We base our estimate on our review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 3,536 hours. The estimated reporting burden for this information collection is 1,655 hours and the estimated recordkeeping burden for this information collection is 1,881 hours. From FY 2014 to FY 2016, we processed an average of 7,524 responses (requests for certification of batches of color additives) per year. There were 38 different respondents, corresponding to an average of approximately 198 responses from each respondent per year. Using information from industry personnel, we estimate that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

FDA's web-based Color Certification information system allows submitters to request color certification online, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing submitters to sell their certified color before receiving hardcopy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis.

Dated: September 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20245 Filed 9–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0501]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food

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: Fax written comments on the collection of information by October 23, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0643. 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.

Third Party Disclosure and Recordkeeping Requirements for Reportable Food—21 U.S.C. 350f

OMB Control Number 0910–0643—Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), requires the establishment of a Reportable Food Registry (the Registry) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. Section 417 of the FD&C Act (21 U.S.C. 350f) defines ''reportable food'' as an ''article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.'' (Section 417(a)(2) of the FD&C Act.) We believe that the most efficient and cost effective means to implement the Registry is by utilizing our electronic Safety Reporting Portal. The information collection provisions associated with the submission of reportable food reports has been approved under OMB control number 0910–0643.

In conjunction with the reportable foods requirements, section 417 of the FD&C Act also establishes third party disclosure and recordkeeping burdens. Specifically, we may require the responsible party to notify the immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (section 417(d)(6)(B)(i) to (ii) of the FD&C Act). Similarly, we may also require the responsible party that is notified (*i.e.,* the immediate previous source and/or immediate subsequent recipient) to notify their own immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (section 417(d)(7)(C)(i) to (ii) of the FD&C Act).

Notification to the immediate previous source(s) and immediate subsequent recipient(s) of the article of food may be accomplished by electronic communication methods such as email, fax, or text messaging or by telegrams, mailgrams, or first-class letters. Notification may also be accomplished by telephone call or other personal contacts but we recommend that such notifications also be confirmed by one of the previous methods and/or documented in an appropriate manner. We may require that the notification include any or all of the following data elements: (1) The date on which the article of food was determined to be a reportable food; (2) a description of the article of food including the quantity or amount; (3) the extent and nature of the adulteration; (4) the results of any investigation of the cause of the adulteration if it may have originated with the responsible party, if known; (5) the disposition of the article of food, when known; (6) product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food; (7) contact information for the responsible party; (8) contact information for parties directly linked in the supply chain and notified under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act, as applicable; (9) the information required by FDA to be included in the notification provided by the responsible party involved under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act or required to report under section 417(d)(7)(A) of the FD&C Act; and (10) the unique number described in section 417(d)(4) of the FD&C Act (section 417(d)(6)(B)(iii)(I), (d)(7)(C)(iii)(I), and (e) of the FD&C Act). We may also require that the notification provides information about the actions that the recipient of the notification will perform and/or any other information we may require (section 417(d)(6)(B)(iii)(II) and (III), (d)(7)(C)(iii)(II) and (III) of the FD&C Act).

Section 417(g) of the FD&C Act requires that responsible persons

maintain records related to reportable foods for a period of 2 years.

The congressionally identified purpose of the Registry is to provide ''a reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health'' (FDAAA, section 1005(a)(4)). The reporting and recordkeeping requirements described previously are designed to enable FDA to quickly identify and track an article of food (other than infant formula) for which there is a reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals. We use the information collected under these provisions to help ensure that such products are quickly and efficiently removed from the market.

As required under section 1005(f) of FDAAA and to assist industry, we have issued the guidance document entitled, ''Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007,'' which is available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm180761.htm.* The guidance contains questions and answers relating to the requirements under section 417 of the FD&C Act, including: (1) How, when, and where to submit reports to FDA; (2) who is required to submit reports to FDA; (3) what is required to be submitted to FDA; and (4) what may be required when providing notifications to other persons in the supply chain of an article of food. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in questions 20 and 21 of the guidance have been approved under OMB control number 0910–0249.

