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: FDA CFSAN Usability Study for Feedback on Consumer Food Safety Educator's Planning and Evaluation Toolkit

1. PURPOSE:

   The U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is developing a planning and evaluation toolkit for food safety educators. This toolkit will contain guidance, information, and sample evaluation tools, and will be used by health educators and other public health professionals to evaluate educational food safety programs. A usability test will be implemented to test the toolkit with health educators to assess usability and gain feedback on the format and content of the toolkit. Feedback and suggestions will be used to refine the toolkit and improve its usability.

2. DESCRIPTION OF RESPONDENTS:

   Respondents are health educators who are the target users of this toolkit. Since the toolkit is specifically developed to address the needs of this audience, they will be able to provide insight on whether the toolkit addresses their evaluation needs, is easy for them to understand, and is applicable and practical for them to use for their programs.

3. TYPE OF COLLECTION:

[ ] Customer Comment Card/Complaint Form	[ ] Customer Satisfaction Survey
[X] Usability Testing (e.g., Website or Software	[ ] 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.

Name: Sharmi Das, FDA/CFSAN 240-402-3786, June 24, 2016
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 [X] No
b) If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ] Yes [X] No
c) If Yes, has an up-to-date System of Records Notice (SORN) been published? [ ] Yes [X] 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 [X] No

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

(1) Individuals or Households; Yes. This group will be the primary respondents.
(2) Private Sector; N/A
(3) State, local, or tribal governments; or N/A
(4) Federal Government. N/A

Only one type of respondent can be selected per row.
No. of Respondents: 20 potential respondents for recruitment, which will be narrowed down to 10 actual respondents for review of the toolkit and interview who will be a part of this sample.
Participation Time: The time to complete this study is expected to take 15 minutes for the recruitment portion, 120 minutes to review the toolkit, and between 20 to 30 minutes per respondent to complete the actual study. Therefore, FDA estimates it will take 30 hours total burden to complete this study.

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

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden**
Heath Educators – Society for Public Health Education – Pre Screening	10 (approx. 10 individuals will be reached out to initially in order to recruit 5 health educators)	15 minutes - recruitment	2.5 hours- recruitment
Food Safety Educators – BAC Fighters from the Partnership for Food Safety Education – Pre Screening	10 (approx. 10 individuals will be reached out to initially in order to recruit 5 health educators)	15 minutes - recruitment	2.5 hours- recruitment
Health Educators – Society for Public Health Education – Review of Toolkit	5 (participants)	120 Minutes toolkit review	10 hours – toolkit review
Food Safety Educators – BAC Fighters from the Partnership for Food Safety Education – Review of Toolkit	5 (participants)	120 minutes – toolkit review	10 hours – toolkit review
Heath Educators – Society for Public Health Education - Interview	5 (participants)	30 minutes- interview	2.5 hours- interview
Food Safety Educators – BAC Fighters from the Partnership for Food Safety Education - Interview	5 (participants)	30 minutes- interview	2.5 hours- interview
Totals	**20 potential participants (20 in the recruitment phase, which narrows down to 10 for the actual toolkit review and interview/study)**		**30 hours**

8. FEDERAL COST: The estimated annual cost to the Federal government is approximately five hours of ORISE fellow's time for conducting interviews and approximately three hours for paperwork, transcribing, and recruitment.

The estimated annual cost to the Federal government is $318.24 (ORISE hourly pay of $39.78 x 8 hrs)

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.

The FDA is not conducting a focus group, survey, or plan to employ statistical methods for this study. Respondents will be recruited via a convenience sample. Partners at two organizations (Society for Public Health Education and the Partnership for Food Safety Education) will be contacted to recruit volunteers for the sample. The information will be collected via one-on-one interviews where the interviewer will contact respondents via email or phone to schedule a convenient time for each person to participate in the interview. The interviewer will follow a script and ask a series of predetermined questions about the toolkit. Phone interviews will be recorded and then transcribed.

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.