

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier	Monique O'Leary

[Docket No. 01N-0208]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary National Retail Food Regulatory Program Standards**

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

**ACTION:** Notice.

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**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 use of or planned use of all or part of the Voluntary National Retail Food Regulatory Program Standards.

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

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. 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.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-26, Rockville, MD 20857, 301-827-4659.

11

**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.

### **Voluntary National Retail Food Regulatory Program Standards**

FDA has developed the Voluntary National Retail Food Regulatory Program Standards (the National Standards) to assist and promote the uniform application of provisions of the model FDA Food Code by several thousand local, State, and tribal jurisdictions that have primary responsibility for the regulation or oversight of retail level food operations. The National Standards are intended to serve as a guide to regulatory retail food program managers in the design and management of a retail food program that is focused on the reduction of risk factors known to cause foodborne illness. The National Standards also promote active management control by industry of all risk factors that may cause foodborne illness. Authority for providing such assistance is derived from

section 311 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 related to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). Under 31 U.S.C. 1535, FDA provides financial assistance to other Federal agencies such as the Indian Health Service. FDA has established a section on the Internet at <http://vm.cfsan.fda.gov/dms/ret-toc.html> under "Federal/State Food Programs—Retail Food Safety References" to list jurisdictions that have voluntarily elected to use the National Standards.

Utilization of the National Standards by local, State, and tribal regulatory agencies is an important step to further the goals of the President's Council on Food Safety and FDA program goals. All regulatory agencies are encouraged to voluntarily utilize the National Standards as a guide for the design and management of a retail food safety program. There is no reporting or recordkeeping requirement for those jurisdictions that wish to utilize part or all of the National Standards to enhance or measure program performance. Reporting is only a requirement for those jurisdictions that request to be listed in the FDA National Registry.

Jurisdictions that request listing in the FDA National Registry of participating regulatory agencies will be expected to perform certain management tasks and periodically report the results to FDA. Voluntary listing in the FDA National Registry requires that the following tasks be performed by State, local, and tribal program managers: (1) Conduct a program self assessment, (2) conduct a baseline survey of the regulated industry, and (3) obtain an independent outside audit. All three tasks must be completed within a 3-year time span. The tasks must be performed in accordance with the guidance provided in the National Standards and the results reported to FDA.

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. The presumption being that those agencies most likely to utilize the National Standards are also those agencies with authority to adopt and

enforce the model FDA Food Code. There is only one required report, the FDA National Registry Report (Appendix I), which is used to report program self assessment, baseline surveys of industry, and outside audits. The time required to complete the actual reporting document is minimal, however, additional time is required to analyze and review existing records, conduct baseline inspections, and secure an outside audit. The hour burden estimate includes the time required to review the instructions in the National Standards, search existing data sources, gather and maintain the data needed, complete worksheets, and review the collected information. The estimate of 92 hours to complete a program self assessment is based on the average time reported by the four State and three local jurisdictions that participated in the National Standards Pilot. The amount of time expended by individual jurisdictions ranged from 40 to 215 hours. This range is reflective of the difference in size between jurisdictions. The baseline survey of industry and the outside audit are expected to require a similar amount of time to complete. Because only one of the three tasks is required per year, the average annual reporting burden is estimated to be 92 hours per year for each participating jurisdiction.

Because the records of establishment inspections, investigations, and enforcement activities are routinely maintained and accepted management practices already necessitate the collection of some required information and maintenance of records, the recordkeeping burden is minimal.

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

Table 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Standard No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
9 <sup>2</sup> .....	500	1	500	92	46,000

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

<sup>2</sup> Includes the use of Forms FDA 3519 and 3520.

Table 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

Standard No.	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record-keeper	Total Hours
3, 4, and 6 <sup>2</sup> .....	500	1	500	5	2,500

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

<sup>2</sup> The standards incorporate the best program management practices currently in use in the regulatory community. The recommended policies, procedures, and standard operating procedures contained in the various national standards are considered usual and customary management practices for State, local, and tribal agencies that regulate the retail segment of the food industry.

Dated: 5-4-01

May 5, 2001.

4

*William Hubbard*

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

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*Deborah Oliver*