

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 074126 ....	Atenolol Tablets USP, 25 mg, 50 mg, and 100 mg .....	Do.
ANDA 074589 ....	Minoxidil Topical Solution, 2% .....	Teva Pharmaceuticals USA.
ANDA 074828 ....	Acyclovir Capsules, 200 mg .....	Do.
ANDA 074849 ....	Clomipramine HCl Capsules, 25 mg, 50 mg, and 75 mg .....	Do.
ANDA 074879 ....	Ketoprofen Extended-Release Capsules, 200 mg .....	Alkermes Gainesville LLC, 1300 Gould Dr., Gainesville, GA 30504.
ANDA 074976 ....	Acyclovir Tablets USP, 400 mg and 800 mg .....	Mylan Pharmaceuticals, Inc.
ANDA 074977 ....	Acyclovir Capsules USP, 200 mg .....	Do.
ANDA 075161 ....	Ticlopidine HCl Tablets USP, 250 mg .....	Do.
ANDA 075472 ....	Enalapril Maleate Tablets USP, 2.5 mg, 5 mg, 10 mg, and 20 mg.	Do.
ANDA 075934 ....	Nizatidine Capsules USP, 150 mg and 300 mg .....	Do.
ANDA 076036 ....	Quinapril Tablets USP, 5 mg, 10 mg, 20 mg, and 40 mg .....	Do.
ANDA 076969 ....	Metoprolol Succinate Extended-Release Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg.	Sandoz, Inc.
ANDA 077136 ....	Terbinafine HCl Tablets, 250 mg .....	Mylan Pharmaceuticals, Inc.
ANDA 077163 ....	Sumatriptan Succinate Tablets, 25 mg, 50 mg, and 100 mg ..	Do.
ANDA 077254 ....	Divalproex Sodium Delayed-Release Tablets USP, 125 mg, 250 mg, and 500 mg.	Do.
ANDA 077486 ....	Glimepiride Tablets USP, 1 mg, 2 mg, and 4 mg .....	Do.
ANDA 077705 ....	Fosinopril Sodium and Hydrochlorothiazide Tablets, 10 mg/12.5 mg and 20 mg/12.5 mg.	Do.
ANDA 077934 ....	Meloxicam Tablets USP, 7.5 mg and 15 mg .....	Do.
ANDA 077976 ....	Cromolyn Sodium Nasal Solution USP, 5.2 mg/1 spray .....	HH & P LLC, c/o Kuker Regulatory Consulting, LLC, 18 Dunbar Way, Mahtomedi, MN 55115.
ANDA 078638 ....	Alendronate Sodium Tablets USP, 35 mg and 70 mg .....	Mylan Pharmaceuticals, Inc.
ANDA 078731 ....	Levetiracetam Tablets, 250 mg, 500 mg, 750 mg, and 1,000 mg.	Do.
ANDA 079184 ....	Ursodiol Tablets USP, 250 mg and 500 mg .....	Teva Pharmaceuticals USA.
ANDA 081295 ....	Estradiol Tablets USP, 0.5 mg .....	Bristol-Myers Squibb Co.
ANDA 084499 ....	Estradiol Tablets USP, 1 mg .....	Do.
ANDA 084500 ....	Estradiol Tablets USP, 2 mg .....	Do.
ANDA 085794 ....	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124.
ANDA 085795 ....	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	Do.
ANDA 087176 ....	Chlorthalidone Tablets USP, 50 mg .....	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 087653 ....	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Mutual Pharmaceutical Co., Inc.
ANDA 088833 ....	Triprolidine HCl, pseudoephedrine HCl, and Codeine Phosphate Cough Syrup, 1.25 mg/5 mL, 30 mg/5 mL, and 10 mg/5 mL.	Wockhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 088896 ....	Promethazine VC with Codeine (promethazine HCl, phenylephrine HCl, and codeine phosphate) Cough Syrup, 6.25 mg/5 mL, 5 mg/5 mL, and 10 mg/5 mL.	Do.
NDA 202343 .....	Juvisync (sitagliptin and simvastatin) Tablets, 100 mg/10 mg, 100 mg/20 mg, and 100 mg/40 mg.	Merck Sharp & Dohme Corp., 351 North Sumneytown Pike, P.O. Box 1000, UG2CD-015, North Wales, PA 19454.

