United States Food and Drug Administration Generic Clearance: Customer Satisfaction Surveys OMB Control Number 0910-0360 Gen IC Request for Approval

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement.

Title of Gen IC: OTED Post-Course Satisfaction Evaluation

1. Statement of Need:

The FDA Office of Regulatory Affairs (ORA), Office of Training, Education, and Development (OTED) seeks to understand student satisfaction with FDA-sponsored trainings once course participation has completed. We are requesting to send a 23-item survey to students across all course offerings starting in March 2022 and ongoing thereafter. Completion of the survey is voluntary, and no incentives are offered to complete it.

2. Intended Use of the Information:

This information will provide the Office of Training, Education, and Development (OTED) a better understanding of how student satisfaction with various aspects of FDA-sponsored course instruction, such as with the materials provided, the platform used for training and the pace of the course overall.

3. **Description of Respondents:**

Respondents include FDA employees as well as those students required to attend FDA-sponsored courses from our state, local, tribal, and territorial partners.

4. How the Information is Collected:

Data will be collected through web-based platform (SurveyMonkey) by an FDA employee three months post-participation in one of the nine pilot courses. The survey would only be sent to students once and will be set up in SurveyMonkey to be anonymous. An invitation requesting feedback will be sent via email to students through a link to an online survey using the SurveyMonkey platform.

5. Confidentiality of Respondents:

No personally identifiable information is requested, captured, or stored, and the survey will be set up to ensure anonymity. Demographic items are voluntary and include an option for "prefer not to answer".

6. Amount and Justification for Proposed Incentive:

Is an incentive (e.g., stipend, reimbursement of expenses, token of appreciation) provided to participants? [] Yes [x] No

7. Questions of a Sensitive Nature:

There are no sensitive questions but note there are nine demographic questions added for the purpose of understanding whether there are any differences or gaps among groups. These items allow OTED to respond to data requests regarding the availability of training opportunities provided to students, as well as to support diversity and inclusion initiatives by providing the ability to assess whether satisfaction, post-training confidence in abilities, or the learning experience differs among demographic groups. These items were reviewed and approved by the Privacy office representative, who also provided language for the survey and items containing open response (e.g., comment).

8. Description of Statistical Methods:

Based on an estimation of the number of participants in the same courses in FY21, we estimate approximately 4000 students would be sent the survey. At an average response rate of 65%, we expect approximately 2600 respondents. The survey would be given to all students who participated in each instructor-led course that OTED offers. Data would be analyzed using SPSS and reported as an aggregate looking at things like percent favorable, items most correlated with course quality, any differences by demographic, and how it compares to other course satisfaction data we may have.

9. Burden:

Type of information collection/Category of	No. of Respondents	Participation Time	Burden (hours)
Respondent	- Interposition	(minutes)	
Webform Satisfaction Survey	2600	7/60	303

10. Date(s) to be Conducted: March 3, 2022 - ongoing

11. **Requested Approval Date:** March 1, 2022

12. FDA Contacts:

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- 13. **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.
 - d) Personally identifiable information (PII) is collected only to the extent necessary and is not retained; and
 - e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.