Manufacturing Facility Visits, please submit a request either electronically to *http://www.regulations.gov* or in writing to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lindsay Tobias, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 877–287–1373, email: *lindsay.tobias@fda.hhs.gov*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31; 123 Stat. 1776) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing. The new provisions include, among other things, the authority to issue regulations related to tobacco product manufacturing practice in order to protect the public health and to assure that tobacco products are in compliance with the FD&C Act. Specifically, section 906(e) of the FD&C Act (21 U.S.C. 387f(e)) provides that ''in applying manufacturing restrictions to tobacco, the Secretary shall * * * prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology.''

CTP is instituting Tobacco Product Manufacturing Facility Visits to provide FDA staff with the opportunity to:

- Observe tobacco product manufacturing operations—from the receipt of raw materials to the distribution of finished products, and
- Learn about the manufacturing practices and processes unique to your facility and regulated tobacco products.

This program will also inform FDA staff as they implement the tobacco provisions of the FD&C Act.

II. Description of the Tobacco Product Manufacturing Facility Visits

In this program, groups of FDA staff plan to observe the following facilities and their operations:

- Manufacturing facilities, including facilities that process, package, label, and distribute different types of regulated tobacco products (cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products),
- Laboratory facilities that perform tobacco testing (whether third-party or in-house),
- Manufacturing facilities for components, parts, and accessories (including, but not limited to, cigarette paper, tipping paper, filters), and
- Manufacturing facilities for materials used for further processing in finished tobacco products (including, but not limited to, flavors, casings).

Please note that Tobacco Product Manufacturing Facility Visits are not intended to include or replace official FDA inspections of facilities to determine compliance with the FD&C Act; rather, these facility visits are meant to educate FDA staff and improve their understanding of the tobacco industry and its manufacturing operations.

III. Site Selection

CTP plans to select one or more of each of the following:

- Cigarette manufacturers,
- Cigarette tobacco and roll-your-own tobacco manufacturers,
- Smokeless tobacco manufacturers,
- Tobacco laboratories,
- Importers of finished tobacco products,
- Distributors and wholesalers of regulated tobacco products,
- Manufacturers of components, parts, accessories, and
- Manufacturers of materials used for further processing in finished tobacco products.

Final site selections will be based on the availability of CTP funds and resources for the relevant fiscal year, as well as the following factors, as applicable: (1) Compliance status of the requesting facility and affiliated firm; (2) whether the requesting facility is in arrears for user fees; and (3) whether the requesting facility will be engaged in active manufacturing or processing during the proposed time of the visit. All travel expenses associated with Tobacco Product Manufacturer Facility Visits will be the responsibility of CTP.

IV. Requests for Participation

The request for participation should include the following identification information:

- The name and contact information (including address, phone number, and email) of your point of contact for the request,
- The physical address(es) of the site(s) for which you are submitting a request,
- The type of processes (*e.g.,* manufacturing, laboratory practices, packaging, labeling, and distribution activities) performed at your facility,
- The type of tobacco products tested, processed, or manufactured at your facility, and
- A proposed program agenda.

Requests are to be identified with the docket number found in brackets in the heading of this document. Requests received by the Agency are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–19992 Filed 8–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health/National Institute of Environmental Health Sciences

Proposed Collection; Comment Request; The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

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 of Environmental Health Sciences (NIEHS), 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: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* This is to continue the Phase II follow-up of the Sister Study—a study of genetic and environmental risk factors for the development of breast cancer in a high-risk cohort of sisters of women who have had breast cancer. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible.

Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect at least 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters should be enriched with regard to the prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. From August 2003 through July 2009, we enrolled a cohort of 50,884 women who had not had breast cancer. We estimated that after the cohort was fully enrolled, approximately 300 new cases of breast cancer will be diagnosed during each year of follow-up. Thus far 1,634 participants have reported being diagnosed with breast cancer. *Frequency of Response:* For the remainder of the study, women will be contacted once each year (when not scheduled for ''triennial'') to update contact information and health status (10 minutes per response); and asked to complete short (75 minutes per response) follow-up interviews or questionnaires (''triennial'') every three years. Follow-up and validation of reported incident breast cancer and other health outcomes is conducted under Clinical Exemption CE 2009–09–004. *Affected Public:* Study participants, next-of-kin/proxies. *Type of Respondents:* Participants enrolled in high-risk cohort study of risk factors for breast cancer; next-of-kin/proxies. The annual reporting burden is as follows: *Estimated Number of Respondents:* 50,884 study participants or next-of-kin/proxies. *Estimated Number of Responses per Respondent:* See annualized table below:

Activity	Estimated number of responses	Estimated responses per respondent	Average burden hours per response	Estimated total burden hours requested
Annual Updates	33,923	1	10/60	85,654
Triennial Update	16,961	1	1.25	21,202
Total				26,856

Average Burden Hours Per Response:42 minutes; and *Estimated Total Annual Burden Hours Requested:* 26,856. The estimated total annualized cost to respondents $537,120 (assuming $20 hourly wage × 26,856). There are no capital, operating, or maintenance costs.

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 project or to obtain a copy of the data collection plans and instruments, contact Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3–05, PO Box 12233, Research Triangle Park, NC 27709, or call non-toll free number (919)-541–4668 or Email your request, including your address to: *sandler@niehs.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: August 7, 2012.

Joellen M. Austin,

Associate Director for Management.

[FR Doc. 2012–20067 Filed 8–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 18, 2012, pages 29667–29668 and allowed 60-days for public comment. Two 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 on or after October 1, 1995, unless it displays a currently valid OMB control number.

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 conducted 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). The field test is scheduled to begin in the fall of 2012 and the baseline collection is scheduled to begin in the fall of 2013. Using annual interviews and the collection of biospecimens from adults, the PATH 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,