DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1268]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Additives and Food Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 5, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Food Additives and Food Additive Petitions—21 CFR 171.1 and Parts 172, 173, 175 through 178, and 180—(OMB Control Number 0910–0016)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that any particular use or intended use of a food additive shall be deemed to be unsafe, unless the additive and its use or intended use are in conformity with a regulation issued under Section 409 of the act that describes the condition(s) under which the additive may be safely used, or unless the additive and its use or intended use conform to the terms of an exemption for investigational use, or unless a food contact notification submitted under paragraph (h) is effective. Food additive petitions are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 175 through 178, and 180 (21 CFR parts 172, 173, 175 through 178, and 180) contain labeling requirements for certain food additives to ensure their safe use.

FDA scientific personnel review food additive petitions to ensure the safety of the intended use of the food additive in or on food, or of a food additive that may be present in food as a result of its use in articles that contact food. FDA requires food additive petitions to contain the information specified in § 171.1 in order to determine whether a petitioned use for a food additive is safe, as required by the act. This regulation (§ 171.1) implements section 409(b)(2) of the act.

Respondents are businesses engaged in the manufacture or sale of food, food ingredients, or substances used in materials that come into contact with food.

In the **Federal Register** of May 16, 2000 (65 FR 31178), the agency requested comments 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]

21 CFR Section/Part	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
171.1	13	1	13	5,332	69,316
Part 172	13	1	13	0	0
Part 173	13	1	13	0	0
Parts 175 through 178	13	1	13	0	0
Part 180	13	1	13	0	0
Total					69,316

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

This estimate is based on the number of new food additive petitions received in fiscal year 1999 and the total hours expended by petitioners to prepare the petitions. A reduction was estimated based on expected eligibility of some substances previously submitted as food additive petitions for submission as food contact notices under new section 409(h) of the the act. The burden varies with the complexity of the petition submitted, because food additive petitions involve the analysis of scientific data and information, as well as the work of assembling the petition itself. Because labeling requirements under parts 172, 173, 175 through 178, and 180 for particular food additives involve information required as part of the food petition safety review process under § 171.1, the estimate for the number of respondents is the same and the burden hours for labeling are included in the estimate for § 171.1.

Dated: July 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–19623 Filed 8–2–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1060]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Adoption of the FDA 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 the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 5, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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

FDA has developed the model Food Code to assist and promote consistent implementation of national food safety regulatory policy among the several thousand local, State, and tribal jurisdictions that have primary responsibility for the regulation or oversight of retail level for 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) and delegation of authority from the Public Health Service to the Commissioner of Food and Drugs relative to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). 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 to further the goals of the President's Council on Food Safety for consistent, scientifically sound, and risk-based food safety standards and practices and to work more effectively with partners in State, local, and tribal governments. FDA has established a site on the Internet at http://cfsan.fda.gov under ''Federal/State Food Programs'' and ''Retail Food Safety References'' to list jurisdictions that have reported adoptions of the FDA Food Code. Because it is self-reported, the list is incomplete and has not been evaluated to determine whether all the adopted codes are equivalent to the model Food Code. It is important to FDA to have a comprehensive, accurate, and current inventory of Food Code adoptions to help achieve the aims of the President's Council on Food Safety and the agency's Food Safety Initiative goals.

FDA has obtained the services of the Association of Food and Drug Officials (AFDO) to develop and implement an active surveillance system to track and report on the adoption of the FDA Food Code by State and local agencies and tribal nations of native Americans. AFDO will develop and maintain an active data base to track adoptions of the Food Code; identify and periodically contact State, local, and tribal food safety program administrators to determine the current status of adoptions of the Food Code or its equivalent; evaluate the equivalency of the adopted codes with the FDA Food Code; and provide quarterly progress reports to FDA from the data base in tabular and graphic form. Reports may be placed on the Internet at http://www.fda.gov.

Initial contacts by AFDO to local, State, and tribal program administrators will be by telephone and/or e-mail to determine the Food Code status in their jurisdiction(s). Verbal responses to questions will be acceptable as will electronic or facsimile information. Followup contacts to clarify responses will be by telephone or e-mail to minimize the burden on respondents.

