FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF RAPID RESPONSE SURVEYS (0910-0500)

FDA uses the Rapid Response Surveys to further develop tools and science necessary to better understand where vulnerabilities are and the most effective ways to minimize them, as well as to intervene and respond once a problem occurs.

TITLE OF INFORMATION COLLECTION: Surveillance Sampling Outreach

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **What is the problem to be investigated:**
   The proposed collection will investigate the prevalence of disease-causing bacteria in select foods with the ultimate goal of keeping contaminated foods off of the market. Signed into law in 2011, the FDA Food Safety Modernization Act is based on preventing problems before they occur, rather than solely responding to outbreaks of foodborne illness. However, in order to develop prevention-based systems, the FDA needs data and other information to help identify hazards in commodities that must be addressed and minimized. Sampling is an important part of the agency's preventive approach, and the FDA will use a microbiological surveillance sampling model to identify patterns that may help predict and prevent future contamination by disease-causing bacteria.

   For purposes of stakeholder outreach, the FDA intends to follow a plan that features three steps. During the preliminary "Engage" step, the FDA seeks information to inform which hazard-commodity pairs to sample as well as the design of related sampling assignments. In the "Validate" step, the agency shares specific assignment details with external partners and asks follow-up questions. The "Communicate" step is primarily a one-way communication during which the FDA provides final assignment details to external stakeholders to facilitate the assignment, minimize possible disruption to the operation of any food facility, and further efforts to prevent possible future foodborne illnesses.

   The FDA intends to hold 11 industry calls, one for each hazard/commodity pair of food products to be sampled. The 11 calls represent 11 separate information collections, as each commodity is different from the others, with distinct manufacturing and processing and variation in the extent to which they support the growth of microbial hazards. This would include stakeholder calls, with the sample collections for the first two commodities expected to begin in July 2016.

   It is important to note that industry stakeholders have asked the agency to conduct this very outreach. The FDA estimates the burden for each stakeholder to be two hours in all, with the outreach call(s) and the questionnaire completion each taking about one hour.

   The 11 hazard commodity pairs referenced above are:
   - Listeria monocytogenes, Salmonella, and E. coli in Bagged Loose Leaf Lettuce
   - Listeria monocytogenes, Salmonella, and E. coli in Processed Cantaloupe
   - Listeria monocytogenes, Salmonella, and E. coli in Processed Avocado
   - Listeria monocytogenes and E. coli in Combination Sandwiches
   - Listeria monocytogenes, Salmonella, and E. coli in Potato Salad (with Dressing)

- Salmonella, E. coli in Cilantro
- Salmonella, E. coli in Parsley
- Salmonella, E. coli in Basil
- Salmonella in Raspberries
- Salmonella in Blueberries
- Salmonella in Blackberries

The aforementioned microbiological surveillance sampling model ensures that the FDA will collect sufficient data to determine contamination rates for each of the hazard commodity pairs; it specifically involves issuing assignments to FDA field whereby field staff (and possibly State Partners) collect a comparatively large number of samples of a given commodity over a comparatively short time span of 12 to 18 months. This model allows the FDA to more closely consider given commodities, rates, look for trends (such as those pertaining to seasonality, product variety, region, country of origin, or domestic versus import), and conduct follow-up activities based on the findings.

A key aspect of the FDA's model is "External Stakeholder Engagement," the process that the FDA employs to communicate with industry, states (those commissioned to collect samples, and those non-commissioned), foreign governments, consumer groups, and other stakeholders about upcoming sampling assignments to enhance FDA transparency and leverage resources.

2. **Please describe the method to obtain the convenience sample:**
   The FDA plans to engage external stakeholders via the three-step process mentioned above. During the preliminary "Engage" step, the FDA seeks information from industry and other stakeholders to inform which hazard-commodity pairs to sample as well as the design of related sampling assignments. In the "Validate" step, the agency will share specific assignment details with external partners and may ask follow-up questions. The "Communicate" step will be primarily a one-way communication during which the FDA provides final assignment details to external stakeholders for their awareness

   Appendix A lists the questions to be asked for each hazard/commodity group, and a list of stakeholders for each hazard/commodity group is in Appendix B.

3. **Are there any deviations to the described methods, procedures, and uses of data contained in the Rapid Response Survey 2011 Justification Statement:**
   YES / NO (if no skip to #5)

   No

4. **If yes, please describe:**
   N/A

5. **Burden Chart and Description:**
   The FDA estimates that the outreach call(s) and questionnaire for each hazard/commodity pair group will take approximately 1 hour to complete each, for a total estimated burden of 2 hours per stakeholder. Each hazard/commodity group is

anticipated to have up to 25 potential respondents, and the total burden hours for each pair are as follows:

Bagged Loose Leaf Lettuce	50 hours
Processed Cantaloupe	50 hours
Processed Avocado	50 hours
Combination Sandwiches	50 hours
Potato Salad (with Dressing)	50 hours
Cilantro	50 hours
Parsley	50 hours
Basil	50 hours
Raspberries	50 hours
Blueberries	50 hours
Blackberries	50 hours
Total Estimated Burden Hours	550 hours

The FDA has arrived at this estimate based on its expertise and its knowledge that most of the potential respondents are experts in their fields and will be able to comprehensively answer the questions presented to them in the "Engage" step of the project very quickly. Therefore, the total burden for this collection of information is expected to take 550 hours.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Bagged Loose Leaf Lettuce	25	120	50
Processed Cantaloupe	25	120	50
Processed Avocado	25	120	50
Combination Sandwiches	25	120	50
Potato Salad	25	120	50
Cilantro	25	120	50
Parsley	25	120	50
Basil	25	120	50
Raspberries	25	120	50
Blueberries	25	120	50
Blackberries	25	120	50
Total			550

6. **Attach Questions**

Appendix A contains the questions asked of each category or respondent.

REQUESTED APPROVAL DATE: May 20, 2016

NAME OF PRA ANALYST & PROGRAM CONTACT:

FDA: Ila S. Mizrachi, 301-796-7726, ila.mizrachi@fda.hhs.gov
CFSAN: Michael Ellison, 240-402-2093, michael.ellison@fda.hhs.gov

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