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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1060]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's collection of information from local, State, and tribal agencies concerning their adoption of, or plans to adopt, all or portions of the FDA Food Code or its equivalent by regulation, law, or ordinance. The Association of Food and Drug Officials (AFDO) has been contracted by FDA to telephonically and/or electronically contact local, State, and tribal food program administrators to determine Food Code adoption in their respective jurisdictions.

DATES: Submit written comments on the collection of information by *[insert date 60 days after publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (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.

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 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) 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://www.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 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. The contractor 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 types of questions to be asked will be 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 if not, which 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 BURDEN¹

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

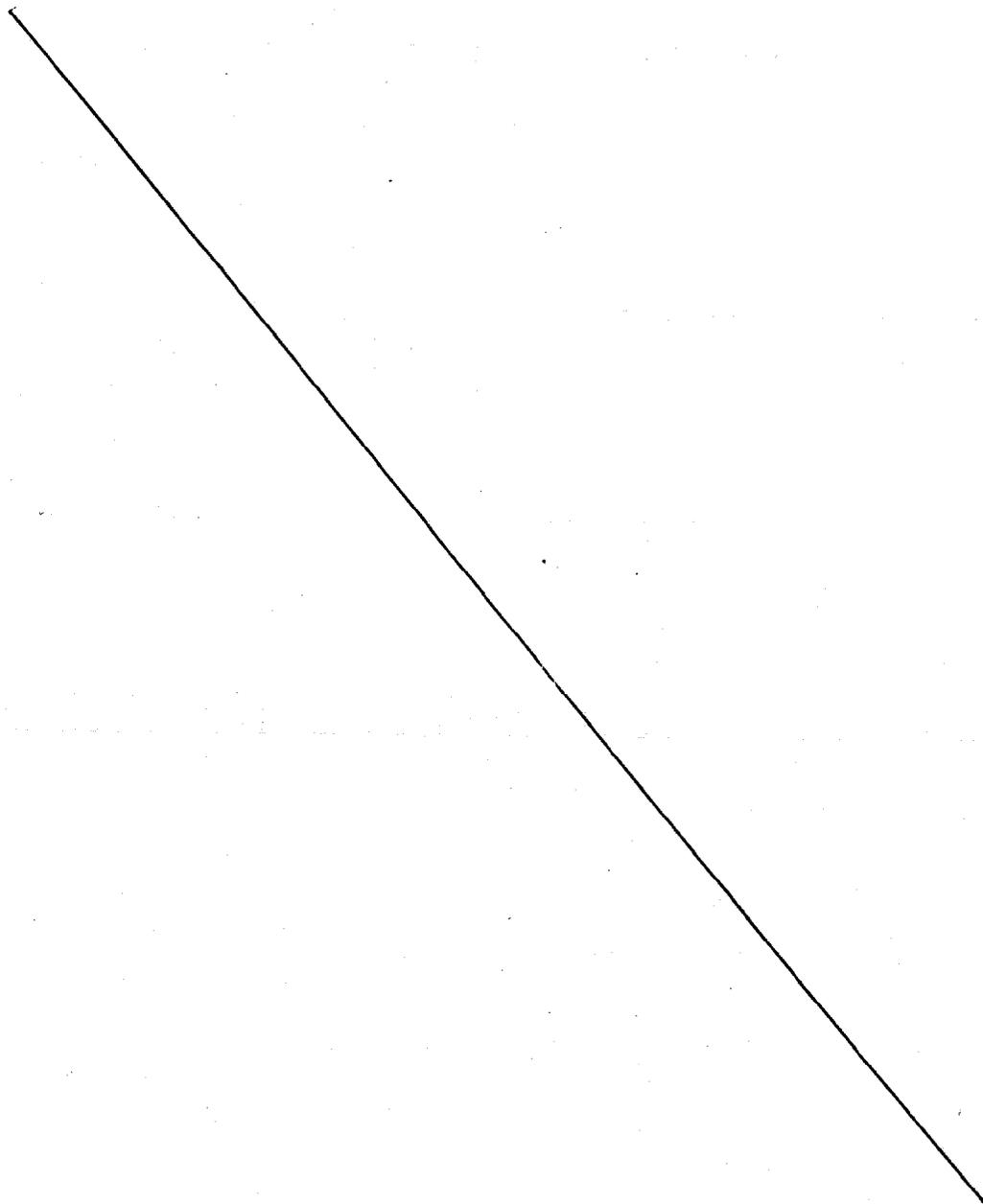
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based its estimate 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 nations' 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 much less than 1 hour.

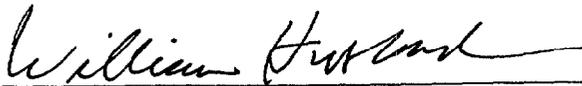
These estimates will fluctuate from year to year as agencies adopt, revise, and consider adoption of the FDA Food Code. Over the next 3 years, the frequency of contacts should decrease

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 more. For example, some States



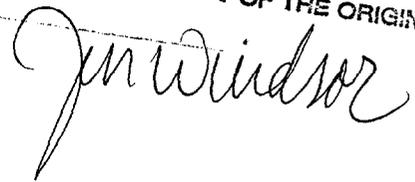
have biennial legislative sessions. Others have extensive notice-and-comment administrative rulemaking procedures that can extend well beyond 1 year.

Dated: March 30, 2000



William K. Hubbard
Senior Associate Commissioner for
Policy, Planning, and Legislation

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