Dated: February 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0501]

Agency Information Collection Activities; Submission for Office and Management 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 March 29, 2010.

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 e-mailed 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: Denver Presley Jr., Office of Information Management (P150–400B), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–796–3793

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

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85). Section 1005 of FDAAA amends the Federal Food, Drug, and Cosmetic Act (the act) by creating a new section 417 (21 U.S.C. 350f), among other things. Section 417 of the act requires the Secretary of Health and Human Services (the Secretary) to establish within the Food and Drug Administration (FDA) a Reportable Food Registry (the Registry). The Secretary has delegated to the Commissioner of FDA the responsibility for administering the act, including section 417.

Section 417 of the act 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 act). Section 417 of the act requires FDA to establish an electronic portal (the Reportable Food electronic portal) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. FDA made the decision that the most efficient and cost effective means to implement the requirements of section 417 of the act relating to the Registry was to utilize the business enterprise system currently under development within the agency: The MedWatchPlus Portal. The electronic portal became operational on September 8, 2009. The collection of information associated with the submission of reportable food reports to FDA using the MedWatchPlus electronic portal has been approved under OMB Control No. 0910–0645.

In addition, section 1005(f) of FDAAA required FDA to issue guidance to industry about submitting reports through the electronic portal of instances of reportable food and providing notifications to other persons in the supply chain of such article of food. FDA issued guidance containing questions and answers relating to the requirements under section 417 of the 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 agency announced the availability of the guidance document titled "Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007," on September 9, 2009 (74 FR 46434). The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in question 28 of the guidance have been approved under OMB Control No. 0910–0249.

Section 417 of the act established third party disclosure and recordkeeping burdens associated with the Reportable Food Registry. Specifically, FDA may require the responsible party to notify the immediate previous source(s) and/or immediate subsequent recipient(s) of the reportable food (sections 417(d)(6)(B)(i) and 417(d)(6)(B)(ii) of the act). Similarly, FDA 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 the reportable food (sections 417(d)(7)(C)(i) and 417(d)(7)(C)(ii) of the 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 e-mail, 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 FDA recommends that such notifications also be confirmed by one of the above methods and/or documented in an appropriate manner. FDA 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 sections 417(d)(6)(B) or 417(d)(7)(C) of the 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 act or required to report under section 417(d)(7)(A) of the act; and (10) the unique number described in section 417(d)(4) of the act. (sections 417(d)(6)(B)(iii)(I), 417(d)(7)(C)(iii)(I), and 417(e) of the act). FDA may also require that the notification provide information about the actions that the

recipient of the notification shall perform and/or any other information FDA may require. (sections 417(d)(6)(B)(iii)(II) and 417(d)(6)(B)(iii)(III), 417(d)(7)(C)(iii)(II), and 417(d)(7)(C)(iii)(III) of the act).

Section 417(g) of the act requires that responsible persons maintain records related to reportable foods reports and notifications under section 417 of the act 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" (Pubic Law 110–085, section 1005(a)(4)). The third party disclosure 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. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market.

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 accordance with 5 CFR 1320.8(d), in the **Federal Register** of October 20, 2009 (74 FR 53746), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two letters in response to the notice before the close of the comment period, each containing one or more comments.

(Comment 1) One comment argued that FDA underestimated the burden of notifying the immediate previous source(s) and the immediate subsequent recipient(s) of the article of food because it underestimated the potential number of such sources and recipients that may require notification. The comment stated that there could be more than 12,500 different sources for the grain portion of a single shipment of finished feed, and more than 80 different immediate previous sources for the other feed ingredients present. Similarly, another comment argued that FDA underestimated the burden of notifying the immediate previous source(s) and the immediate subsequent recipient(s) of the article of food because it assumed only one previous source and one subsequent recipient.

(Response) FDA appreciates the data provided in the comment. However, the agency notes that the comment did not provide any proposed change to the burden hours set forth. Thus, FDA has not changed the burden hour estimate in table 1 of this document. Please note that we expect to be able to obtain relevant data from the electronic reporting system that we can use to better estimate the burden of this reporting. We also note that this burden is imposed by the law itself. The reporting to immediate previous source(s) and immediate subsequent recipient(s) of a reportable food is authorized by sections 417(d)(6)(B)(i), 417(d)(6)(B)(ii), 417(d)(7)(C)(i), and 417(d)(7)(C)(ii) of the act. FDA has no way of knowing how long each supply chain is or how many ingredients will be involved with each reportable event. However, we did attempt to account for this reporting. We estimated burdens assuming two immediate previous sources and two immediate subsequent recipients for each of the 1,200 estimated annual reportable food events.