Description of Respondents: Mandatory respondents to this collection of information are the owners, operators, or agents in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States (''responsible parties'') who have information on a reportable food. Voluntary respondents to this collection of information are Federal, State, and local public health officials who have information on a reportable food.

In the **Federal Register** of June 7, 2017 (82 FR 26489), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notifying immediate previous source of the article of food under section 417(d)(6)(B)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(6)(B)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the FD&C Act (mandatory reporters only).	1	1,200	0.6 (36 minutes)	720.	
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Total	.....	.....	.....	.....	2,880

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

Third Party Disclosure: We estimate that approximately 1,200 reportable food events with mandatory reporters will occur annually. Based on past FDA experiences, we estimate that we could receive 200 to 1,200 ''reportable'' food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. We utilized the upper-bound estimate of 1,200 for these calculations.

We estimate that notifying the immediate previous source(s) will take 0.6 hours per reportable food and notifying the immediate subsequent recipient(s) will take 0.6 hours per reportable food. We also estimate that it will take 0.6 hours for the immediate previous source and/or the immediate subsequent recipient to also notify their immediate previous source(s) and/or immediate subsequent recipient(s). The Agency bases its estimate on its experience with mandatory and voluntary reports submitted to FDA.

Although it is not mandatory under FDAAA, section 1005, that responsible persons notify the sources and recipients of instances of reportable food, for purposes of the burden estimate we are assuming FDA would exercise its authority and require such notifications in all such instances for mandatory reporters. This notification burden will not affect voluntary reporters of reportable food events. Therefore, we estimate that the total burden of notifying the immediate previous source(s) and immediate subsequent recipient(s) under section 417(d)(6)(B)(i) and (ii), (d)(7)(C)(i) and (ii) of the FD&C Act for 1,200 reportable foods will be 2,880 hours annually ($1,200 \times 0.6$ hours) + ($1,200 \times 0.6$ hours) + ($1,200 \times 0.6$ hours) + ($1,200 \times 0.6$ hours). This annual burden is shown in table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of reportable food records under section 417(g) of the FD&C Act—mandatory reports.	1,200	1	1,200	0.25 (15 minutes)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act—voluntary reports.	4	1	4	0.25 (15 minutes)	1
Total	.....	.....	.....	.....	301

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

Recordkeeping: As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications under section 417 of the FD&C Act for a period of 2 years. Based on past FDA experiences, we estimate that each mandatory report and its associated notifications will require 30 minutes of recordkeeping for the 2-year period, or 15 minutes per record per year. The annual recordkeeping burden for mandatory reportable food reports and their associated notifications is thus estimated to be 300 hours ($1,200 \times 0.25$ hours).

We do not expect that records will always be kept in relation to voluntary reportable food reports. Therefore, we estimate that records will be kept for four voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 1 hour annually (4×0.25 hours). The estimated total annual recordkeeping burden will be 301 hours annually ($1,200 \times 0.25$ hours) + (4×0.25 hours). This annual burden is shown in table 2.

Dated: September 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–20283 Filed 9–21–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0019]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Customer/Partner Service Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Fax written comments on the collection of information by October 23, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0360. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Customer/Partner Service Surveys

OMB Control Number 0910–0360—Extension

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the Agency. Executive Order 12862, entitled, ''Setting Customer Service Standard,'' directs Federal Agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as food processors; cosmetic drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers ''partner'' (State and local governments) customer service surveys.

FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will measure timeliness, appropriateness and accuracy of information, and courtesy and problem resolution in the context of individual programs.

FDA estimates conducting 15 customer/partner service surveys per year, each requiring an average of 15 minutes for review and completion. We estimate respondents to these surveys to be between 100 and 20,000 customers. Some of these surveys will be repeats of earlier surveys for purposes of monitoring customer/partner service and developing long-term data.

In the **Federal Register** of June 7, 2017 (82 FR 26497), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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