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

by the Bureau of the Census collected data in September 1998 and January and May 1999 from the civilian non-institutionalized population on tobacco use and smoking prevalence, smoking intervention dissemination of workplace smoking policies and cessation programs as well as medical and dental advice to stop smoking, and changes in smoking norms and attitudes. Due to an administrative error, in January and May 1999 data collection included a small set of incorrect questions which does not permit an accurate estimate of total tobacco use. The proposed information collection will ask the correct set of questions (comparable to the correctly fielded set in September 1998) for other tobacco usage (cigars, pipes, chewing tobacco and snuff), along with the standard cigarette smoking prevalence questions in order to estimate total tobacco usage. This survey will provide valuable information to Government agencies and to the general public necessary for tobacco control research. The data will be used by the National Cancer Institute to evaluate the effectiveness of the American Stop Smoking Intervention Study for Cancer Prevention (ASSIST), a large scale 17 state demonstration project. The survey will allow state specific estimates to be made. Data will be collected in January 2000 and May 2000 from approximately 170,000 respondents. *Frequency of Response:* One-time study. *Affected Public:* Individuals or households. *Type of Respondents:* Persons 15 yrs. of age or older. The annual reporting burden is as follows: *Estimated Number of Respondents:* 170,000; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 0.0113; and *Estimated Total Annual Burden Hours Requested:* 1921. The annualized cost to respondents is estimated at: $19,210. There are no Operating or Maintenance Costs to report.

**Request for Comments**

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms on information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Anne Hartman, Health Statistician, National Cancer Institute, Executive Plaza North, Room 313, Bethesda, Maryland 20892–7344, or call non-toll free number (301) 496–4970, or FAX your request to (301) 435–3710, or E-mail your request, including your address, to *ah42t@nih.gov* or Anne __Hartman@nih.gov.

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received on or before November 15, 1999.

Date: September 7, 1999.

**Reesa L. Nichols,**

*NCI Project Clearance Liaison.*

[FR Doc. 99–23844 Filed 9–13–99; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closing Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group Diabetes, Endocrinology and Metabolic Diseases B Subcommittee.

*Date:* October 29, 1999.

*Time:* 8:00 am to 5:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Ned Feder, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Building 45, Room 6AS25S, 9000 Rockville Pike, Bethesda, MD 20892.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group Digestive Diseases and Nutrition C Subcommittee.

*Date:* October 29, 1999.

*Time:* 8:00 am to 5:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Dan Matsumoto, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS–37B, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8894.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group Kidney, Urologic and Hematologic Diseases D Subcommittee.

*Date:* October 29, 1999.

*Time:* 8:00 am to 5:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Ann A. Hagan, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Building 45, Bethesda, MD 20892, (301) 594–8886.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: September 3, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99–23846 Filed 9–13–99; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning