

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006D–0246]

### Draft Manufactured Food Regulatory Program Standards; Availability

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Manufactured Food Regulatory Program Standards” (draft program standards). The draft program standards, which establish a uniform foundation for the design and management of State programs responsible for regulation of plants that manufacture, process, pack, or hold foods in the United States, are being distributed for comment purposes only. This document is neither final nor is it intended for implementation at this time.

**DATES:** Written comments on the draft program standards may be submitted by [*insert date 60 days after date of publication in the **Federal Register***].

General comments on the draft program standards are welcome at any time.

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

**ADDRESSES:** Submit written comments on the information collection provisions 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>. Identify

comments with the docket number found in brackets in the heading of this document.

Submit written requests for single copies of the draft program standards to the Division of Federal-State Relations (HFC-150), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 716-551-3845. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft program standards.

**FOR FURTHER INFORMATION CONTACT:** Beverly Kent, Division of Federal-State Relations, Food and Drug Administration, 300 Pearl St., suite 100, Buffalo, NY 14202, 716-541-0331.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft document entitled “Manufactured Food Regulatory Program Standards.” The standards were developed after the Department of Health and Human Services, Office of Inspector General (OIG) audited FDA’s oversight of food firm inspections conducted by States through contracts. In June 2000, the OIG released its findings. The OIG recommended that FDA take steps to promote “equivalence among Federal and State food safety standards, inspection programs, and enforcement practices.” The report is on the Internet at *http://www.oig.hhs.gov/oei/reports/oei-01-98-00400.pdf*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

In response to the OIG’s findings, FDA established a committee to draft a set of quality standards for manufactured food regulatory programs. The

committee was comprised of officials from FDA and from State agencies responsible for the regulation and inspection of food plants.

These draft program standards establish a uniform foundation for the design and management of a State program that is an operational unit(s) responsible for the regulatory oversight of food plants that manufacture, process, pack, or hold foods in the United States. The elements of the draft program standards describe best practices of a high-quality regulatory program. Achieving conformance with these program standards will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation. All self-assessment worksheets and supporting documents will be retained by the State agency.

## **II. Significance of Program Standards**

These draft program standards represents the agency's current thinking on how to build a uniform foundation for managing a State program that is an operational unit(s) responsible for the regulatory oversight of food plants that manufacture, process, pack, or hold foods in the United States. The elements of the draft program standards describe best practices of a high-quality regulatory program.

## **III. Electronic Access**

Persons with access to the Internet may obtain the draft program standards at either [http://www.fda.gov/ora/fed\\_state/default.htm](http://www.fda.gov/ora/fed_state/default.htm) or <http://www.fda.gov.ohrms/dockets/default.htm>.

## **IV. Paperwork Reduction Act of 1995**

Under the Paperwork Reduction Act of 1995 (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

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 of 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 the following topics: (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.

*Title:* Manufactured Food Regulatory Program Standards

*Description:* The elements of the draft program standards are intended to ensure that the States have the best practices of a high-quality regulatory program to use for self-assessment and continuous improvement and innovation. The ten standards describe the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the State program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education

and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets, and certain standards have supplemental worksheets and forms that will assist State programs in determining their level of conformance with the standard. The State program is not required to use the forms and worksheets contained herein; however, alternate forms should be equivalent to the forms and worksheets in the draft program standards. These draft program standards do not address the performance appraisal processes that a State agency may use to evaluate individual employee performance. When finalized, FDA will use the program standards as a tool to improve contracts with State agencies. The program standards will assist both FDA and the States in fulfilling their regulatory obligations.

The implementation of the program standards will be negotiated as an option for payment under the State contract. States that are awarded this option will receive up to \$5,000 to perform the self assessment and to maintain an operational plan for self improvement. FDA recognizes that full use and implementation of the program standards by those States will take several years. Such States will, however, be expected to implement improvement plans to demonstrate that their programs are moving toward full implementation. Those self assessments and improvement plans will be audited as a part of the program oversight of the FDA state contracts.

The goal is to enhance food safety by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help Federal and State programs better direct their regulatory activities at reducing foodborne illness hazards in plants that

manufacture, process, pack, or hold foods. Consequently, the safety and security of the food supply in the United States will improve.

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

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
40	0.5	20	40	800

<sup>1</sup> Because State agencies already keep records of the usual and customary activities required by their inspection programs, the burden from compiling these records is not included in the burden chart.

TABLE 2.—ESTIMATED 5-YEAR SELF ASSESSMENT BURDEN

No. of Respondents	5-Year Frequency per Response	Total 5-Year Responses	Hours per Response <sup>1</sup>	Total Hours <sup>1</sup>
40	1	40	100/40	4,000/1,600

<sup>1</sup> The initial self assessment is estimated at 100 hours per respondent. Subsequent updates of the self assessments will be conducted every 5 years and should be completed in 40 hours or less.

TABLE 3.—ESTIMATED ANNUAL “IMPROVEMENT PLAN” BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
40	1	40	5	200

## V. Comments

The draft program standards are being distributed for comment purposes only and are not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy

of the draft program standards and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

Dated: July 14, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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