

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2008-N-0352. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Alfred Kempinski, Office of the PDUFA Business Program Manager, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1127, Silver Spring, MD 20993-0002, 301-796-1999.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an updated IT plan entitled "PDUFA IV Information Technology Plan." This plan will meet one of the performance goals agreed to under the 2007 reauthorization of PDUFA IV (Title I of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85)). Under section XIV of the PDUFA Performance Goals, FDA agreed to develop, periodically update, and publish for comment an IT plan for achieving the objectives defined in section XIV, Information Technology Goals, of the PDUFA Performance Goals (see <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm>). This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications, to achieve the objectives defined in section XIV of the PDUFA Performance Goals. The objectives of the PDUFA IV IT Goals are to move FDA towards the long-term goal of an automated standards-based information technology environment for the exchange, review, and management

of information supporting the process for the review of human drug applications throughout the product life cycle.

In the **Federal Register** of June 30, 2008 (73 FR 36880), FDA issued a notice announcing the availability of an earlier version of the IT plan entitled "Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan" (June 2008 plan). This updated plan revises the June 2008 plan; it communicates the progress and strategic changes for key initiatives that illustrate the accomplishment of near-term objectives and describes FDA's strategy for meeting the long-term goal of a fully electronic submission and review environment. The sections that have been revised are identified in the Revision Index (after the Table of Contents) in the updated plan.

FDA conducts an annual IT assessment to measure performance against the IT plan. The 2010 Annual IT Assessment is available at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm183308.htm>.

II. Electronic Access

Persons with access to the Internet may obtain the updated plan at <http://www.regulations.gov>.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 12, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2011-23923 Filed 9-16-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on

proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-0165.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) 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.

Proposed Project: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy) (OMB No. 0915-0047)—[Extension]

The regulations for the Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program contain a number of reporting and recordkeeping requirements for schools and loan applicants. The requirements are essential for assuring that borrowers are aware of rights and responsibilities, know the history and status of each loan account in order to pursue aggressive collection efforts to reduce default rates, and that they maintain adequate records for audit and assessment purposes. Schools are free to use improved information technology to manage the information required by the regulations.

The estimated total burden is 49,489 hours. The annualized burden estimates are as follows:

RECORDKEEPING REQUIREMENTS

| Regulatory/section requirements | Number of recordkeepers | Hours per year | Total burden hours |
|---|-------------------------|----------------|--------------------|
| HPSL Program: | | | |
| 57.206(b)(2), Documentation of Cost of Attendance | 435 | 1.17 | 509 |
| 57.208(a), Promissory Note | 435 | 1.25 | 544 |
| 57.210(b)(1)(i), Documentation of Entrance Interview | 435 | 1.25 | 544 |
| 57.210(b)(1)(ii), Documentation of Exit Interview | * 477 | 0.33 | 157 |
| 57.215(a) & (d), Program Records | * 477 | 10 | 4,770 |
| 57.215(b), Student Records | * 477 | 10 | 4,770 |
| 57.215(c), Repayment Records | * 477 | 18.75 | 8,944 |
| HPSL Subtotal | | | 20,238 |
| NSL Program: | | | |
| 57.306(b)(2)(ii), Documentation of Cost of Attendance | 304 | 0.3 | 91 |
| 57.308(a), Promissory Note | 304 | 0.5 | 152 |
| 57.310(b)(1)(i), Documentation of Entrance Interview | 304 | 0.5 | 152 |
| 57.310(b)(1)(ii), Documentation of Exit Interview | * 486 | 0.17 | 83 |
| 57.315(a)(1) & (a)(4), Program Records | * 486 | 5 | 2,430 |
| 57.315(a)(2), Student Records | * 486 | 1 | 486 |
| 57.215(b)(3), Repayment Records | * 486 | 2.51 | 1,220 |
| NSL Subtotal | | | 4,614 |

* Includes active and closing schools.

HPSL data include active and closing Loans for Disadvantaged Students (LDS) program schools.

