TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
101.14(d)(2)	300,000	1.5	450,000	0.75	337,500
101.22(i)(4)	25	1	25	1	25
101.100(d)(2)	1,000	1	1,000	1	1,000
101.105(t)	100	1	100	1	100
Total					676,150

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

TABLE 3—ESTIMATED REPORTING BURDEN[1]

21 CFR Section/ Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.9(j)(18) and 101.36(h)(2)/ Form FDA 3570	10,000	1	10,000	8	80,000

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

The estimated annual reporting and recordkeeping burdens are based on agency communications with industry and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

In this request for extension of OMB approval under the PRA, FDA is combining the burden hours associated with OMB control numbers 0910–0395 (collection entitled ''Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis'') and 0910–0515 (collection entitled ''Food Labeling: Trans Fatty Acids in Nutrition Labeling'') with the burden hours approved under OMB control number 0910–0381 (collection entitled ''Food Labeling Regulations'').

Dated: October 9, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25102 Filed 10–19–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0501]

Agency Information Collection Activities; Proposed Collection; 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 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 the information collection provisions of FDA's third party disclosure and recordkeeping requirements for reportable food.

DATES: Submit written or electronic comments on the collection of information by December 21, 2009.

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: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, *Jonnalynn.Capezzuto@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.

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 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.'' (see 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 entitled ''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 (see section 417(d)(6)(B)(i) and (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 (section 417(d)(7)(C)(i) and (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 previous 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 (section 417(d)(6)(B)(iii)(I), (d)(7)(C)(iii)(I), and (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 (section 417(d)(6)(B)(iii)(II), (d)(6)(B)(iii)(III), (d)(7)(C)(iii)(II), and (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'' (Public 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.

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

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 63153 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 section 417(d)(6)(B)(i), (d)(6)(B)(ii), (d)(7)(C)(i), and (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).

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.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records[2]	Hours per Records	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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records[2]	Hours per Records	Total Hours
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: October 13, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25100 Filed 10–19–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0487]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

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 guidance on informed consent for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable.

DATES: Submit written or electronic comments on the collection of information by December 21, 2009.

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: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—OMB Control Number 0910–0582—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812 (21 CFR part 812), Investigational Device Exemptions, under § 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1; 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed