NOTIFICATION PROCEDURES:

To determine if a record exists, write to the Systems Manager at the address listed above. The Privacy Act provides that, except under certain conditions specified in the law, only the subject of the records may have access to them. All requests must be submitted in the following manner: identify the system of records you wish to have searched, have your request notarized to verify your identify, indicate that you are aware that the knowing and willful request for or acquisition of a Privacy Act record under false pretenses is a criminal offense subject to a $5,000 fine. Your letter must also provide sufficient particulars to enable OCSE to distinguish between records on subject individuals with the same name.

RECORD ACCESS PROCEDURES:

Write to the Systems Manager specified above to attain access to records. Requesters should provide a detailed description of the records contents they are seeking.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under System Manager above, and identify the record and specify the information to be contested and corrective action sought with supporting justification to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Information is obtained from departments, agencies, or instrumentalities of the United States or any State and from multi-state financial institutions.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 99–23809 Filed 9–13–99; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0572]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Collection of Letters of Interest and Food Safety Data in a Voluntary Pilot Program Using HACCP Principles for Retail Food Operations

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 (the PRA).

DATES: Submit written comments on the collection of information by October 14, 1999.

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: 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 section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Collection of Letters of Interest and Food Safety Data in a Voluntary Pilot Program Using HACCP Principles for Retail Food Operations

Section 402 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342) enables FDA to regulate the safety of foods in interstate commerce. In addition, under authority granted in the Public Health Service Act (the PHS Act) (42 U.S.C. 241, 243, and 264), the agency engages in a range of activities intended to ensure the safety of the nation's food supply, from regulating food when it can be a vector of disease to assisting, and cooperating with, the States to ensure effective State and local food safety programs. FDA endeavors to assist the more than 3,000 Federal, tribal, State, and local regulatory agencies that have primary responsibility for monitoring retail food establishments to ensure that consumers are protected.

FDA is proposing to collect information, through a voluntary pilot program, on how hazard analysis critical control points (HACCP) principles might be implemented in the retail food industry. The pilot program is designed to provide insight into the problems, costs, and benefits of developing and implementing HACCP principles for food service, retail food stores, and other retail food establishments, in order to improve and provide direct guidance to both the retail industry and regulatory authorities for the implementation of HACCP principles in the retail food sector. FDA will select candidates with a goal of ensuring that the participants in the program cross the spectrum of retail activities, have a range of scientific capabilities, have facilities of varying sizes, and have a range of HACCP experience. FDA has been approached by State and local governments to provide guidance for applying HACCP principles at retail; therefore, the agency intends to collect information through the pilot program to develop and enhance guidance. The agency intends to make a summary of the results of the retail pilot program publicly available.

The agency will request retail food establishments and regulatory agencies interested in participating in the pilot program to send to FDA a letter of interest. Letters from regulatory agencies need only state an interest in participating. FDA requests that the letters of interest from retail food establishments describe their menu, the location and size of their facility, the type of techniques they use to prepare their products, and the extent to which, and how, they employ HACCP; identify area government officials with whom they have worked to implement or reinforce the system; identify which State, local, and/or tribal government officials they would like to work with in the pilot program; and identify trade associations they would like to work with in the pilot. FDA will review the letters of interest from retail applicants and identify a limited number of individual establishments that represent a broad spectrum of the retail food industry and that, in the judgment of the agency, are best suited to participate in the pilot program. The retail pilot participants will maintain a food safety program based upon HACCP principles for the duration of the pilot. FDA will study the information and data the pilot participants use to maintain their food safety programs.

In the **Federal Register** of July 30, 1998 (63 FR 40716), the agency requested comments on the proposed collection of information. The agency received one comment from a trade association that represents one segment of the retail food industry. The comment recommended that FDA not pursue the pilot program as currently planned. Instead, the comments suggested that the agency solicit industry and academic input into the development of a ''new, more inclusive'' HACCP pilot program. The comment's recommendation was based on several concerns.

First, the comment expressed concern that a mandatory information collection regulation may mark the end of cooperative industry development of HACCP programs.

