Acquisition Regulation, Regulatory Secretariat (VPR) will be submitting to the Office of Management and Budget (OMB) a request to reinstate a previously approved information collection requirement concerning Economic Purchase Quantity—Supplies.

Public comments are particularly invited on: Whether this collection of information is necessary; whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before August 17, 2009.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC 20405. Please cite OMB Control No. 9000–0082, Economic Purchase Quantity—Supplies, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Ms. Lori Sakalos, Procurement Analyst, Contract Policy Division, GSA, (202) 208–0498.

SUPPLEMENTARY INFORMATION:

A. Purpose

The provision at 52.207–4, Economic Purchase Quantity—Supplies, invites offerors to state an opinion on whether the quantity of supplies on which bids, proposals, or quotes are requested in solicitations is economically advantageous to the Government. Each offeror who believes that acquisitions in different quantities would be more advantageous is invited to (1) recommend an economic purchase quantity, showing a recommended unit and total price, and (2) identify the different quantity points where significant price breaks occur. This information is required by Public Law 98–577 and Public Law 98–525.

B. Annual Reporting Burden

Respondents: 1,524.
Responses per Respondent: 25.
Annual Responses: 38,100.
Hours per Response: .83.
Total Burden Hours: 31,623.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC, 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0082, Economic Purchase Quantity—Supplies, in all correspondence.

Dated: June 9, 2009.

Al Matera,

Director, Office of Acquisition Policy.

[FR Doc. E9–14105 Filed 6–15–09; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0261]

Agency Emergency Processing Under Office of Management and Budget Review; Reporting and Recordkeeping Requirements for Reportable Food Registry

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). This notice solicits comments on the proposed collection of information associated with 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.'' The draft guidance, when finalized, will assist the industry in complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Fax written comments on the collection of information by July 16, 2009. FDA is requesting approval of this emergency processing by August 17, 2009.

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: 202–395–6974. 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.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. On September 27, 2007, the President signed FDAAA into law (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 to establish, within FDA, a Reportable Food Registry (the Registry); the Registry is to be established not later than 1 year after the date of enactment (i.e., by September 27, 2008).

To further the development of the Registry, section 417 of the act requires FDA to establish, also within 1 year after the date of enactment (i.e., by September 27, 2008), 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 MedWatch^{Plus} Portal. This would permit the agency to establish an electronic portal through which instances of reportable food may be submitted to the agency. However, FDA recognized that the MedWatch^{Plus} Portal would not be implemented in time to meet the September 27, 2008, deadline for establishing the Reportable Food electronic portal and therefore announced that it was delaying its implementation until spring 2009 (73 FR 30405; May 27, 2008).

The agency now expects the system to be operational on September 8, 2009.

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. In a notice published in the **Federal Register** of June 11, 2009, FDA announced the availability of 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.''

Because this guidance involves a collection of information, the PRA is implicated. However, the delay associated with normal PRA clearance procedures can reasonably be anticipated to prevent the finalization of the agency's guidance document in advance of the launch of the portal on September 8, 2009. As a result, given the need for immediate action, FDA requests emergency processing of this collection of information request.

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.

Title: Reporting and Recordkeeping Requirements for Reportable Food Registry

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.

The draft guidance restates the requirements of section 417 of the act and presents FDA's recommendations for complying with section 417 of the act. 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 110–85, section 1005(a)(4) of FDAAA). To further the development of the Registry, section 417 of the act requires FDA to establish an electronic portal by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials.

Responsible parties will be required to submit reports regarding instances of reportable food via the Reportable Food electronic portal established by FDA: The MedWatch^{Plus} portal. The MedWatch^{Plus} portal is a new electronic system for collecting, submitting and processing adverse event reports and other safety information for all FDA-regulated products and includes the Reportable Food electronic portal. FDA is developing and implementing the MedWatch^{Plus} portal in a phased fashion. Responsible parties must comply with section 417 of the act using the Reportable Food electronic portal on September 8, 2009. The prohibited act provisions of the act related to the Registry will also apply on September 8, 2009.

Reporting

Under section 417(d)(1) of the act, the ''responsible party'' must submit a report to FDA through the Reportable Food electronic portal including certain information on a reportable food (''reportable food report''). The ''responsible party'' is defined in section 417(a)(1) of the act as a person that submits the registration under section 415(a) of the act (21 U.S.C. 360d(a)) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. Persons who are required to submit a facility registration under section 415 of the act are the owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States. A ''reportable food'' is defined in section 417(a)(2) of the act 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.

The MedWatch^{Plus} Portal will provide one central point-of-entry for persons submitting information to FDA regarding the safety of FDA-regulated products. The agency believes that providing one central point-of-entry will better enable persons to submit their information to FDA. In addition, mandatory reporters will be able to use the Internet to access the MedWatch^{Plus} Portal to report safety concerns about human and animal food, thus fulfilling the mandatory reporting requirements of FDAAA that are the subject of the draft guidance.