REPORTING REQUIREMENTS

| Regulatory/section requirements | Number of respondents | Responses per respondent | Total annual responses | Hours per response | Total burden hours |
|---|-----------------------|--------------------------|------------------------|--------------------|--------------------|
| HPSL Program: | | | | | |
| 57.206(a)(2), Student Financial Aid Transcript | 4,600 | 1 | 4,600 | 0.25 | 1,150 |
| 57.208(c), Loan Information Disclosure | 435 | 68.73 | 29,898 | 0.0833 | 2,490 |
| 57.210(b)(1)(i), Entrance Interview | 435 | 68.73 | 29,898 | 0.167 | 4,993 |
| 57.210(b)(1)(ii), Exit Interview | * 477 | 12 | 5,724 | 0.5 | 2,862 |
| 57.210(b)(1)(iii), Notification of Repayment | * 477 | 30.83 | 14,706 | 0.167 | 2,456 |
| 57.210(b)(1)(iv), Notification During Deferment | * 477 | 24.32 | 11,601 | 0.0833 | 966 |
| 57.210(b)(1)(vi), Notification of Delinquent Accounts ... | * 477 | 10.28 | 4,904 | 0.167 | 819 |
| 57.210(b)(1)(x), Credit Bureau Notification | * 477 | 8.03 | 3,830 | 0.6 | 2,298 |
| 57.210(b)(4)(i), Write-off of Uncollectable Loans | 20 | 1 | 20 | 3 | 60 |
| 57.211(a), Disability Cancellation | 10 | 1 | 10 | 0.75 | 8 |
| 57.215(a)(2), Administrative Hearings | 0 | 0 | 0 | 0 | 0 |
| 57.215(a)(d), Administrative Hearings | 0 | 0 | 0 | 0 | 0 |
| HPSL Subtotal | | | | | 18,102 |
| NSL Program: | | | | | |
| 57.306(a)(2), Student Financial Aid Transcript | 4,100 | 1 | 4,100 | 0.25 | 1,025 |
| 57.310(b)(1)(i), Entrance Interview | 304 | 23.51 | 7,147 | 0.167 | 1,193 |
| 57.310(b)(1)(ii), Exit Interview | * 486 | 3.77 | 1,832 | 0.5 | 916 |
| 57.310(b)(1)(iii), Notification of Repayment | * 486 | 6.18 | 3,003 | 0.167 | 501 |
| 57.310(b)(1)(iv), Notification During Deferment | * 486 | 0.65 | 316 | 0.083 | 26 |
| 57.310(b)(1)(vi), Notification of Delinquent Accounts ... | * 486 | 4.61 | 2,240 | 0.167 | 374 |
| 57.310(b)(1)(x), Credit Bureau Notification | * 486 | 8.3 | 4,033 | 0.6 | 2,420 |
| 57.310(b)(4)(i), Write-off of Uncollectable Loans | 20 | 1 | 20 | 3.5 | 70 |
| 57.311(a), Disability Cancellation | 10 | 1 | 10 | 0.8 | 8 |
| 57.315(a)(1)(ii), Administrative Hearings | 0 | 0 | 0 | 0 | 0 |
| 57.316(a)(d), Administrative Hearings | 0 | 0 | 0 | 0 | 0 |
| NSL Subtotal | | | | | 6,535 |

* Includes active and closing schools.

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 13, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–23892 Filed 9–16–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 Site Visit (2012/01).

Date: October 24–26, 2011.

Time: 8 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Springhill Suites by Marriott, Pittsburgh Southside Works, 2950 South Water Street, Pittsburgh, PA 15203.

Contact Person: John K. Hayes, PhD, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Room 959, Bethesda, MD 20892, 301–451–3398, hayesj@mail.nih.gov.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Health Disparities SBIR 2012/01.

Date: November 7, 2011.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NIBIB, DEM II, 6707 Democracy Blvd, 900, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Ruixia Zhou, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, 301–496–4773, zhour@mail.nih.gov.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; 2012–01 K-Award Review Meeting.

Date: November 16, 2011.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: John K. Hayes, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Room 959, Bethesda, MD 20892, 301–451–3398, hayesj@mail.nih.gov.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Development of Multiscale Models (U01).

Date: November 17, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Manana Sukhareva, PhD, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301–451–3397, sukharem@mail.nih.gov.

Dated: September 13, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–24031 Filed 9–16–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

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

The meeting 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Initial Review Group; Genome Research Review Committee; Centers of Excellence in Genomic Science (CEGS).

Date: November 3–4, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ken D. Nakamura, PhD, Scientific Review Officer, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301 402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: September 13, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–24026 Filed 9–16–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIDCD.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Deafness and Other Communication Disorders, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDCD.

Date: October 27–28, 2011.

Closed: October 27, 2011, 10 a.m. to 10:30 a.m.