space is limited, and we will close registration when maximum seating capacity (approximately 500) is reached.

We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

If you require special accommodations due to a disability, please contact Patricia A. Stewart at least 7 days in advance.

If you would like to submit comments regarding PDUFA IV, please send your comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

D. Will Meeting Transcripts Be Available?

We will prepare a meeting transcript, and we will make the transcript available on our Web site (*http://www.fda.gov*) after the meeting. We anticipate that transcripts will be available approximately 30 working days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management (see **ADDRESSES**), between 9 a.m. and 4 p.m. Monday through Friday.

Dated: October 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20875 Filed 10–14–05; 8:57 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review, Comment Request; 5 A Day Customized Survey

SUMMARY: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), 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. The proposed information collection below was previously published in the **Federal Register** on May 18, 2005, page 28544–28545 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised or implemented after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: *Title:* 5 A Day Customized Survey. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of the 5 A Day Customized Survey is to further the development of standardized measures of consumer knowledge, attitudes, and behaviors regarding the consumption of fruits and vegetables. Specifically, the Customized Survey will allow for validation of the new ''cup'' portion sizes (consistent with the 2005 Dietary Guidelines) and identify the most efficacious short screener methods of fruit and vegetable intake. In addition, the Customized Survey will measure established predictors of fruit and vegetable consumption at the national level and explore new predictors and constructs not previously examined for fruit and vegetable consumption. The sample will be drawn from a consumer opinion panel methodology using balancing techniques to mirror the U.S. general population on a set of key demographic variables. A separate sample of African Americans will be drawn from the panel.

Prior to fielding the Customized Survey, two pilot studies will be completed as the first phase of this research. Pilot respondents will be drawn from the same consumer panel and have similar demographics as respondents in the main study. A brief description of the two pilot studies follows. In pilot study 1, respondents will initially complete a brief screener questionnaire, three 24-hour dietary recalls over the phone, followed by the Customized Survey by mail. To account for diversity in eating habits, dietary recalls will be obtained for 2 weekdays and 1 weekend per respondent. The recalls will be conducted via phone by trained interviewers using the University of Minnesota's Nutrition Data System (NDS). After completing the dietary recalls pilot respondents will be mailed the Customized Survey within 2 weeks. Fruit and vegetable consumption as assessed by the average of the three 24-hour recalls will be compared with the fruit and vegetable consumption measures from the Customized Survey. In pilot study 2, respondents will complete the Customized Survey by mail at two points in time, six to eight weeks apart. The analysis in pilot study 2 will focus on a rigorous evaluation of the psychometric properties of the Customized Survey instrument to ensure that item-level and instrument-level reliability and validity has been achieved before proceeding to the main data collection phase of the study. Based on the findings of the pilot studies, minor modifications may be made to the Customized Survey prior to the implementation of the main study. *Frequency of response:* Main study, one time response (5 A Day Customized Survey). Pilot study 1, five times (screener, three 24-hour dietary recalls, 5 A Day Customized Survey). Pilot study 2, two times (5 A Day Customized Survey at two points in time). *Affected Public:* Individuals. *Type of Respondents:* U.S. adults. The annual reporting burden is as follows: *Estimated Number of Respondents:* 5,875; *Estimated Number of Responses per Respondent:* 1, 2 or 5; *Average Burden Hours per Response:* .416; and *Estimated Total Annual Burden Hours Requested:* 2,467.90. The annualized cost to respondents is estimated at: $46,384.28. The annual reporting burden is summarized in exhibit 1 below. There are no Operating or Maintenance Costs to report.

EXHIBIT 1

Type of respondents *	Number of respondents	Frequency of response	Average burden hours	Annual hour burden
Pilot Study 1:				
Screener	480	1	.08	38.4
Dietary Recall 1	380	1	.50	190
Dietary Recall 2	325	1	.50	162.5

EXHIBIT 1—Continued

Type of respondents *	Number of respondents	Frequency of response	Average burden hours	Annual hour burden
Dietary Recall 3	290	1	.50	145
Mail Survey	200	1	.42	84
Pilot Study 2:				
Mail Survey	200	2	.42	168
Main Implementation				
5 A Day Customized Survey	4,000	1	.42	1,680
Total	5,875			2,467.90

**All respondents are consumer panel members.*

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 proposed performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the 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 of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Amy Lazarus Yaroch, Ph.D., Project Officer, National Cancer Institute, NIH, EPN 4074, 6130 Executive Boulevard MSC 7335, Bethesda, Maryland 20892–7335, or call non-toll-free number 301–402–8425, or FAX your request to 301–480–2087, or E-mail your request, including your address, to *yarocha@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of this notice.

Dated: October 5, 2005.

Rachelle Ragland-Greene,

NCI OMB Clearance Liaison, National Institutes of Health.

[FR Doc. 05–20756 Filed 10–17–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities, Office of the Director; Notice of 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 a special meeting of the National Science Advisory Board for Biosecurity (NSABB) that was held by teleconference on September 29, 2005. The Secretary determined that advance notice was not possible, and that the meeting had to 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.

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established NSABB to provide advice, guidance and leadership regarding Federal oversight of dual-use research, defined as biological research with legitimate scientific purposes that could be misused to pose a biological threat to public health and/or national security.

Name of Committee: National Science Advisory Board for Biosecurity.

Date: September 29, 2005.

Closed: 10 a.m. to 12 p.m.

Agenda: To review confidential information.

Place: 6705 Rockledge Drive, Bethesda, Maryland, (Telephone Conference Call).

Contact Person: Allison Chamberlain, NSABB Program Assistant, 6705 Rockledge Drive, Bethesda, Maryland 20892, (301) 496–9838.

Dated: October 4, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–20748 Filed 10–17–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the President's Cancer Panel, October 24, 2005, 8 a.m. to October 24, 2005, 5 p.m., Hotel Washington, Pennsylvania Ave at 15th Street, NW., Washington, DC, 20004 which was published in the **Federal Register** on September 27, 2005, 70 FR 56477.

This meeting is amended to change the end time of the open session from 5 p.m. to 4 p.m. on October 24, 2005 and the date and time of the closed session from 1 p.m.–4 p.m. on October 25, 2005 to 4:15 p.m.–6:15 p.m. on October 24, 2005. The meeting is partially Closed to the public.

Dated: October 5, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–20742 Filed 10–17–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closing 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.