In the **Federal Register** of October 23, 2008 (73 FR 63153), FDA requested public comments on a proposed collection of information entitled ''Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire.'' In that document, the agency calculated the reporting burden for reportable food reports. Specifically, the agency estimated the number of respondents and the total annual responses for reportable food based on the mandatory and voluntary reports recently submitted to FDA that would be considered reportable food reports in the future (73 FR 63153 at 63156 and 63157). FDA estimated that it would receive 200 to 1,200 reportable food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. The agency based these estimates on the receipt of 625 voluntary food complaints leading to adverse events from January 1, 2008, to June 30, 2008, and also on the 206 and 182 Class 1 Recalls for human food that took place in fiscal years 2006 and 2007, respectively. FDA utilized the upper-bound estimate of 1,200 reports per year for calculating the reportable food reporting burden. FDA estimated the reporting burden for a mandatory reportable food report to be 0.6 hours, for a total burden of 720 hours annually (1,200 reports $\times$ 0.6 hours = 720 hours). FDA estimated the reporting burden for a voluntary reportable food report to be 0.6 hours, for a total burden of 720 hours annually (1,200 reports $\times$ 0.6 hours = 720 hours). The estimated total annual responses are based on initial reports and amendments to those reports. These burden estimates have been submitted to OMB in the proposed collection of information entitled ''Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire,'' which is currently under review (74 FR 23721; May 20, 2009).

In addition to the burden estimates submitted to OMB for approval, the agency has subsequently determined that there will be additional reporting burdens associated with the Registry requirements of FDAAA. Specifically, FDA may require the responsible party to notify the immediate previous source and/or immediate subsequent recipient of the reportable food (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 and/or immediate subsequent recipient of the reportable food (section

417(d)(7)(C)(i) and (d)(7)(C)(ii) of the act). We estimate these reporting burdens in the following paragraphs.

Notification to the immediate previous source and immediate subsequent recipient 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 previously mentioned 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 section 417(d)(6)(B) or (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 section 417(d)(6)(B) or (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).

FDA estimates that notifying the immediate previous recipient will take 0.6 hours per reportable food and notifying the immediate subsequent recipient 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 and/or immediate subsequent recipient. 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).

FDA estimates that all mandatory reports will require that the immediate previous source and subsequent recipient be notified. We do not expect that this notification burden will apply to voluntary reporters of reportable foods. Therefore, the total estimated burden of notifying the immediate previous source and immediate subsequent recipient 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 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours). FDA's utilization of an upper-bound estimate of 1,200 reports and 0.6 hours per report is likely an overestimate of the number of reports that may be received and an overestimate of the time necessary to notify 1 immediate previous source and 1 immediate subsequent recipient. However, these overestimates may be justified because FDA cannot know how often multiple immediate previous sources or immediate subsequent recipients may need to be notified for each reportable food event. FDA requests comment on these burden estimates.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	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 or operating and maintenance costs associated with this collection of information.

Recordkeeping

The agency has determined that there will be recordkeeping burdens associated with FDAAA. 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 a similar ''per event'' type of recordkeeping for food and cosmetics derived from cattle materials. For that recurring recordkeeping burden, which involves sending, verifying, and storing documents regarding shipments of cattle material used in human food and cosmetics, we estimated that the recurring recordkeeping burden would be about

15 minutes per week (71 FR 59653 at 59667; October 11, 2006).

The annual recordkeeping burden for mandatory 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 reporting, nor is any such recordkeeping required by section 417 of the act. 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 × 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 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.

The draft 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.

Dated: June 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–14048 Filed 6–15–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NIH Intramural Research Training Program Applications

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NIH Intramural Research Training Program Applications.

Type of Information Collection Request: Revision/OMB No. 0925–0299; 8/31/2009.

Need and Use of Information Collection: The proposed information collection activity is for the purpose of collecting applicant data for Training Fellowships in the NIH Intramural Research Program. This information must be submitted in order to receive due consideration for a fellowship and will be used to determine the eligibility and quality of potential awardees.

Frequency of Response: On occasion.

Affected Public: Individuals seeking intramural training opportunities and references for these individuals.

Type of Respondents: Postdoctoral, predoctoral, postbaccalaureate, technical, clinical, and student IRTA applicants.

There are no capital costs, operating costs, and/or maintenance costs to report.

Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Postdoctoral	3,424	2.00	1.00	6,848
Predoctoral	1,458	1.00	1.00	1,458
Postbaccalaureate	4,750	1.00	1.00	4,750
Technical	233	1.00	1.00	233
Clinical	400	1.00	1.00	400
Student	14,334	1.00	1.00	14,334
All categories (Race/Gender/Ethnicity survey)	4,307	1.00	0.25	1,077
References for all categories	38,725	1.00	1.00	38,725
Total	67,631	1.125	0.90625	67,825