

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

A. TITLE OF INFORMATION COLLECTION: Office of Regulatory Affairs Strategic Plan Development Survey

1. PURPOSE:

The Office of Regulatory Affairs (ORA) is developing a ten-year strategic plan to drive internal planning, decision-making, and resource allocation. Only high-level goal and objective information will be shared in certain public forums. The purpose for engaging the states and selected industry associations is to gain a better understanding of the external influences that may impact ORA over the next ten years. This includes understanding how ORA is doing with key partners and what ORA can do better in the future. Due to the partnerships with the states and industry associations, it is important to understand their perspective.

The feedback collected by the customer satisfaction survey will directly support the development of the ORA strategic plan, but none of the information collected will be posted publicly or lead directly to a policy or guidance.

The feedback will be collected on an FDA.gov website that was developed specifically for this purpose. This website is currently in draft form, pending approval, and can be viewed in Appendix I and Appendix II. Once this package is approved, the URL of the public page will be: <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/ora-strategic-planning-initiative/ora-strategic-plan-development-survey>. This link is provided as a reference and will not work until the package is approved. The external website includes three open-ended questions with the option to provide the customer’s information.

This method for the collection of feedback was developed to allow the selected customers to submit their feedback in an easy-to-use format that avoids the expectation of two-way communication.

2. DESCRIPTION OF RESPONDENTS:

The 50 states and selected industry associations deal directly with ORA on a routine basis. The targeted groups were selected because of their experience working with ORA and the expectation that the partnerships will continue for the foreseeable future.

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 checked="" type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group |

Focus Group

Other: _____

4. **CERTIFICATION:** Please read the certification carefully. If you incorrectly certify, OMB will return the generic as improperly submitted or it will be disapproved.

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.

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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) Private Sector;
- (2) State, local, or tribal governments

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.

| Category of Respondent | No. of Respondents | Participation Time | Burden |
|-------------------------------------|---------------------------|---------------------------|-----------------|
| Private Sector | 30 | 60 minutes | 30 hours |
| State, local, or tribal governments | 50 | 60 minutes | 50 hours |
| Totals | 80 | | 80 hours |

8. **FEDERAL COST:** There is NO estimated annual cost to the Federal government.

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?

ORA compiled a list of meetings and forums in which ORA is scheduled to interact with the states and industry associations between January 2020 and April 2020. By using existing meetings and forums, ORA can target state and association leadership that have experience with ORA and plan to continue working with ORA for the foreseeable future. The list of meetings and forums has already been filtered to ensure a balanced spread across the regulatory portfolio (food, drugs, etc).

There is no intention of employing statistical methods to the results. The questions will be open-ended only.

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.

Attached:

Appendix I: Survey Tool

Appendix II: Survey Tool Snapshot

Appendix III: View After Submitting Survey

Appendix IV: Customer List

REQUESTED APPROVAL DATE: January, 2020.

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