The voluntary retail HACCP pilot program is neither mandatory, nor is it a regulation. The purpose of the pilot program is to enhance understanding and implementation of HACCP principles through cooperation among industry, FDA, and participating State and local regulatory authorities. Any participant may leave the program at any time. The agency hopes that the pilot will promote rather than curtail the cooperative efforts toward building HACCP into retail. The agency agrees with the statement in the comment that ''There are many problems to overcome before HACCP can be fully implemented in the retail industry and clearly cooperation and inclusion will provide the answers to those problems.'' This is exactly why industry is being invited to participate; the agency recognizes that industry involvement is critical to furthering a cooperative relationship.

Second, the comment expressed concern about the disclosure of proprietary information and cautioned that access to voluntary HACCP plans, including records and customer complaints, must be restricted. The comment also stressed that the records must remain the property of the establishment.

The information collected at individual establishments will be held as proprietary, and contracts are to be signed by all parties involved limiting the use of the proprietary information. The agency intends to review the systems implemented by the retail establishment, including records, in order to document how the system works, but the records will remain the property of the establishment. After the pilot, the data collected at individual establishments will be generalized, and a collective retail HACCP pilot report will be publicly disseminated. The names and locations of the participating firms will be held as proprietary unless authorized for release by the participant.

Third, the comment raised several issues relating to consultation, participation, and fairness. The comment expressed concern that FDA is duplicating efforts by the restaurant industry and asserted that FDA has not consulted with developers of existing HACCP programs or evaluated these ongoing programs. The comment also charged that FDA intends to exclude universities and trade associations from direct participation in the pilot to prevent them from having input into any final recommendations resulting from the pilot. More generally, the comment expressed the view that FDA lacks the knowledge and detachment to select participants in the pilot on an objective basis.

The agency believes these concerns are unfounded. FDA intends to build on retail industry efforts through the retail HACCP pilot program by studying ongoing HACCP systems and documenting activities used by the retail industry to fully implement a HACCP system. During the design of the program, industry representatives shared their views on how an effective pilot program should proceed and provided feedback and guidance on this effort of collecting information. This information was used in designing the retail HACCP pilot program.

With regard to selection of participants, the design and intent of the pilot is inclusive, not exclusionary. The pilot seeks to include establishments that represent a broad spectrum of retail activities, geographic locations, sizes, and levels of experience with HACCP. Since each participant has the right, within the limits of the law, to control access to its proprietary information, each participant has the right to invite entities such as State, local, and tribal regulatory agencies, universities, and trade associations to work with it during the pilot, and it also has the right not to work with any such entities (although participants will, of course continue to be subject to applicable food safety laws and regulations in all jurisdictions during the pilot).

FDA will involve the pilot participants in the summary of results and formation of conclusions at the end of the pilot program, and will make the summary report publicly available. The pilot is designed to encourage voluntary evolution of retail HACCP plans with the involvement of all stakeholders: Government, industry, academia, and trade associations.

Fourth, the comment expressed doubts about the need for the pilot program. The comment stated that the retail food industry has used HACCP for many years with great success. According to the comment, FDA should remain only an evaluator of the success of HACCP programs, and should not attempt to institute or mandate such programs.

FDA disagrees with the comment. The PHS Act provides that the agency shall assist States and political subdivisions in the prevention and suppression of communicable diseases, and with respect to other public health matters, shall cooperate with and aid State and local authorities in the enforcement of their health regulations, and shall advise the States on matters relating to the preservation and improvement of the public health. FDA is also entrusted with regulating food safety under the act. Therefore, the agency is responsible for carrying out these functions and intends to do so. The retail HACCP pilot program is one of many elements necessary to enable FDA to perform these statutory responsibilities.

Fifth, the comment expressed concern about the recordkeeping burdens that the retail HACCP pilot program would create for participants. The comment asserted that massive recordkeeping paperwork for the hundreds of items on restaurant menus would be required. The comment expressed hope that the pilot does not move to apply a single, ''one-size-fits-all'' FDA recordkeeping system.

