DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 12, 2012, from 12 p.m. to 4:30 p.m.

Location: National Institutes of Health (NIH), Bldg. 29, Conference Room 121, 9000 Rockville Pike, Bethesda, MD 20892. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at *http://www.nih.gov/about/visitor/index.htm.* Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm.* Due to the limited available parking, visitors are encouraged to use public transportation.

Contact Person: LCDR Bryan Emery or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the advisory committee information line, or visit our Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* to learn about possible modifications before coming to the meeting.

Agenda: On June 12, 2012, the Committee will meet in open session to hear updates on the research programs of the Laboratory of Emerging Pathogens and the Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On June 12, 2012, from 12 p.m. to approximately 3:45 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 1, 2012. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 24, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 25, 2012.

Closed Committee Deliberations: On June 12, 2012, from approximately 3:45 p.m. to 4:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the site visit report of the intramural research programs and make recommendations regarding personnel staffing decision.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact LCDR Bryan Emery or Rosanna Harvey at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 15, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–12164 Filed 5–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 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.

Proposed Collection: Title: Population Assessment of Tobacco and Health (PATH) Study. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This is a large national longitudinal cohort study on tobacco use behavior and health in the United States. It is scheduled to begin in the fall of 2013 under the direction of the National Institutes of Health

(NIH) National Institute on Drug Abuse (NIDA), and in partnership with the Food and Drug Administration (FDA). Using annual interviews and the collection of bio-specimens from adults, the study is designed to establish a population-based framework for monitoring and evaluating the behavioral and health impacts of regulatory provisions by FDA as it meets its mandate under the Family Smoking Prevention and Tobacco Control Act (FSPTCA) to regulate tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. These regulatory changes are expected to influence tobacco-product risk perceptions, exposures, and use patterns in the short term, and to reduce tobacco-related morbidity and mortality in the long term. By measuring and accurately reporting tobacco product use behaviors and health effects associated with these regulatory changes, this study will provide an empirical evidence base to inform the development, implementation, and evaluation of tobacco-product regulations in the U.S.

Frequency of Response: Annually. *Affected Public:* Individuals or households. *Type of Respondents:* Youth (ages 12–17) and Adults (ages 18+). The annual reporting burden for the field test is presented in Table 1, and the annual reporting burden for the baseline data collection is presented in Table 2. The annualized cost to respondents for the field test is estimated at: $24,495; and the annualized cost to respondents for the baseline data collection is: $1,947,567. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—PATH STUDY FIELD TEST HOUR BURDEN ESTIMATES

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults—Household Screener	1,295	1	22/60	479
Adults—Individual Screener	840	1	6/60	84
Adults—Extended Interview	590	1	1 26/60	844
Adults—Tobacco Use Form	590	1	2/60	18
Youth—Extended Interview	100	1	55/60	92
Adult—Parent Interview	100	1	24/60	40
Total	3,515	1	.....	1,557

TABLE 2—PATH STUDY BASELINE HOUR BURDEN ESTIMATES

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults—Household Screener	100,983	1	22/60	37,364
Adults—Individual Screener	63,000	1	6/60	6,300
Adults—Extended Interview	42,730	1	1 26/60	61,104
Adults—Tobacco Use Form	42,730	1	2/60	1,282
Youth—Extended Interview	16,857	1	55/60	15,508
Adult—Parent Interview	16,857	1	24/60	6,743
Total	283,157	1	.....	128,301

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 of 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 Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Blvd., Room 5185; 301–443–8755; email *PATHprojectofficer@mail.nih.gov*.

Comments 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.

Dated: May 11, 2012.

Helio Chaves,

Deputy Executive Officer (OM Director), NIDA.

[FR Doc. 2012–12017 Filed 5–17–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for