections are voluntary;
2. The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
3. The collections are noncontroversial and not of a sensitive nature;
4. Personally identifiable information (PII) is collected only to the extent necessary[[1]](#footnote-1) and is not retained; and
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.[[2]](#footnote-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. [↑](#footnote-ref-1)
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.” [↑](#footnote-ref-2)