possible modifications before coming to the meeting.

Agenda: On June 17, 2011, the committee will discuss biologics license application (BLA) 125387, aflibercept ophthalmic solution, proposed trade name EYLEA, sponsored by Regeneron Pharmaceuticals, Inc., indicated for the treatment of neovascular age-related macular degeneration (wet AMD).

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 link.

Procedure: 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 3, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 25, 2011. 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 26, 2011.

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 Yvette Waples 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 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–12741 Filed 5–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; comment request; Web-Based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment)

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, 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: Web-based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment).

Type of Information Collection Request: New.

Need and Use of Information Collection: The project aims to increase the provision of screening, brief intervention, and referral to treatment (SBIRT) for substance use in primary care by developing an engaging, interactive case-based training program that will be delivered over the Internet, providing convenient access to screening and brief intervention skills training and resources for busy PCPs. The goal of this study is to evaluate the effectiveness of this training on provider behavior and/or patient outcome and the program's utility as a training tool in a real-world medical setting. The training is named SBIRT–PC. Study participants will be randomly assigned to complete SBIRT–PC or a control training, consisting of online reading materials. Effectiveness will be evaluated in terms of differential SBIRT-related knowledge, attitudes, self-efficacy, self-reported clinical practices, skills as measured by virtual standardized patient evaluations (VSPE) and a telephone-based standardized patient (SP) interaction. Participants in each condition will also complete a training satisfaction questionnaire.

Frequency of Response: On occasion.

Affected Public: Private Sector; Businesses or other for-profit.

Type of Respondents: Primary Care Providers.

The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per set of responses	Estimated total annual burden hours requested
Primary Care Providers	94	1	2.0	188

There are no Capital Costs to report. 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 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 Quandra Scudder, Project Officer, National Institute on Drug Abuse NIDA, NIH, 6001 Executive Boulevard, Bethesda, MD 20892–9557, or call non-toll-free number (301) 594–0394 or E-mail your request, including your address to *scudderq@nida.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 18, 2011.

Mary Affeldt,

Executive Officer, (OM Director) NIDA.

[FR Doc. 2011–12726 Filed 5–23–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; Comment Request; Process Evaluation of the NIH Roadmap Epigenomics Program

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** in Vol. 76, No. 49, pages 13648–13649 on March 14, 2011, and allowed 60 days for public comment. No public comments were received on the planned study or any of the specific topics outlined in the 60-day notice. The purpose of this notice is to allow an additional 30 days for public comment. 5 CFR 1320.5 (General requirements) *Reporting and Recordkeeping Requirements:* Final Rule requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Proposed Collection

Title: Process Evaluation of the NIH Roadmap Epigenomics Program.

Type of Information Collection Request: New.

Need and Use of Information Collection: The proposed information collection is essential to the process evaluation of the NIH Roadmap Epigenomics Program. The process evaluation is a requirement of each of the relevant RFAs funded under the NIH Roadmap Epigenomics Program which require participating in evaluation research activities.

This evaluation study, a mixed-methods study which uses secondary source documentation and information from tracking and monitoring systems along with primary data to assess program process and progress, is non-experimental. The assessment is based on secondary source information, with primary source information collection added to augment the reliability and internal validity. The primary data collection uses information categories that genuinely tap added distinctions and opinions that relate to it to build the weight of evidence from first-hand sources that substantiate the initial hypotheses about the program phenomenon and its differences from a typical research portfolio of individual and insular projects.

The synthesized results across primary and secondary data sources will provide critical insights on transformativeness of high-impact, trans-NIH programs and contribute important information about the synergies and collaborations in multi-component scientific research. It will also identify areas for program improvement and lessons learned that might be useful to other research programs of the Agency.

To reduce response bias and to make the survey as accessible as possible to busy principal investigators, the survey will be web-based.

Frequency of Response: Once.

Affected Public: Principal Investigators of the program at not-for-profit institutions.

Type of Respondents: Principle Investigators.

The annual reporting burden is as follows:

Estimated Number of Respondents: 53.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: .33.

Estimated Total Annual Burden Hours Requested: 17.49.

The annualized cost to respondents is estimated at: $891.99.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

ESTIMATED ANNUALIZED BURDEN HOURS AND COSTS

Type of respondent	Number of respondents	Number of responses per respondent	Total number of responses	Avg. burden hours per response	Annual burden hours requested	Avg. hourly wage rate	Total annual respondent cost
Principal Investigators ..	53	1	1	[1]33	17.49	51	891.99

[1] 20 minutes.

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.

Direct Comments to OMB: Written comments and/or suggestions regarding the 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, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, *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 Genevieve deAlmeida-Morris, PhD, M.P.H., Project Officer, Office of Science Policy and