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

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Operating and Maintenance Costs	Total Hours
820.198(a) through (c)	8,924	1	8,924	5		44,620
820.200(a) and (d)	8,924	1	8,924	3		26,772
820.25	8,924	1	8,924	1		8,924
Total					1,300,805	3,105,552

[1] There are no capital costs associated with this collection of information.

Explanation of Recordkeeping Burden Estimate

FDA estimates respondents will have a total annual recordkeeping burden of approximately 3,105,552 hours. This figure also consists of approximately 143,052 hours spent on a startup basis by 734 new firms.

Burden (labor) hour and cost estimates were originally developed under FDA contract by Eastern Research Group, Inc. (ERG) in 1996 when the CGMP/QS regulation became final. Additional factors considered in deriving estimates included the following:

- Establishment type: Query has been made of CDRH's registration/listing data bank and the current count was 7,748 domestic firms subject to CGMPs. It was also calculated that each year, the number of new domestic firms subject to CGMPs is 734. The average amount of firms therefore subject to CGMPs over the 3 years is therefore 8,924 and this figure has been used to calculate the total burden. Because the total number of registered firms is not static, the number of respondents will fluctuate from year to year resulting in slight changes to the overall burden.
- During the last report it was estimated that this number was 8,963. When the last set of numbers was calculated, FDA was still using a paper based system to register and list firms. On October 1, 2007, FDA switched to an electronic system for registration and listing. Also at that time the Food and Drug Administration Amendments Act of 2007 instituted an establishment registration fee for some types of facilities. FDA believes that during the FY 2008 annual registration cycle, establishments that had previously registered but were not required to do so, removed themselves from inventory of active establishments. FDA believes that the current figures reported by the electronic system more accurately reflect the inventory of registered establishments.
- Potentially affected establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to Quality Policy (§ 820.20(a)), Document Control (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to Subpart C, Design Controls. The type of firm subject to each requirement was identified by the ERG.
- FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992, under OMB Paperwork Reduction Act Control Number 0910–0073. It was approved by OMB on July 16, 1992, and expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became final rule. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 8,924 respondents), which compensates for differences in methodology.

Dated: June 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15338 Filed 6–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0180]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adoption of the Food and Drug Administration Food Code by Local, State, and Tribal Governments

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 July 26, 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 0910–0448. 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, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, 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.

Adoption of the FDA Food Code by Local, State, and Tribal Governments—42 U.S.C. 243(a) (OMB Control Number 0910–0448)—Extension

FDA has developed its model Food Code to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal governmental agencies that have primary responsibility for the regulation or oversight of retail level food operations. The FDA Food Code provides a scientifically sound technical and legal basis for regulating the retail segment of the food industry. Authority for providing such assistance is derived from section 311(a) of the Public Health Service Act (42 U.S.C. 243(a)). Under 31 U.S.C. 1535, FDA provides assistance to other Federal agencies such as the Indian Health Service (IHS).

Nationwide adoption of the model FDA Food Code is an important step toward the agency's goal for consistent, scientifically sound, and risk-based food safety standards and practices. A current, comprehensive, and accurate inventory of food code adoptions by States and U.S. territories, local, and tribal governments is necessary to determine the status of up-to-date protection of the U.S. population and to identify areas where assistance to these governments may promote the adoption of regulations based on the FDA Food Code.

This collection effort, which began in 2001, has had remarkable success with 97 percent participation from State and territorial governmental agencies. FDA contracted with the Association of Food and Drug Officials (AFDO) to conduct the initial survey using the OMB approved survey form. The rulemaking process that local, State, territorial, and tribal governmental agencies must follow to adopt the model FDA Food Code is often a long and complicated process that can extend for several years. For this reason, many agencies have reported that they are still in the rulemaking process to adopt or update their food codes. Thus, FDA believes that extension of OMB approval of the survey is needed in order to keep the current database accurate and up-to-date. The contractor will collect the information electronically and/or telephonically and will be able to provide respondents with previous survey responses already in the database. Respondents to this information collection are States and U.S. territories, local, and tribal governmental agencies.

In the **Federal Register** of April 14, 2010 (71 FR 19405), 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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Food Code Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Respondents	75	4	300	1	300

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

This estimate is based on FDA's experience and the number of updates received in the past 3 years. FDA estimates that 75 respondents will provide four quarterly updates each, resulting in an estimated 300 total annual responses. The agency estimates that each quarterly update will take about 1 hour. Of the 75 respondents, those who amend their regulations with changes unrelated to the risk factors and interventions, and those who are not adopting model FDA Food Code provisions, but are incorporating certain Conference for Food Protection recommendations only, will likely need only annual contact.

Dated: June 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15337 Filed 6–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Establishment

Pursuant to Section 10413, Part V of the Patient Protection and Affordable Care Act (which established Section 399NN of the Public Health Service Act, as amended); Public Law 111–48, the Director, Centers for Disease Control and Prevention (CDC), announces the establishment of the Advisory Committee on Breast Cancer in Young Women.

This committee is established to assist in creating a national evidence-based public education and media campaign to provide age-appropriate messages and materials to: (1) Increase awareness of good breast health habits; (2) identify risk factors based on familial, racial ethnic and cultural backgrounds; (3) encourage young women and healthcare professionals to increase early detection of breast cancers; and (4) increase the availability of health information and other resources for young women diagnosed with breast cancer.

The Advisory Committee on Breast Cancer in Young Women will advise the Secretary, HHS, the Assistant Secretary for Health, and the Director, CDC regarding the formative research, development, implementation and evaluation of evidence-based activities designed to prevent breast cancer (particularly among those at heightened risk) and promote the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

For more information, contact Ena Wanliss, M.S., Lead Public Health Advisor, CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control, 4770 Buford Highway, Mailstop K–57, Chamblee, Georgia 30316, Telephone: 770–488–4225.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.