primarily a coding worksheet designed to facilitate data reduction and retrieval into the ASPEN system. The information needed to make certification decisions is available to us only through the use of information abstracted from the form.

Form Numbers: CMS–1856 and CMS–1893 (OMB control number: 0938–0065); *Frequency:* Annually, occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 700; *Total Annual Responses*: 700; *Total Annual Hours:* 613. (For policy questions regarding this collection contact James Cowher at 410–786–1948.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Reporting Requirements for Grants to States for Rate Review Cycle I, Cycle II, Cycle III, and Cycle IV and Effective Rate Review Program; *Use:* Under the section 1003 of the Affordable Care Act (ACA) (section 2794 of the Public Health Service Act), the Secretary, in conjunction with the states and territories, is required to establish a process for the annual review, beginning with the 2010 plan year, of unreasonable increases in premiums for health insurance coverage. Section 2794(c) requires the Secretary to establish the Rate Review Grant Program to states to assist states to implement this provision. In addition, section 2794(c) requires the Rate Review Grant Program to assist states in the establishment and enhancement of ''Data Centers'' that collect, analyze, and disseminate health care pricing data to the public.

Concurrent with this information collection request (ICR), HHS released Cycle IV of the Rate Review Grants, ''Grants to States to Support Health Insurance Rate Review and Increase Transparency in the Pricing of Medical Services.'' The purpose of Cycle IV of the Rate Review Grant Program is to continue the rate review successes of Cycles I, II, and III, as well as to provide greater support to Data Centers, thereby enhancing medical pricing transparency. States and territories that apply for funds are required to complete the grant application. States and territories that are awarded funds under this funding opportunity are required to provide the Secretary with rate review data, four quarterly reports, and one annual report per year until the end of the grant period detailing the state's progression towards a more comprehensive and effective rate review process. A final report is due at the end of the grant period. This information collection is required for effective monitoring of grantees and to fulfill statutory requirements under section 2794(b)(1)(A) of the ACA that requires grantees, as a condition of receiving a grant authorized under section 2794(c), to report to the Secretary information about premium increases.

On May 23, 2011, CMS published a final rule with comment period (76 FR 29964) to implement the annual review of unreasonable increases in premiums for health insurance coverage called for by section 2794. Under the regulation, if CMS determines that a state has an Effective Rate Review Program in a given market, using the criteria set forth in the rule, CMS will adopt that state's determinations regarding whether rate increases in that market are unreasonable, provided that the state reports its final determinations to CMS and explains the bases of its determinations. The final rule titled ''Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review'' (78 FR 13406; February 27, 2013) amends the standards under the Effective Rate Review Program. Currently, CMS relies on publicly available information and annual calls with individual states to obtain the information needed to evaluate whether a state has begun to or continues to satisfy the Effective Rate Review Program criteria. CMS is proposing to instead collect the information in writing from all states that would like to request effective status. No comments were received in response to the 60-day **Federal Register** notice published on June 2, 2014 (79 FR 31336). *Form Number:* CMS–10380 (OMB control number: 0938–1121); *Frequency:* Annually and On occasion; *Affected Public:* Public Sector and State and Territory Governments; *Number of Respondents:* 50; *Total Annual Responses:* 553; *Total Annual Hours:* 20,951. (For policy questions regarding this collection contact Susie Lorden at 301–492–4162.)

Dated: August 19, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–20041 Filed 8–22–14; 8:45 am]

BILLING CODE 4120–01–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 September 24, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE–14526, Silver Spring, MD 20993–0002 *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 0910–0645.

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 (sections 417(d)(6)(B)(i) and (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 (sections 417(d)(7)(C)(i) and (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 sections 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act or required to report under sections 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 (sections 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 (sections 417(d)(6)(B)(iii)(II), (d)(6)(B)(iii)(III), (d)(7)(C)(iii)(II), and (d)(7)(C)(iii)(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'' (Pub. L. 110–85, 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 regulations 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 draft guidance document entitled, ''Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2),'' which is available at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/RFR/ucm212793.htm*. The draft 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 D5 and D6 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 3, 2014 (79 FR 31946), 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

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

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)(7)(C)(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)(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), (d)(6)(B)(ii), (d)(7)(C)(i), and (d)(7)(C)(ii) of the FD&C Act for 1,200 reportable foods will be 2,880 hours annually (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 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 recordkeeping	Total annual records [2]	Average burden per record	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.	600	1	600	0.25 (15 minutes) ..	150
Total	.....	.....	.....	.....	450

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

[2] For purposes of estimating number of records and hours per record, a ''record'' means all records kept for an individual reportable food by the responsible party or a voluntary reporter.

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 × 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 600 of the 1,200 voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 150 hours annually (600 × 0.25 hours). The estimated total annual recordkeeping burden will be 450 hours annually (1,200 × 0.25 hours) + (600 × 0.25 hours). This annual burden is shown in table 2.

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20021 Filed 8–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Advisory Committee Renewals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of certain FDA advisory committees by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the