

**Request for Approval under the “Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery”**  
**(OMB Control Number: 0910-0697)**

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**A. TITLE OF INFORMATION COLLECTION:** Biomarker Qualifications Program

1. PURPOSE:

FDA oversees the Biomarker Qualifications Program to increase transparency and expedite drug approvals. It encourages drug researchers to identify and then qualify biomarkers, or measures of physical health, in a way that other researchers can use them in drug development.

To promote biomarker qualification, FDA has developed a series of communications products, including videos, podcasts and website content. We would like to associate a short online survey with the materials to solicit input that will be used to understand user reactions to the FDA biomarkers material and inform production of subsequent materials. It will not be used for policymaking.

2. DESCRIPTION OF RESPONDENTS:

Responding to the Biomarkers Feedback Survey will be completely voluntary. Respondents will be individuals who access the materials on fda.gov. These individuals will be from industry, government, academia, organizations, and the general public.

3. TYPE OF COLLECTION: (Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.)

- |  |   |
|--|---|
| <input type="checkbox"/> Customer Comment Card/Complaint Form          | <input type="checkbox"/> Customer Satisfaction Survey           |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group                 |
| <input type="checkbox"/> Focus Group                                   | <input checked="" type="checkbox"/> Other: <u>online survey</u> |

4. CERTIFICATION:

I certify the following to be true:

- a) The collection is voluntary.
- b) The collection is low-burden for respondents and low-cost for the Federal Government.
- c) The collection is non-controversial and does not raise issues of concern to other Federal Agencies.
- d) The results are not intended to be disseminated to the public.
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.

- f) The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Lauren Shaham

**Lauren Shaham**

*Director, Division of Health Communications, Office of Communications, CDER*

To assist review, please provide answers to the following question:

5. **PERSONALLY IDENTIFIABLE INFORMATION (PII):** Provide answers to the questions. Note: Agencies should only collect PII to the extent necessary, and they should only retain PII for the period of time that is necessary to achieve a specific objective.
- a) Is personally identifiable information (PII) collected?  Yes  No  
b) If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974?  Yes  No  
c) If Yes, has an up-to-date System of Records Notice (SORN) been published?  Yes  No
6. **GIFTS OR PAYMENT:** If you answer yes to the question, please describe the incentive and provide a justification for the amount.

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

**BURDEN HOURS:** Identify who you expect the respondents to be in terms of the following categories:

- (1) Individuals or Households;  
(2) Private Sector;  
(3) State, local, or tribal governments; or  
(4) Federal Government.

Only one type of respondent can be selected per row.

**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 or participate in a focus group)

7. **BURDEN:** Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

<b>Category of Respondent</b>	<b>No. of Respondents</b>	<b>Participation Time</b>	<b>Burden</b>
Private Sector	100	1	1:40

**8. FEDERAL COST:** [Provide an estimate of the annual cost to the Federal government.]

The estimated annual cost to the Federal government is \$0; survey to be conducted with allocated resources.

## **B. STATISTICAL METHODS**

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

**The selection of your targeted respondents:** Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

Yes  No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

[insert description]

**Administration of the Instrument:** Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.

1. How will you collect the information? (Check all that apply)

- Web-based or other forms of Social Media
- Telephone
- In-person
- Mail
- Other, Explain

2. Will interviewers or facilitators be used?  Yes  No

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