evaluation of surveillance and prevention activities. The OD2A TA Center is designed to enhance the efficiency, coordination, and effectiveness of TA efforts by streamlining and centralizing the provision of overdose surveillance and prevention TA. TA to OD2A recipients is divided into four different levels with multiple modes of TA delivery and involves a wide range of TA providers including CDC staff, internal and external subject matter experts (SMEs), and program partners, as well as contract staff.

The evaluation consists of two web-based surveys designed to collect process and outcome measures about TA access, utilization, and outcomes across all 66 OD2A recipient programs. The Technical Assistance Feedback Form will be administered to collect immediate feedback following individual TA encounters and group events such as webinars and in-person trainings. The Annual OD2A TA Survey will be distributed twice (mid-point and final) to assess satisfaction with overall TA provided and the extent to which TA supports informed implementation of OD2A strategies. The information obtained through this evaluation will allow TA providers to assess OD2A recipients' experience and utility of knowledge and resources gained through individual TA support, peer-to-peer sessions, and other group trainings. Ultimately, the evaluation data will inform subsequent rounds of TA and allow TA providers to make necessary adjustments to the overall TA strategy for continuous quality improvement. This will ensure recipients have the support necessary to implement strategies that will improve opioid surveillance and prevention policies and practices within their communities.

The total annualized burden estimate is 222 hours. There is no cost to respondents other than the time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
OD2A Recipients	TA Feedback Form	671	2	5/60
	Annual OD2A Survey	440	1	13/60
	Email invitation and reminders for OD2A Survey.	440	1	2/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–12208 Filed 6–9–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Agriculture and Food Defense Strategy Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 12, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0855. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

National Agriculture and Food Defense Strategy Survey

OMB Control Number 0910–0855—Extension

We are seeking OMB approval of the National Agriculture and Food Defense Strategy (NAFDS) under section 108 of the FDA Food and Safety Modernization Act (FSMA). This is a voluntary survey of State, local, territorial, and/or tribal (SLTT) 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 NAFDS followup Report to Congress. The authority for us 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 SLTT governments as well as private sector partners. On January 4, 2011, the President signed into law 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 U.S. 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. The NAFDS charts a direction for how Federal Agencies, in cooperation with SLTT 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, 2027, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

FDA is the Agency primarily responsible for obtaining the information from Federal and SLTT partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or SLTT agencies have completed (or are planning on completing) from 2021 to 2025. Planning for the local, territorial, and tribal information collections will commence during this period of renewal. The survey will continue to be repeated approximately every 2 to 4 years, as described in section 108 of FSMA. The NAFDS survey is being administered for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy is employed, such that the government agencies participating in food and agricultural defense are asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction are identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the FDA.gov web portal, and results will be analyzed by the interagency working group.

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

In the **Federal Register** of January 4, 2021 (86 FR 104), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SLTT Surveys	500	1	500	0.33 (20 minutes)	165

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

The FDA Office of Partnerships reviewed the questionnaire and provided the estimate of time to complete the survey. The total burden is based on our previous experiences conducting surveys. The burden has been revised to reflect the total number of States and possible number of local, tribal, and territorial entities that may partake of the survey. Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 149 hours (from 16.17 to 165 hours) and 451 respondents (from 49 to 500 respondents).

Dated: June 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12188 Filed 6–9–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–5338; FDA–2019–E–5346; and FDA–2019–E–5343]

Determination of Regulatory Review Period for Purposes of Patent Extension; EVENITY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for EVENITY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by August 9, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 7, 2021. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 9, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 9, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.