U.S. Food and Drug Administration

National Agriculture and Food Defense Strategy Survey

OMB Control No. 0910-NEW

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

We are seeking OMB approval of the National Agriculture and Food Defense Strategy Survey under the Food Safety Modernization Act (Public Law 111-353)(FSMA), section 108) (NAFDS) This is a voluntary survey of State governments intended to gauge government activities in food and agriculture defense from intentional contamination and emerging threats. The collected information will be included in the mandatory 2019 NAFDS followup Report to Congress. The authority for FDA to collect the information derives from the Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(c)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by Federal, State, local, tribal, and territorial governments as well as private sector partners. On January 4, 2011, the President signed FSMA. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention, and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA (NAFDS) requires the Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA), in coordination with the Department of Homeland Security (DHS), to work together with State, local, territorial, and tribal governments-to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA.

2. Purpose and Use of the Information Collection

The NAFDS charts a direction for how the Federal agencies, in cooperation with State, local, territorial, and tribal governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (i.e., 2019, 2023, 2017, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress. FSMA 108-NAFDS directs FDA to coordinate with the agencies to obtain information to complete the NAFDS report. An interagency working group consisting of representatives from HHS, USDA, and DHS will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

HHS/FDA is primarily responsible for obtaining the information from Federal and State, local, territorial, and tribal partners to complete the NAFDS Report to Congress. The proposed voluntary survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or State Agencies have completed (or are planning) from 2015 to 2019. Planning for the local, territorial, and tribal information collections will commence after the collection and reporting of Federal and State Agency level data.

This voluntary survey will be repeated approximately every 2 to 4 years, as described in section 108 of FSMA, NAFDS, for the purpose of monitoring progress in food and agricultural defense by government agencies.

Respondents to this collection are state representatives (survey respondents) who are food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdictions.

3. Use of Improved Information Technology and Burden Reduction

To reduce respondent burden, the survey will be administered electronically and responses accepted electronically. Targeted respondents will receive a link by email to complete the survey online using survey application software designed for highly private information. The survey will be administered by FDA contractors administered using an internal server for data capture. The survey will be conducted electronically on FDA's Web portal, FDA.gov, and the results will be analyzed by the interagency working group. The number of respondents completing the survey electronically is expected to be 100%.

4. Efforts to Identify Duplication and Use of Similar Information

The National Agriculture and Food Defense Strategy Survey is a unique survey instrument. No other survey of Federal and State NAFDS cooperative agreement partners on monitoring food and agriculture defense goals, objectives, key initiatives, and activities related to achieving the goals outlined in the NAFDS is being conducted. Of the Federal Agencies responsible for accomplishing the NAFDS, the Food and Drug

Administration has the primary responsibility for collecting the information that will be used in the first follow-up Report to Congress (estimated 2019) about the status of the national strategy

Therefore, no duplication of information exists for this collection of information.

5. Impact on Small Businesses or Other Small Entities

No small businesses would be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This data collection is important because it is the first follow-up to the NAFDS 2015 Report to Congress. The collection will be the among the first indicators Federal and State response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined within FSMA.

The information for this collection is collected occasionally: the voluntary survey will be repeated approximately every 2 to 4 years to assist in the monitoring progress in food and agricultural defense by government agencies.

If the information from the survey is not collected, FDA will be unable to complete the mandatory 2019 NAFDS follow up report to Congress.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require respondents to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus 2 copies of the information; or, retain records for more than 3 years. The survey design will not produce results that cannot be generalized to the universe of study. The study will not use a methodology that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of March 28, 2018 (83 FR 13284). Although one

comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be offered to respondents.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will be kept secure to the extent provided by law. The survey questionnaire and screener contain a statement that responses will be kept secure to the extent provided by law. Private information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). Identifying information will not be included in the data files received by the agency.

All data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The study does not include any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Survey	49	1	49	0.33 (20 minutes)	16.17

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The FDA Office of Partnership reviewed the questionnaire and provided the amount of time to complete the survey. The total burden is based on our previous experience conducting surveys.

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $917.49 (16.17 hours x $56.74) at the 2017 median wage rate for those in management occupations in the United States.[1]

Table 2. – Estimated Annualized Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Responding to Survey	16.17	$56.74	$917.49

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated cost to the federal government is $10,000. This cost includes FDA staff time to develop the study materials, obtain clearances, contact the sample, collect the survey data, create a database of the data, tabulate and summarize the survey data, and prepare a final report.

15. Explanation for Program Changes or Adjustments

This is a new information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

Activities associated with the outcomes of this survey will consist only of a top-line report summarizing the survey findings included in the NAFDS follow-up Report to Congress. The planned schedule for project activities is shown below.

Project Schedule

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to FDA staff to proceed with data collection activities	Not applicable
Within 60 days after staff notification	Completion of data collection	Not applicable
Within 6 months after receipt of final data files	Insertion of findings into NAFDS follow-up Report to Congress	U.S. Congress

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed August, 2017.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested. FDA is not seeking approval to not display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.