The questions will concern whether or not the FDA Food Code has been adopted in the respondent's jurisdiction; which version of the Food Code is in effect; and whether local jurisdictions need to be contacted for Food Code adoption status. AFDO will also determine with the local/State/tribal governments that it has the latest version of the code for analysis.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
500	2	1,000	1	1,000
Total				1,000

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

FDA based its estimates on the number of State agencies (100) involved in Food Code-related regulatory programs, 300 local agencies with local ordinance authority that may consider Food Code adoption in any one year, and 100 tribal agencies. Estimating the number of local agencies is difficult before the start of this project because in some States, adoption by a State agency automatically applies to all local jurisdictions in that State. In other States, some metropolitan jurisdictions may adopt the FDA Food Code individually. Similar circumstances may apply to tribal nation's agencies that may be adopting the FDA Food Code. When the initial information gathering is completed, FDA will be able to identify more accurately the number of local and tribal agencies for which tracking adoption of the FDA Food Code will be necessary.

Frequency of reporting will range from once per year to quarterly for any one jurisdiction. This is because agencies that have already adopted the Food Code will require less frequent contact, perhaps only annually, than those that are in the process of adopting the Food Code. An average of two contacts in 1 year, therefore, was selected. Because most reporting will be done telephonically or electronically, reporting times often will be less than 1 hour.

These estimates will fluctuate from year to year as agencies adopt, revise, and consider adoption of the FDA Food Code. Over the next 3 years, the frequency of contacts should decrease as jurisdictions adopt the FDA Food Code. This project will take several years to complete because the adoption process in some States can extend to 2 years or longer. For example, some States have biennial legislative sessions. Others have extensive notice-and-comment administrative rulemaking procedures that can extend well beyond 1 year.

In accordance with 5 CFR 1320.8(d) on April 6, 2000 (65 FR 18110), a 60-day notice for public comment was published in the **Federal Register**. One comment was received which questioned the necessity for the information and criticized the funding mechanism for obtaining the information. FDA disagrees with the commentator on both points.

Regarding the necessity for a nationwide adoption of the model FDA Food Code is an important step to further the goals of the President's Council on Food Safety for consistent, scientifically sound, and risk-based food safety standards and practices and to work more effectively with partners in State, local, and tribal governments and with other Federal agencies. To help achieve these aims and FDA's Food Safety Initiative goals, FDA needs a comprehensive, accurate, and current inventory of Food Code adoptions to monitor the effectiveness of FDA's assistance to these agencies and to identify gaps where additional assistance may be needed.

FDA has established a site on the Internet at http://www.cfsan.fda.gov ''Federal/State Food Programs'' and ''Retail Food Safety References'' to list agencies that have reported adoptions of the FDA Food Code. Because it is self-reported, the current list is incomplete and those codes adopted have not been evaluated for consistency with the model FDA Food Code. FDA has obtained the services of AFDO to develop and implement an active surveillance system to track and report on the adoptions of the FDA Food Code by State and local agencies and tribal nations of native Americans.

AFDO will develop an active computer data base that will capture adoptions of the FDA Food Code; identify and periodically contact State, local, and tribal food safety program administrators to determine the current status of Food Code adoptions; collect information to identify consistency of adopted codes with the FDA Food Code focused only on the Centers for Disease Control identified risk factors and the FDA Food Code interventions; and provide quarterly progress reports to FDA from the data base in tabular and graphic form. Reports may be placed on the Internet at http://www.cfsan.fda.gov.

On the comment's second point regarding propriety of funding the project, the purchase requisition for services was well within the limits and fully compliant with regulations for purchasing the services of AFDO to conduct the information gathering.

Dated: July 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–19626 Filed 8–2–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10013]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration; HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New collection; *Title of Information Collection:* Medicare beneficiary line survey; *Form No.:* HCFA–10013 (OMB# 0938–NEW); *Use:* This survey will be used by the Michigan Peer Review Organization to obtain information that will assist it in improving its services; *Frequency:* On occasion; *Affected Public:* Individuals or households; *Number of Respondents:* 3,600; *Total Annual Responses:* 360; *Total Annual Hours:* 90.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 25, 2000.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–19675 Filed 8–2–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0094]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration; HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Sterilization Regulations and Consent Form; *Form No.:* HCFA–R–0094 (OMB# 0938–0481); *Use:* All Medicaid-eligible individuals seeking sterilization are required to provide informed consent, acknowledging that they understand the risks and benefits; *Frequency:* On occasion; *Affected Public:* Individuals or households; State, local or tribal gov't;