TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93	2,200	1	2,200	0.75 (45 minutes)	1,650

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

We believe that there will be minimal burden on the industry to generate information to meet the notification requirements of section 403(r)(6) of the FD&C Act by submitting information regarding section 403(r)(6) of the FD&C Act statements on labels or in labeling of dietary supplements. We also believe that submission via FURLS will not affect the burden estimates. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We estimate that, each year, approximately 2,200 firms will submit the information required by section 403(r)(6) of the FD&C Act. This estimate is based on the average number of notification submissions received by us in the preceding 3 years. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a communication to us, for a total of 1,650 hours (2,200 × 0.75).

Dated: March 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05478 Filed 3–10–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Division of Intramural Research Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Division of Intramural Research Board of Scientific Counselors, NIAID.

Date: June 6–7, 2016.

Time: 7:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, Rooms 1227 and 1223, 50 Center Drive, Rockville, MD 20852.

Contact Person: Hugh J. Auchincloss, MD, Deputy Director, NIAID Deputy Director, National Inst. of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 7A03, MSC 2520, Bethesda, MD 20892–2520, 301–496–9677, *auchinclossh@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 7, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–05429 Filed 3–10–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Study To Estimate Radiation Doses and Cancer Risks From Radioactive Fallout From the Trinity Nuclear Test—National Cancer Institute (NCI)

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, 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.

Written comments and/or suggestions from the public and affected agencies are invited to address 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 of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Steve Simon, Dosimetry Unit Head and Staff Scientist, Radiation Epidemiology Branch, Division of Cancer Epidemiology & Genetics, National Cancer Institute, NIH, 9609 Medical Center Drive, MSC9778, Bethesda, MD 20892–9778 or call non-toll-free number (240)-276–7371 or Email your request, including your address to: *ssimon@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Study to Estimate Radiation Doses and Cancer Risks from Radioactive Fallout from the Trinity Nuclear Test, 0925–NEW, New Submission, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This research plan is for a radiation-related cancer risk projection study for the residents of the state of New Mexico (NM) potentially exposed to radioactive fallout from the Trinity nuclear test conducted in 1945. Data will be collected on diet and lifestyle from three groups in NM (non-Hispanic white, Hispanic, and Native American)

alive in the 1940s via focus groups and key informant interviews and will be used to derive means and ranges of exposure-related parameters, such as consumption of contaminated foodstuffs, collection and use of water, time spend outdoors, and building materials. These parameter values will be used with historical fallout deposition data in fallout dose assessment models to estimate external and internal radiation doses to typical persons in all counties in New Mexico by ethnicity and age. The estimated doses will be used with literature-derived risk and parameter values on risk/unit dose to project the excess cancers expected (per 1,000 persons within each stratum) including uncertainty on each estimate. Endpoints are leukemia, thyroid cancer, stomach cancer, colon cancer, and all solid cancers combined.

This data collection is needed to accomplish the overall Trinity Study goals, which are to: (1) Estimate external and internal radiation dose to the four primary organs/tissues of interest (thyroid, stomach, colon, and red bone marrow) from primary radionuclides in nuclear testing fallout in each county of New Mexico as a result of the Trinity test, stratified by age, gender, ethnicity, and conditions of exposure (low, medium, high); (2) in each county, estimate the number of excess cancer cases to organs of interest per 1,000 (hypothetical) persons stratified by age, gender, ethnicity, and conditions of exposure (low, medium, high).

The study data will be collected via focus group and individual interview. Between 10 and 15 focus groups with up to 8 participants are planned. These participants will be 70 years old and older, living in New Mexico, who were alive at the time of the Trinity nuclear test and living in any of 19 Native American pueblos/tribes or Hispanic/Latino and non-Hispanic white communities in or near the fallout region in New Mexico. Additionally, up to 30 individual interviews are planned with key informants chosen to represent a variety of experiences and expertise. Individuals who prefer not to take part in a focus group will be interviewed individually as key informants. The investigators will collaborate with community representatives who will recommend potential participants for either the focus groups or interviews.

The objective of the focus groups and interviews is to collect information directly from community members who were alive at the time of the Trinity test, or with direct knowledge of specific life circumstances, cultural patterns, and dietary practices of Native Americans, Hispanics/Latinos, or non-Hispanic whites living in New Mexico at this time. In this study, two interviewers, including one with extensive experience working with tribal communities, will moderate the focus groups and conduct in-depth interviews. Translators and interpreters with experience in the study populations will be presented when needed. Each focus group and interview will be scheduled for no more than two hours and will take place in office settings, community facilities, or municipal facilities.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 395.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Instrument	Number of respondents	Frequency of response	Average time per response (in hours)	Annual burden hours
Individuals	Screener	300	1	10/60	50
	Consent Form	150	1	10/60	25
	Focus Groups	120	1	120/60	240
	Pre-Focus Group Guide	120	1	10/60	20
	Key Informants and Academics Interview	30	1	120/60	60
Totals		300	720		395

Dated: March 1, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016–05426 Filed 3–10–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 60-Day Comment Request; Population Assessment of Tobacco and Health (PATH) Study

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 Institute on Drug Abuse (NIDA), 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.

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 of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443–8755 or Email your request, including your address, to: *PATHprojectofficer@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if