(Comment 2) One comment argued that FDA underestimated the burden of notifying the immediate previous source(s) and the immediate subsequent recipient(s) of the article of food, arguing that the 0.6 hours estimated by the agency does not adequately allow for recall notification writing, editing, review and approval by the notifying entity and FDA. The comment estimated that it would take a minimum of 4 hours to prepare an FDA-approved Class I recall notification. The comment further argued that recall followup activities and communications between the affected entity(ies) and the FDA will take additional time.

(Response) FDA disagrees and notes that the comment references the Class I recall procedures governed by part 7 of FDA's regulations (21 CFR part 7). We did not estimate a burden for this process because the procedures and the associated burden estimates have already been approved under OMB control number 0910–0249 (FDA Recall Regulations, 21 CFR part 7).

(Comment 3) One comment argued that FDA underestimated the burden of notifying the immediate previous source(s) and the immediate subsequent recipient(s) of the article of food because it assumed that one form of notification, noting that multiple methods of notification are typically necessary: E-mail, facsimile, and postal mail.

(Response) FDA disagrees. With regard to the method of notification for the purposes of this information collection, as described elsewhere in this document, notification may be accomplished by electronic communication methods such as e-mail, 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 FDA recommends that notifications also be confirmed or documented in an appropriate manner. Multiple forms of notifications are not required and, therefore, were not included in the burden estimate.

Third Party Disclosure

FDA estimates that approximately 1,200 reportable food events with mandatory reporters will occur annually. FDA received 625 voluntary food complaints leading to adverse events from January 1, 2008, to June 30, 2008, and there were 206 and 182 Class 1 Recalls for human food in Fiscal Years 2006 and 2007, respectively. Based on these experiences, FDA estimates that FDA could receive 200 to 1,200 "reportable" food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. FDA will utilize the upper-bound estimate of 1,200 for these calculations (73 FR 63153 at 63157 (October 23, 2008); 74 FR 23721 at 23727 (May 20, 2009)).

FDA estimates 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. FDA also estimates 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 recently submitted to FDA that would be considered reportable food reports in the future. (73 FR at 63157).

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, FDA estimates that the total

burden of notifying the immediate previous source(s) and immediate subsequent recipient(s) under sections 417(d)(6)(B)(i) and 417(d)(6)(B)(ii) and 417(d)(7)(C)(i) and 417(d)(7)(C)(ii) of the act for 1,200 reportable foods will be 2,880 hours annually (1,200 x 0.6 hours) + (1,200 x 0.6 hours) + (1,200 x 0.6 hours) + (1,200 x 0.6 hours).

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

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

Activity	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
Notifying immediate previous source of the article of food under section 417(d)(6)(B)(i) of the act	1,200	1	1,200	0.6	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(6)(B)(ii) of the act	1,200	1	1,200	0.6	720
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the act	1,200	1	1,200	0.6	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the act	1,200	1	1,200	0.6	720
Total					2,880

[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 act requires that responsible persons maintain records related to reportable foods reports and notifications under section 417 of the act for a period of 2 years. 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. FDA bases its estimate on its experience with recordkeeping for food and cosmetics derived from cattle materials (71 FR 59653 at 59667; October 11, 2006). The annual recordkeeping burden for mandatory reportable food reports and their associated notifications is thus estimated to be 300 hours (1,200 x 0.25 hours).

We do not expect that records will always be kept in relation to voluntary reportable food reports. Therefore FDA estimates 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 x 0.25 hours). The estimated total annual recordkeeping burden is shown in table 2 of this document.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records[2]	Hours per Record	Total Hours
Maintenance of reportable food records under section 417(g) of the act—Mandatory reports	1,200	1	1,200	0.25	300
Maintenance of reportable food records under section 417(g) of the act—Voluntary reports	600	1	600	0.25	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.

Dated: February 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0088]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reporting and recordkeeping, general and specific requirements, and the availability of sample electronic products for manufacturers and distributors of electronic products.

DATES: Submit written or electronic comments on the collection of information by April 27, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products (OMB Control Number 0910–0025)—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in title 21 of the Code of Federal Regulations, chapter I, subpart J, parts 1000 through 1050 (parts 1002 through 1050).

Section 532 of the act directs the Secretary of the Department of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) of the act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliances with performance standards. Section 537(b) of the act contains the authority to require manufacturers of electronic products to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

21 CFR parts 1002 through 1010 specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall.

FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050.

FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the act or were developed to aid the agency in performing its obligations under the act. The data reported to FDA and the records maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection:

- FDA Form 2579 "Report of Assembly of a Diagnostic X-Ray System"
- FDA Form 2767 "Notice of Availability of Sample Electronic Product"
- FDA Form 2877 "Declaration for Imported Electronic Products Subject To Radiation Control Standards"
- FDA Form 3649 "Accidental Radiation Occurrence (ARO)"