these report types change over the product's marketed life cycle?

(4) What are the roles of reports by health care professionals and consumers in safety signal detection?

(5) Are there any types of AE reports that are not helpful to safety signal detection?

(6) What do we know about non-reported AEs or characteristics associated with non-reporting?

FDA is working to refine the workshop agenda and to invite panel members. We are seeking broad participation by safety researchers, health system officials, the pharmaceutical industry, and others. We anticipate issuing a summary of the workshop findings, including a discussion of implications and next steps for further development.

II. Comments

The agency is interested in hearing comments at the public workshop or receiving written comments (see **ADDRESSES**) on the issues described previously. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Attendance and Registration

The Conference Facility (terrace level) located at 5635 Fishers Lane is a Federal facility with limited seating and security procedures for entrance. Workshop attendees will be required to show proper identification and are asked to allow time for security procedures. Seating will be made available on a first-come basis. Individuals who wish to speak during the public workshop must register on or before January 15, 2008. You should identify the subject matter you wish to address during the public workshop. Please specify either panel one or panel two (see section I of this document). To register to speak, please contact Lana Pauls (see **FOR FORTHER INFORMATION CONTACT**).

Ample time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage written comments to the docket.

If you need special accommodations because of disability, please contact Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

IV. Workshop Transcripts

The workshop will be transcribed. The transcript will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets*, approximately 30 days after the workshop.

Dated: December 18, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–24960 Filed 12–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Loan Repayment; Proposed Collection; Comment Request; National Institutes of Health Loan Repayment Programs

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 Division of Loan Repayment, 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: National Institutes of Health Loan Repayment Programs. *Type of Information Collection Request:* Revision of currently approved collection (OMB No. 0925–0361, expiration date 6/30/08). Form Numbers: NIH 2674–1, NIH 2674–2, NIH 2674–3, NIH 2674–4, NIH 2674–5, NIH 2674–6, NIH 2674–7, NIH 2674–8, NIH 2674–9, NIH 2674–10, NIH 2674–11, NIH 2674–12, NIH 2674–13, NIH 2674–14, NIH 2674–15, NIH 2674–16, NIH 2674–17, NIH 2674–18, and NIH 2674–19. *Need and Use of Information Collection:* The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm.D., D.D.S., D.M.D., D.P.M., D.C., and N.D. degree holders, or the equivalent, who perform biomedical or behavioral research in NIH intramural laboratories or as extramural grantees for a minimum of 2 years (3 years for the General Research Loan Repayment Program (LRP)) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS–LRP) is authorized by Section 487A of the Public Health Service Act (42 U.S.C. 288–1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR–LRP) is authorized by Section 487E (42 U.S.C. 288–5); the General Research Loan Repayment Program (GR–LRP) is authorized by Section 487C (42 U.S.C. 288–3); the Loan Repayment Program Regarding Clinical Researchers (LRP–CR) is authorized by Section 487F (42 U.S.C. 288–5a); the Pediatric Research Loan Repayment Program (PR–LRP) is authorized by Section 487F (42 U.S.C. 288–6); the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR-LRP) is authorized by an amendment to Section 487E (42 U.S.C. 288–5); the Contraception and Infertility Research LRP (CIR–LRP) is authorized by Section 487B (42 U.S.C. 288–2); and the Health Disparities Research Loan Repayment Program (HD–LRP) is authorized by Section 485G (42 U.S.C. 287c-33).

The Loan Repayment Programs provide for the repayment of up to $35,000 a year of the principal and interest of the educational loan debt of qualified health professionals who agree to conduct qualifying research for each year of obligated service. The information proposed for collection will be used to determine an applicant's eligibility for participation in the program. *Frequency of Response:* Initial application and annual or biennial renewal application. *Affected Public:* Applicants, financial institutions, research institutions, recommenders. *Type of Respondents:* Physicians, other scientific or medical personnel, and organizational officials. The annual reporting burden is as follows:

Type of respondents	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual burden hours requested
Intramural LRPs				
Initial Applicants	30	1	10.11	303.30
Advisors/Supervisors	30	1	.5	15.00
Recommenders	90	1	.33	29.70
Financial Institutions	10	1	1.25	12.50

Type of respondents	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual burden hours requested
Subtotal	160			360.50
Extramural LRPs				
Initial Applicants	1,900	1	10.35	19,665.00
Advisors/Supervisors	1,750	1	.5	875.00
Recommenders	5,700	1	.33	1881.00
Financial Institutions	300	1	1.25	375.00
Subtotal	9,650			22,796.00
Intramural LRPs				
Renewal Applicants	60	1	7.42	445.20
Advisors/Supervisors	60	1	1.33	79.80
Subtotal	120			525.00
Extramural LRPs				
Renewal Applicants	1,225	1	8.58	10,510.50
Advisors/Supervisors	925	1	1.00	925.00
Recommenders	3,675	1	.33	1,212.75
Subtotal	5,825			12,648.25
Total	15,755			36,329.75

The annualized cost to respondents is estimated at $1,298,341. There are no capital costs, operating costs, 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: Sherry Mills, M.D., M.P.H., Acting Director, Division of Loan Repayment, National Institutes of Health, 6011 Executive Blvd, Room 206 (MSC 7650), Bethesda, Maryland 20892–7650. Dr. Mills may be contacted via e-mail at *Millsshe@od.nih.gov* or by calling 301–402–2642 (not a toll-free number).

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

Dated: December 17, 2007.

Raynard S. Kington,

Deputy Director, National Institutes of Health.

[FR Doc. E7–24899 Filed 12–21–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Blood Substitute Study.

Date: January 15, 2008.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Youngsuk Oh, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924, 301–435–0277, *yoh@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Vaccine Study.

Date: January 22, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Youngsuk Oh, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924, 301–435–0277, *yoh@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Cardiovascular and Lung Imaging.

Date: January 23, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Youngsuk Oh, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924, 301–435–0277, *yoh@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases