Based on the history of the PHN program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–7642 Filed 12–21–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0274]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments

AGENCY: Food and Drug Administration, HHS.

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 January 23, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (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.

Voluntary Hazard Analysis and Critical Control Point (HACCP) Manuals for Operators and Regulators of Retail and Food Service Establishments

The draft Operator's Manual contains information and recommendations for operators of retail and foodservice establishments who wish to develop and implement a voluntary food safety management system based on HACCP principles. Operators may decide to incorporate some or all of the principles presented in the draft manual into their existing food safety management systems. The recordkeeping practices discussed in the draft manual are voluntary and may include documenting certain activities, such as monitoring and verification, which the operator may or may not deem necessary to ensure food safety. The draft manual includes optional worksheets to assist operators in developing and validating a voluntary food safety management system.

The draft Regulator's Manual contains recommendations for State, local, and tribal regulators on conducting risk-based inspections of retail and foodservice establishments, including recommendations about recordkeeping practices that can assist operators in preventing foodborne illness. These recommendations may lead to voluntary actions by operators based on consultation with regulators. For example, an operator may develop a risk control plan as an intervention strategy for controlling specific out-of-control foodborne illness risk factors identified during an inspection. Further, the draft manual contains recommendations to assist regulators when evaluating voluntary food safety management systems in retail and foodservice establishments. Such evaluations typically consist of the following two components: Validation (assessing whether the establishment's voluntary food safety management system is adequate to control food safety hazards) and verification (assessing whether the establishment is following its voluntary food safety management system). The draft manual includes a sample ''Verification Inspection Checklist'' to assist regulators when conducting verification inspections of establishments with voluntary food safety management systems.

Types of operator records discussed in the manuals and listed in the following burden estimates include: Food safety management systems (plans that delineate the formal procedures to follow to control all food safety hazards in an operation); risk control plans (HACCP-based, goal-oriented plans for achieving active managerial control over specific out-of-control foodborne illness risk factors); hazard analysis (written assessment of the significant food safety hazards associated with foods prepared in the establishment); prerequisite programs (written policies or procedures, including but not limited to, standard operating procedures, training protocols, and buyer specifications that address maintenance of basic operational and sanitation conditions); monitoring (records showing the observations or measurements that are made to help determine if critical limits are being met and maintained); corrective action (records indicating the activities that are completed whenever a critical limit is not met); ongoing verification (records showing the procedures that are followed to ensure that monitoring and other functions of the food safety management system are being implemented properly); and validation (records indicating that scientific and technical information is collected and evaluated to determine if the food safety management system, when properly implemented, effectively controls the hazards).

All recommendations in both manuals are voluntary. For simplicity and to avoid duplicate estimates for operator recordkeeping practices that are discussed in both manuals, the burden for all collection of information recommendations for retail and foodservice operators are estimated together in table 1 of this document, regardless of the manual in which they appear. Collection of information recommendations for regulators in the Regulator's Manual are listed separately in table 2 of this document.

The likely respondents to this collection of information are operators and regulators of retail and foodservice establishments.

In the **Federal Register** of July 21, 2005 (70 FR 42072), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR OPERATORS[1]

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Food Safety Management System	50,000[2]	1	50,000	60	3,000,000
Hazard Analysis	50,000[2]	1	50,000	20	1,000,000
Prerequisite Program Records	100,000[3]	365	36,500,000	0.1	3,650,000
Monitoring Records	100,000[3]	365	36,500,000	0.3	10,950,000
Corrective Action Records	100,000[3]	365	36,500,000	0.1	3,650,000
Ongoing Verification Records (includes calibration records)	100,000[3]	365	36,500,000	0.1	3,650,000
Validation Records	50,000[3]	1	50,000	4	200,000
Total First Year Burden[4]:					26,100,000
Annual Burden[4]:					22,100,000
Risk Control Plan	50,000	1	50,000	2	100,000
Monitoring Records	100,000	90	9,000,000	0.3	2,700,000
Corrective Action Records	100,000	90	9,000,000	0.1	900,000
Ongoing Verification Records (includes calibration records)	100,000	90	9,000,000	0.1	900,000
Annual Burden[5]					4,600,000
Total Annual Burden for Operators (Excluding First Year)					26,700,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] First year burden only.
[3] Annual burden.
[4] Burden for developing and implementing a food safety management system based on the Operator's Manual.
[5] Annual burden for developing and implementing a risk control plan based on the Regulator's Manual.

The burden for these activities may vary among retail and foodservice operators depending on the type and number of products involved, the complexity of an establishment's operation, the nature of the equipment or instruments required to monitor critical control points, and the extent to which an operator uses the Operator's Manual and/or the Regulator's Manual. The estimate does not include collections of information that are a usual and customary part of an operator's normal activities. FDA has established as a goal to have 50,000 (1/2 of 1 percent) of the approximately one million U.S. retail and foodservice operators implement the recommendations outlined in the two manuals. This target figure is used in calculating the burden in tables 1 and 2 of this document because the agency lacks data on how to base an estimate of how many retail and foodservice establishments are likely to use one or more of the manuals to voluntarily implement a comprehensive food safety management system based on HACCP principles or a risk control plan for out-of-control processes identified during an inspection. FDA's estimate of the total number of retail and foodservice establishments is based on numbers obtained from the two major trade organizations representing these industries, the Food Marketing Institute and the National Restaurant Association, respectively. FDA seeks comments on this estimate.

The hour burden estimates in table 1 of this document for operators who follow the HACCP-based recommendations in the Operator's Manual are based on the estimated average annual information collection burden for mandatory HACCP rules, including seafood HACCP (60 FR 65096 at 65178, December 18, 1995) and juice HACCP (66 FR 6138 at 6202, January 19, 2001). FDA estimates that during the first year, 20 labor hours are needed to conduct the hazard analysis and 60 labor hours are needed to develop a food safety management system (HACCP plan). Once the system is in place, the annual frequency of records is based on 365 operating days per year. Assuming there is one recordkeeper per shift of operation, the agency estimates that two recordkeepers per day would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the system. The agency further estimates that validation will be conducted once per year, based on menu or food list changes, changes in distributors, or changes in food preparation processes used. The validation will require a total of 4 labor hours.

The second set of estimates in table 1 of this document shows the annual burden for developing and implementing a risk control plan to control specific out-of-control foodborne illness risk factors identified during an inspection by a State, local, or tribal regulatory authority. If an operator decides to use a risk control plan as recommended in the Regulator's Manual, one person from the establishment is needed to work with the regulator to develop the written plan. FDA estimates that two recordkeepers per day (one recordkeeper for each shift) would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the risk control plan. The estimated duration of

implementation for a risk control plan is 90 days, which is the minimum recommended time to achieve long-term behavior change.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR REGULATORS[1]

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Voluntary Food Safety Management System Evaluation (includes validation, verification, and completion of verification inspection checklist)	50,000	1	50,000	16	800,000
Total Annual Burden for Regulators					800,000

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

It is difficult to predict the number of State, local, and tribal regulatory jurisdictions that will use the Regulator's Manual. But FDA anticipates that retail and foodservice establishments which voluntarily develop and implement a food safety management system based on the Operator's Manual will request their regulatory authorities to conduct an evaluation of their system. The estimates in table 2 of this document for the annual burden to State, local, and tribal regulators that follow the recommendations in the Regulator's Manual were calculated based on the usual time needed for one person to evaluate a voluntarily-implemented food safety management system and record the findings. The number of times an inspector may be asked by an operator to evaluate a voluntarily-implemented system is not expected to exceed once per year.

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Tentative Schedule of Meetings for 2006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 2006. During 1991, at the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of the IOM's recommendations was for the agency to publish an annual tentative schedule of its meetings in the **Federal Register**. This publication implements the IOM's recommendation.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of the FDA's advisory committees. In its final report in 1992, one of the IOM's recommendations was for FDA to adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the **Federal Register**; FDA has implemented this recommendation. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. Because the schedule is tentative, amendments to this notice will not be published in the **Federal Register**. However, changes to the schedule will be posted on the FDA advisory committees' Internet site located at *http://www.fda.gov/oc/advisory/default.htm*. FDA will continue to publish a **Federal Register** notice 15 days in advance of each upcoming advisory committee meeting, to announce the meeting (21 CFR 14.20).

The following list announces FDA's tentatively schedule advisory committee meeting for 2006. You may also obtain up-to-date information by calling the Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area).

Committee Name	Tentative Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
OFFICE OF THE COMMISSIONER		
Pediatric Advisory Committee	March, June, and November day(s) to be announced.	8732310001
Science Board to the Food and Drug Administration	April and November day(s) to be announced.	3014512603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		
Allergenic Products Advisory Committee	March 31, September 13.	3014512388
Blood Products Advisory Committee	March 9–10, July 13–14, October 26–27.	3014519516
Cellular, Tissue and Gene Therapies Advisory Committee	February 9–10, July 13–14, November 2–3.	3014512389
Transmissible Spongiform Encephalopathies Advisory Committee	To be announced.	3014512392