

**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:** Food Defense Plan Builder

1. PURPOSE:

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN)/Office of Analysis and Outreach is seeking OMB approval under the generic clearance 0910-0697 to conduct a focus group to collect qualitative information on version 2.0 the Food Defense Plan Builder, a software tool developed by FDA to assist owners and operators of food facilities with developing personalized food defense plans for their facilities. This is a collection request that was originally approved by OMB in June 2016, in which FDA asked OMB approval to conduct four Food Defense Plan Builder focus groups, but was only able to conduct one focus group. This approval request is for the conducting of Food Defense Plan Builder focus groups for the remaining three focus groups.

FDA/CFSAN plans to use the information collected during the focus groups to ensure that version 2.0 of the Food Defense Plan Builder is user-friendly, appropriate for the intended user base, and that the content and functionality of the tool would help the food industry in meeting the requirements of the FSMA Intentional Adulteration rule.

In May 2013, FDA launched version 1.0 of the Food Defense Plan Builder. As of July 2018 the tool has been downloaded over 45,600 times. This software tool was originally developed using existing FDA tools, guidance, and resources for food defense under the voluntary food defense framework. With the finalization of the FSMA Intentional Adulteration rule, FDA/CFSAN plans to update the Food Defense Plan Builder and launch a version 2.0 so that the food industry can use the FDPB to develop a food defense plan that could be compliant with the FDA requirements.

The information gathered during the focus groups will help FDA with ensuring that version 2.0 of the FDPB is easy to use and will help the food industry comply with FDA requirements. Specifically, we are interested in feedback on user interface, content, and usefulness to the food industry as well as any recommendations on how to improve the tool. We will use this information to make changes to the tool as well as develop user manual and training materials.

2. DESCRIPTION OF RESPONDENTS:

A total of three focus groups are planned of up to 20 participants in each. All three focus groups will be with food industry stakeholders who have the responsibility of developing or assisting with the development of a food defense plan within a food facility. We will recruit 20 participants for each focus group.

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

The respondents to this survey are expected to be from the private sector who are food industry stakeholders who have the responsibility of developing or assisting with the development of a food defense plan within a food facility.

**No. of Respondents:** Provide an estimate of the Number of respondents. 60  
**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). 240 minutes.

- 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 (Minutes)</b>	<b>Burden (Hours)</b>
Individuals from the food industry who are responsible for developing and maintaining a facility food defense plan	60	240	240

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

The estimated annual cost to the Federal government is \$89,994.80, which is broken down as follows:

<u>Usability Study Preparation/Planning:</u>	
Staff hours: 40 hours x \$59.13 hourly rate =	\$2,365.20
<u>Usability Study:</u>	
Staff hours: 720 hours x \$59.13 hourly rate =	\$42,573.60
Contract support: 720 hours x \$59.80=	\$43,056.00
Other (administrative support) =	\$2,000.00
<b>Total =</b>	<b>\$89,994.80</b>

## **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?

FDA/CFSAN has longstanding relationships with many stakeholders (i.e., food companies, trade associations, and academia) within the food industry and has worked collaboratively with such stakeholders in the past 14 years on food defense activities. FDA will identify participants utilizing these existing relationships as well as through industry and government contacts within the Food and Agriculture Government Coordinating Council and the Sector Coordination Council. In selecting participants for the focus groups, FDA will attempt to identify individuals who have used version 1.0 of the FDPB as well as users who have never used the tool. FDA would like to also target smaller companies who may not be as familiar with the concept of food defense and food defense planning. Ideally participants will include a good cross section of the food industry as a whole.

**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 (See explanation below)

Participants would be asked to bring their own laptop computer to the focus group session. During the session, a moderator will guide participants through the entire process starting from installing the tool. Then the moderator will walk participants through each section of the tool and allow for time for participants to use and play with

each section of the tool. Then the moderator will ask specific questions about the tool's content, functionality, ease of use, etc. and solicit feedback from participants on how to improve or changes to be made to the tool. Notes will be taken by FDA/CFSAN staff during the discussion portions of the focus group. There will be an internal report generated on the focus group findings but no official analysis or report will be conducted.

2. Will interviewers or facilitators be used?  Yes [ ] No

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

**REQUESTED APPROVAL DATE:** August 13, 2018

**NAME OF PRA ANALYST & PROGRAM CONTACT:**

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**FDA CENTER: Center for Food, Safety, and Applied Nutrition (FDA/CFSAN)**