

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: 0583-0151)

TITLE OF INFORMATION COLLECTION: Enhancing Foodborne Illness Information for Healthcare Providers

PURPOSE:

Surveillance for, and detection of, foodborne disease outbreaks depends importantly upon the ordering of diagnostic tests by clinicians and subsequent testing and reporting by clinical laboratories. FSIS is interested in maximizing early detection and reporting of foodborne illness.

During foodborne illness outbreak investigations, we are often challenged by low numbers of case-patients providing adequate food and purchase histories required for a thorough traceback investigation. Healthcare providers play a key role in the reporting of illnesses that may be part of an outbreak, especially through the submission of clinical specimens for testing. Healthcare providers also have the ability to alert local and state health departments of unusual or above baseline illness clusters. Culture-independent diagnostic testing is being used more frequently by healthcare providers, but these tests don’t allow for pathogens to be submitted for testing that allows for characterization during an outbreak investigation.

This project aims to identify guidance and tools needed for healthcare providers to maximize the diagnosis and management of patients with foodborne illness through the convening of focus groups. These focus groups will consist of representatives from the healthcare community that see patients affected by foodborne illness and, thus, are most likely to order tests for foodborne pathogens and report illnesses.

Findings from the focus groups will be used to identify which clinician groups tend to order tests, perceived or real barriers to clinicians ordering tests, catalog the types of resources (e.g., Up to Date, smartphone apps) most consulted by these clinicians for relevant guidance, identify options for incorporating public health guidance on the diagnosis and reporting of foodborne illness and food safety education materials into these resources, and explore the use of electronic health records in informing the ordering of laboratory tests.

DESCRIPTION OF RESPONDENTS:

These focus groups will consist of representatives from the healthcare community that see patients affected by foodborne illness and, thus, are most likely to order tests for foodborne pathogens and report illnesses. The focus groups will be conducted at 4 regional venues, with 2 focus groups conducted at each location.

TYPE OF COLLECTION: (Check one)

- Customer Comment Card/Complaint Form
- Usability Testing (e.g., Website or Software)
- Focus Group

- Customer Satisfaction Survey
- Small Discussion Group
- Other: _____

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. 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: Geraldine French

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

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [] Yes [X] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [] Yes [] No
3. If Applicable, has a System or Records Notice been published? [] Yes [X] No

Gifts or Payments:

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

We may offer refreshments during the focus group for participants. In addition, we may offer incentives to focus group participants not to exceed a monetary value of \$150 per participant. We anticipate conducting 8 focus groups with 8-10 participants per focus group so the total incentive costs would be within the range of \$9,600-\$12,000.

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time	Burden
Individuals (Healthcare Providers)	80	1.75 hours	140 hours
Totals	80	1.75 hours	140 hours

FEDERAL COST: The estimated annual cost to the Federal government is \$175,000

Contractor support has been procured for this effort. The estimated cost above includes the estimated costs associated with contractor support as well as additional costs for internal travel

and salaries for the FSIS employees who will attend the focus group as observers as well as any recruitment incentives.

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

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?
[X] 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?

Our plan is to work with organizations such as the American College of Emergency Physicians, The American Academy of Family Physicians, and the Infectious Diseases Society of America that have regularly scheduled regional or national meetings this year that are attended by representatives from the healthcare community that see patients affected by foodborne illness. If there are meetings scheduled during the time period of this study that we would like to target, we will work with the organizations to identify the registrants for these meetings and then select a sample of these registrants for participation in the focus groups. We may also target recruitment efforts in identified regions to identify other healthcare providers that may not be represented by these groups, including pediatricians, nurses, or other providers that may see patients affected by foodborne illness. We will have pre-screening questions to ensure that those selected to participate are those providers that regularly see patients affected by foodborne illness. We anticipate that we will select up to 4 regional or national meetings to attend and conduct 2 focus groups at each site location. However, the timing of OMB approval will determine which scheduled regional or national meetings will be selected.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
[] Web-based or other forms of Social Media
[] Telephone
[X] In-person
[] Mail
[] Other, Explain
2. Will interviewers or facilitators be used? [X] Yes [] No

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

Attached are the focus group questions.

Instructions for completing Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback”

TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is the subject of the request. (e.g. Comment card for soliciting feedback on xxxx)

PURPOSE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Provide a brief description of the targeted group or groups for this collection of information. These groups must have experience with the program.

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.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: 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.

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)

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

FEDERAL COST: Provide an estimate of the annual cost to the Federal government.

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.

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.

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