The agency is seeking information through the pilot program on the amount and extent of recordkeeping that retail establishments have determined necessary to effectively implement and manage their HACCP systems. To be part of the voluntary pilot, the only recordkeeping requirement is a letter to FDA expressing interest to participate in the pilot program. The agency will not determine the amount or type of records needed during the pilot; rather, each industry participant will determine the amount and type of records it needs to effectively verify that its system is working. Thus, the pilot program will not create an undue burden and will not impose a single recordkeeping system on all establishments.

The comment also expressed the belief that FDA's burden estimate did not account for all the time that would be required by the smallest participants in this program to learn about and institute a HACCP program. The comment further stated that FDA has not shown a willingness to encourage or assist vital small restaurant operator participation in this pilot.

The agency will select candidates with a goal of ensuring that the participants in the program cross the spectrum of retail activities, have a range of scientific capabilities, have facilities of varying sizes, and have a range of HACCP experience. The pilot program will encompass the challenges unique to the retail environment, such as multiple menu items, size of the facility, and employee turnover. The agency intends to work with establishments with preexisting HACCP programs and those establishments intending to start designing their HACCP systems. The agency is seeking information that will document the costs and time necessary for developing and implementing a HACCP system.

FDA will also provide guidance and counseling upon request to those participating establishments that are in the process of developing HACCP systems, although the agency will not write HACCP plans.

Finally, the comment expressed concern that agencies could make use of prior establishment records as the basis for enforcement action.

In order to deal with this concern, the agency intends to provide clear direction to the pilot site teams to separate HACCP activities, such as the establishment's performance of corrective action, from system failures when risk factors are uncontrolled and enforcement action may be necessary. FDA has initiated and intends to further train the pilot site teams on how to evaluate a HACCP system and identify items that are important. The establishment has the primary responsibility to ensure the food is safe by fully implementing its HACCP system, and the pilot site teams will evaluate the effectiveness of that program.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Letters of interest from State/local/tribal authorities [2]	50	1	50	1	50
Letters from interested retail firms [2]	50	1	50	1	50
Total					100

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Plan development	40	1	40	100	4,000
Plan implementation documents	40	7,000	280,000	.05	14,000
Implementation review	40	4	160	4	640
Total					18,640

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

These estimates are based on FDA's experience with other pilot programs and on comments received through the Conference for Food Protection, public meetings, and through retail industry advice. This information was utilized to design the pilot program with the least amount of burden to the retail industry.

Because only one letter of interest need be submitted per prospective participant in the pilot, submitting the letter will create only a minimal one time burden. Once the pilot program begins, FDA estimates that the burden of collecting and maintaining food safety information based upon HACCP principles will vary considerably across the wide spectrum of retail activities and establishments, the types, and numbers of products involved, and the nature of the equipment or instruments required by the retail establishment for monitoring. The recordkeeping burden to each retail participant would involve maintaining a food safety plan based upon HACCP principles, generating the necessary records to implement that plan, and checking the records to verify implementation. Those participants who do not already have a HACCP plan in place would also have to develop such a plan.

Since the publication of the July 1998 **Federal Register** notice seeking comment on the pilot program, FDA has learned from conversations with potential participants that approximately 20 percent of these potential participants are already using HACCP plans in the normal course of their business activities. The PRA regulations (5 CFR 1320.3(b)(2)) provide that the time, effort, and financial resources that would be incurred by persons in the normal course of usual and customary activities are excluded from the burden of a collection of information. Therefore, the agency has revised its estimates to reflect the fact that the pilot program would impose no additional recordkeeping burden on the establishments that are already using HACCP.

Dated: September 8, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–23811 Filed 9–13–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) Final Evaluation: ''Tobacco Use Supplement to the 1998–2000 Current Population Survey''

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) Final Evaluation: ''Tobacco Use Supplement to the 1998–2000 Current Population Survey''. *Type of Information Request:* OMB #0925–0368, Exp. 12/31/99, REVISION. *Need and Use of Information Collection:* The ''Tobacco Use'' supplement to the Current Population Survey conducted