*Annual Responses:* 3300; *Total Annual Hours:* 275.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Form Number:* CMS–2728 (OMB#: 0938–0046); *Use:* The End Stage Renal Disease Medical Evidence (CMS–2728) is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life.

The data reported on the CMS–2728 is used by the Federal Government, ESRD Networks, treatment facilities, researchers and others to monitor and assess the quality and type of care provided to end stage renal beneficiaries. The data collection captures the specific medical information required to determine the Medicare medical eligibility of End Stage Renal Disease claimants. It also collects data for research and policy on this population. *Frequency:* Reporting—Once; *Affected Public:* Individuals or households, Business or other-for-profit, Not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 75,000.

4. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Worksheet for Recording Results of Medicare Site Visits of Independent Diagnostic Testing Facilities (IDTFs) Form; *Form Number:* CMS–10221 (OMB#: 0938–New); *Use:* Prior to enrolling in Medicare, independent diagnostic testing facilities (IDTFs) must undergo a site visit as required under 42 CFR 410.33. The purpose of the site visit is to ensure that the IDTF is in compliance with the provisions of 42 CFR 410.33, as well as all other applicable Federal, State and local laws and regulations. It is also used to verify the information the IDTF furnished on its CMS–855B enrollment application.

Section 410.33 contains a significant number of standards that IDTFs must meet in order to enroll in Medicare. Compliance with the standards further ensures that only qualified and legitimate IDTFs can bill Medicare. This is especially important in light of concerns about recent fraudulent activity by some IDTFs. We are submitting the ''Worksheet for Recording Results of Medicare Site Visits of Independent Diagnostic Testing Facilities (IDTFs),'' for OMB approval. The purpose of this document is to ensure that the individuals performing IDTF site visits take into account both new and existing IDTF standards in a consistent fashion. *Frequency:* Reporting—On occasion; *Affected Public:* Business or other-for-profit, Not-for-profit institutions; *Number of Respondents:* 2,000; *Total Annual Responses:* 2,000; *Total Annual Hours:* 4,000.

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Program: Process for Making National Coverage Determinations; *Form Number:* CMS–R–290 (OMB#: 0938–0776); *Use:* On September 26, 2003 (68 FR 55634), we published a notice that described how we revised the process we use to make Medicare coverage decisions including decisions regarding whether new technology and services can be covered. In accordance with section IV.B of the aforementioned notice, CMS' Revised Process for Making National Coverage Determinations, we require an individual or entity to make a formal request for a national coverage determination. Upon receipt of a formal request and adequate supporting documentation, we will make a determination based on the evidence presented, to cover the device or service or not to cover the device or service where it is not supported by the medical evidence. We are resubmitting this information collection request (ICR) to the Office of Management and Budget as an extension of the currently approved collection. We have not made any material modifications to the ICR since the last submission. *Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* Business or other-for-profit, Not-for-profit institutions; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 8,000.

6. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Information Collection Requirements (ICRs) Contained in the Clinical Laboratory Improvement Amendments (CLIA) Regulations 42 CFR part 493.801, 493.803, 493.1232, 493.1233, 493.1234, 493.1235, 493.1236, 493.1239, 493.1241, 493.1242, 493.1249, 493.1251, 493.1252, 439.1253, 493.1254, 493.1255, 493.1256, 493.1261, 493.1262, 493.1263, 493.1269, 493.1273, 493.1274, 493.1278, 493.1283, 493.1289, 493.1291, and 493.1299; *Form Numbers:* CMS–R–26 (OMB#: 0938–0612); *Use:* The ICRs referenced in 42 CFR part 493 outline the requirements necessary to determine an entity's complicance with CLIA. CLIA requires laboratories that perform testing on human beings to meet performance requirements (quality standards) in order to be certified by the Department of Health and Human Services (HHS). HHS conducts inspections to determine a laboratory's compliance with CLIA requirements. CLIA implements the certificate, laboratory standards and inspection requirements; *Frequency:* Reporting—As needed; *Affected Public:* State, Local or Tribal Governments, Federal Government, Business or Other for profit and Not-for-profit institutions; *Number of Respondents:* 168,688; *Total Annual Responses:* 756,241; *Total Annual Hours:* 11,363,680.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on June 12, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 6, 2007.

**Michelle Shortt,**

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

[FR Doc. E7–6990 Filed 4–12–07; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007N–0015]**

### 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 May 14, 2007.

**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.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**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 Food and Drug Administration Food Code by Local, State, and Tribal Governments (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.

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. AFDO will collect the information electronically and/or telephonically and will be able to provide respondents with previous survey responses already in the database.

*Description of Respondents*: States and U.S. territories, local, and tribal governmental agencies.

In the **Federal Register** of January 26, 2007 (72 FR 3862), FDA published a 60-day notice requesting public comment on the information collection provisions. We received one comment, which was non-responsive to our request for comments on the proposed information collection.

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 has reduced the estimated number of annual respondents from 150 to 75. 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: April 9, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–6983 Filed 4–12–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2006N–0525]**

### Supplements and Other Changes to an Approved Application; Public Meeting; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until May 18, 2007, the comment period for a notice of public meeting that published in the **Federal Register** of January 5, 2007 (72 FR 574). In the notice, FDA announced a February 7, 2007, meeting to solicit input on issues that the agency should consider if it decides to propose revisions to its regulations regarding chemistry, manufacturing, and controls (CMC) supplements and other changes to approved marketing applications for human drugs. FDA is reopening the comment period in light of continued public interest in this topic.

**DATES:** Submit written or electronic comments by May 18, 2007.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug