pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**), (see section 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(iii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Akhigbe, in any capacity during Dr. Akhigbe's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Akhigbe provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Akhigbe during his period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B)).

Any application by Dr. Akhigbe for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2010–N–0235 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 2010.

Howard R. Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2010–31776 Filed 12–16–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: January 19, 2011, 8:30 a.m.–4 p.m., January 20, 2011, 8:30 a.m.–12:15 p.m.

Place: Hilton Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. Telephone: (301) 468–1100.

Status: The meeting will be open to the public.

Agenda: On the morning of January 19, following welcoming remarks from the COGME Chair, HRSA senior management, and the Executive Secretary of COGME, there will be an introduction of COGME members.

The rest of the first day will consist of presentations covering various aspects of graduate medical education, Bureau of Health Professions activities concerning health workforce issues, a study of primary care physician projections by state, and work of the Medicare Payment and Advisory Commission on GME issues.

On January 20, there will be presentations on the findings and recommendations of COGME's 20th report, *Advancing Primary Care* (cover date December 2010). It is expected that the rest of the morning will be taken up in discussions in exploring the topic for COGME's next report.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerald M. Katzoff, Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–4443. The Web address for information on the Council and the January 19–20, 2011 meeting agenda is *http://cogme.gov.*

Dated: December 9, 2010.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–31712 Filed 12–16–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors: Improving the Safety of the U.S. Blood Supply Through Hemovigilance

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), 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 September 28, 2010, Volume 75, No. 187, pages 59724–59725 and allowed 60 days for public comment. 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 current valid OMB control number.

Proposed Collection: Title: Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the U.S. blood supply through hemovigilance. Type of Information Collection Request: NEW. Need and Use of Information Collection: Information on current risk factors in blood donors as assessed using analytical study designs is largely unavailable in the U.S. Studies of risk factor profiles among HIV-infected donors were funded by the CDC for approximately 10 years after implementation of serologic screening in the mid-1980s, whereas studies of HTLV- and HCV-seropositive (and indeterminate) donors, funded by NIH, were conducted in the early 1990s, but unfortunately, none of these studies is ongoing. Infection trend analyses have been conducted by the American Red Cross (ARC). The findings show continued HIV risk with the prevalence of HIV in first time donors hovering around 10 per 100,000 donations in each of the last 10 years and the incidence in repeat donors increasing from 1.49 per 100,000 person-years in 1999–2000 to 2.16 per 100,000 persons-years in 2007–2008. While the prevalence of HCV in first time donors decreased over this time interval from 345 to 163 per 100,000 donations, the incidence in repeat donors did not decrease and evidence of incident infection in first time donors increased. Moreover specific age, gender and race/ethnicity groups were over-represented. Significantly increased incidence of both HIV and HCV were observed in 2007/2008 compared to 2005/2006. Similar analyses for HBV have shown an incidence in all donors of 3.4 per 100,000 person-years which is lower

than earlier estimates, but remains higher than for HIV and HCV.

This project represents a collaborative pilot research study that will include a comprehensive interview study of viral infection positive blood donors at the American Red Cross (ARC), Blood Systems Inc. (BSI) and New York Blood Center (NYBC) in order to identify the current predominant risk factors for virus positive donations and will also establish a donor biovigilance capacity that currently does not exist in the U.S. At this time it is not easy to integrate risk factor data and disease marker surveillance information within or across different blood collection organizations because common interview procedures and laboratory confirmation procedures are not being used and so we cannot easily tabulate and analyze behavioral risks or viral infections in U.S. blood donors. This creates the potential for gaps in our understanding of absolute incidence and prevalence as well as risks that could lead to transfusion-transmitted disease. Combined data are critical for appropriate national surveillance efforts. For example, this information could be used to target educational interventions to reduce donations from persons with high risk behaviors. This is particularly important in the case of behaviors associated with incident (recently acquired) infections because these donations have the greatest potential transmission risk because they could be missed during routine testing. As part of the project a comprehensive research-quality biovigilance database will be created that integrates existing operational information on blood donors, disease marker testing and blood components collected by participating organizations into a research database. The combined database will capture infectious disease and risk factor information on nearly 60% of all blood donors and donations in the country. Following successful completion of the risk factor interviews and research database development, the biovigilance network pilot can be expanded to include additional blood centers and/or re-focused on other safety threats as warranted, such as XMRV. This pilot biovigilance network will thereby establish a standardized process for integration of information across blood collection organizations.

The Specific Aims are to:

(1) Define consensus infectious disease testing classification algorithms for HIV, HCV, HBV, and HTLV that can be used to consistently classify donation testing results across blood collection organizations in the U.S. This will allow for better estimates of infection disease marker prevalence and incidence in the U.S.

(2) Determine current behavioral risk factors associated with prevalent and incident (when possible) HIV, HCV, HBV and HTLV infections in blood donors, including parenteral and sexual risks, across the participating blood collection organizations using a case-control study design.

(3) Determine nationally-representative infectious disease marker prevalence and incidence for HIV, HCV, HBV, and HTLV overall and by demographic characteristics of donors. This will be accomplished by forming research databases from operational data at BSI and NYBC into formats that can be combined with the ARC research database.

(4) Analyze integrated risk factor and infectious marker testing data together because when taken together these may show that blood centers are not achieving the same degree of success in educational efforts to prevent donation by donors with risk behaviors across all demographic groups.

Frequency of Response: Once. Affected Public: Individuals. Type of Respondents: Adult blood donors. The annual reporting burden is as follows: Estimated Number of Respondents:4150; Estimated Number of Responses per Respondent: 1; Average Burden of Hours per Response: 0.58 and Estimated Total Annual Burden Hours Requested: 2407. The annualized cost to respondents is estimated at: $43,326 (based on $18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1–1—ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Cases	1650	1	0.58	957
Controls	2500	1	0.58	1450
Total	4150			2407

TABLE 1–2—ANNUALIZED COST TO RESPONDENTS

Type of respondents	Number of respondents	Frequency of response	Average time per respondents	Hourly wage rate	Respondent cost
Cases	1650	1	0.58	$18	17,226
Controls	2500	1	0.58	18	26,100
Total	4150				43,326

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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: Dr. Simone Glynn, Project Officer, NHLBI, Two Rockledge Center, Room 9142, 6701 Rockledge Drive, Bethesda, MD 20892–7950, or call 301–435–0065, or E-mail your request to *glynnsa@nhlbi.nih.gov.*

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

Dated: December 16, 2010.

Simone Glynn,

Branch Chief, Transfusion Medicine and Cellular Therapeutics Branch, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, NIH.

[FR Doc. 2010–31734 Filed 12–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Study of Substance Abuse doc.com Module Project

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, 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: Study of Substance Abuse doc.com Module Project. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This is a request for a two-year generic clearance to a conduct research study to assess the efficacy of a specific interactive web-based teaching module in the field of professional education of healthcare providers. This online module was developed as a work product by the same team of investigators from Drexel University College of Medicine (DUCOM) and University of Pennsylvania School of Medicine (Penn Med) under a contract as part of NIDA's Center of Excellence (CoE) for Physician Information. This project will assess efficacy of the NIDA CoE online teaching module with educational interventions in enhancing: (1) The knowledge of healthcare professionals about substance use disorders; (2) attitudes of healthcare professionals toward patients with these disorders and (3) communication skills in providing assessment and referral to treatment for patients who abuse substances. The overall goal of this project is to assess the efficacy of an educational intervention, which should result in an increase in the involvement of primary care providers in the screening, managing and, when appropriate, referring patients with substance use disorders. This effort is made according to Executive Order 12862, which directs Federal agencies that provide significant services directly to the public to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.

The project will utilize a randomized cluster controlled trial design that compares the group that receives educational exposure to the set of new educational interventions (NIDA online teaching module plus educational adjuncts) to a control group that receives exposure to the standard medical school or residency educational curriculum related to substance use disorders. The project will use a repeated measures approach to assess the educational intervention's efficacy (*i.e.,* individuals will take surveys before and after exposure to the intervention or to the control curriculum). The outcomes of the study will be based on changes in knowledge, attitudes and indirect measures of communication skills before and after the intervention, compared to the changes in these parameters in the control group.

Frequency of Response: This project will be conducted annually or biennially. *Affected Public:* Individuals and businesses. *Type of Respondents:* medical students and resident physicians. The annual reporting burden is calculated as follows: *Estimated Total Annual Number of Respondents:* 708; *Estimated Number of Responses per Respondent:* 4 for medical students; 2 for resident physicians; *Average Burden Hours per Response:* 0.17. *Estimated Total Annual Burden Hours Requested:* 377; There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. The estimated annualized burden is summarized below.

Respondents	Estimated number of subjects	Estimated number of surveys per subject	Average burden hours per survey	Estimated total burden hours
Medical Students	400	4	0.17	272
Primary Care Resident Physicians	308	2	0.17	105
Total	708			377

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 functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFROMATION CONTACT: To request more information on the proposed projects or to obtain a copy of the information collection plans, contact Elisabeth Davis, Project Officer, National Institute on Drug Abuse, NIDA/NIH/DHHS, 6001 Executive Boulevard, MSC 9591, Bethesda, MD 20852; or call non-toll-free number (301) 594–6317; fax (301) 480–2485; or e-mail your request, including your address to: *davise2@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.