# 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:

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[1] 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."