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

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: David J. Cummings, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3525, Rockville, MD 20993–0002, 301–796–2400, e-mail: *David.Cummings@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On February 7, 2007, FDA held a public meeting to solicit comments on issues that FDA should consider if it decides to propose revisions to § 314.70 (21 CFR 314.70) regarding CMC supplements and other changes to approved marketing applications for human drugs. In the notice announcing the public meeting (72 FR 574), FDA stated that current § 314.70 categorizes postapproval CMC changes and their associated reporting requirements without consideration of the applicant's risk management activities or internal quality systems and practices; therefore, § 314.70 reflects a rules-based, or prescriptive, approach to regulating postapproval manufacturing changes. Current § 314.70 may create regulatory burdens and costs that discourage beneficial manufacturing changes and may not support a desirable level of innovation, modernization, and flexibility for the industry as described in FDA's pharmaceutical current good manufacturing practices for the 21st century initiative (CGMP Initiative). Consistent with the agency's risk-based approach to regulating pharmaceutical manufacturing described in the CGMP Initiative, FDA is considering possible revisions to § 314.70 to allow for more manufacturing changes to be made without prior FDA approval using a firm's internal change control system and to allow for consideration of risk-based approaches based on manufacturing process understanding, including prior knowledge of similar products, and overall quality systems to provide an enhanced risk-based approach to the CMC regulatory process.

Interested persons were given until March 7, 2007, to submit written or electronic comments to the agency related to the focus of the public meeting. As a result of continued public interest, FDA is reopening the comment period until May 18, 2007, to allow interested persons additional time to submit comments.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments related to this topic (see **DATES**). All relevant data and information should be submitted with the written comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with Docket No. 2006N–0525. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6985 Filed 4–12–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB No. 0915–0193) Revision for 2008

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by the Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and other grantees under Section 330. The authorizing statute is section 330 of the Public Health Service Act, as amended.

HRSA collects data in the UDS which is used to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of data collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The 2008 calendar year UDS will be revised in several ways. Certain UDS tables are being proposed for elimination or modification to streamline data collection and reporting. A limited number of clinical measures will be added for reporting quality of care, health outcomes, and disparities data. In addition, the tool used to report calendar year UDS data will be changed to a Web-based tool.

Estimates of Annualized Reporting Burden are as Follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Universal report	1076	1	30	32,280
Grant report	240	1	18	4,320
Total	1076			36,600