<sup>1</sup> This product included an oral pressurized metered-dose inhaler that contained chlorofluorocarbons (CFCs) as a propellant. CFCs may no longer be used as a propellant for any flunisolide metered-dose inhalers (see 75 FR 19213, April 14, 2010).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective January 5, 2015. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in

Table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 1, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2014-28541 Filed 12-4-14; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork

Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than January 5, 2015.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA\_submission@omb.eop.gov* or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Health Professions Student Loan (HPSL) Program and Nursing Student Loan

(NSL) Program Administrative Requirements (Regulations and Policy). OMB No. 0915-0047—Extension.

**Abstract:** The statutory authorities for the Health Professions Student Loan (HPSL) Program, as authorized by Public Health Service (PHS) Act sections 721-722, and 725-735, and the Nursing Student Loan (NSL) Program, as authorized by PHS Act sections 835-842, contain a number of recordkeeping and reporting requirements for academic institutions and loan applicants. The applicable regulations for these programs under 42 CFR part 57 details the various requirements (see chart below).

**Need and Proposed Use of the Information:** The requirements are essential for assuring that borrowers are aware of their rights and responsibilities, academic institutions have accurate records of the history and status of each loan account in order to pursue aggressive collection efforts to reduce default rates, and that academic institutions maintain adequate records for audit and assessment purposes to help the U.S. Department of Health and Human Services safeguard federal funds

made through the Federal Capital Contribution (FCC). Academic institutions are free to use improved information technology to manage the information required by the regulations.

**Likely Respondents:** Financial Aid Directors working at institutions participating in the HPSL and NSL Programs.

**Burden Statement:** Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS  
RECORDKEEPING REQUIREMENTS**

Regulatory/section requirements	Number of record keepers	Hours per year	Total burden hours
<b>HPSL Program:</b>			
57.206(b)(2), Documentation of Cost of Attendance .....	50	325	16,250
57.208(a), Promissory Note .....	90	325	29,250
57.210(b)(1)(i), Documentation of Entrance Interview .....	40	325	13,000
57.210(b)(1)(ii), Documentation of Exit Interview .....	80	334	26,720
57.215(a)&(d), Program Records .....	140	334	46,760
57.215(b), Student Records .....	70	334	23,380
57.215(c), Repayment Records .....	150	334	50,100
<b>HPSL Subtotal .....</b>	<b>.....</b>	<b>.....</b>	<b>205,460</b>
<b>NSL Program:</b>			
57.306(b)(2)(ii), Documentation of Cost of Attendance .....	16.0	282	4,512
57.308(a), Promissory Note .....	4.5	282	1,269
57.310(b)(1)(i), Documentation of Entrance Interview .....	1.5	282	423
57.310(b)(1)(ii), Documentation of Exit Interview .....	1.5	348	522
57.315(a)(1)&(a)(4), Program Records .....	21.0	348	7,308
57.315(a)(2), Student Records .....	8.5	348	2,958
57.315(a)(3), Repayment Records .....	5.0	348	1,740
<b>NSL Subtotal .....</b>	<b>.....</b>	<b>.....</b>	<b>18,732</b>

\* Includes active and closing schools.  
HPSL data includes 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 hour burden
<b>HPSL Program:</b>					
57.206(a)(2), Student Financial Aid Transcript .....	n/a	.....	.....	.....	.....
57.208(c), Loan Information Disclosure .....	325	299.5	97,338	0.63	60,836
57.210(b)(1)(i), Entrance Interview .....	325	139.5	45,338	0.50	22,669
57.210(b)(1)(ii), Exit Interview .....	334	113.5	37,909	1.00	37,909

REPORTING REQUIREMENTS—Continued

Regulatory/section requirements	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total hour burden
57.210(b)(1)(iii), Notification of Repayment .....	334	862.5	288,075	0.38	108,028
57.210(b)(1)(iv), Notification During Deferment .....	334	17.0	5,678	0.63	3,549
57.210(b)(1)(vi), Notification of Delinquent Accounts ...	334	172.5	57,615	1.25	72,019
57.210(b)(1)(x), Credit Bureau Notification .....	334	6	2,004	0.50	1,002
57.210(b)(4)(i), Write-off of Uncollectible Loans .....	5	1	5	3.00	15
57.211(a) Disability Cancellation .....	3	1	3	1.00	3
57.215(a)(2), Administrative Hearings .....	0	0	0	0	0
57.215(a)(d), Administrative Hearings .....	0	0	0	0	0
<b>HPSL Subtotal</b> .....					<b>306,029</b>
<b>NSL Program:</b>					
57.306(a)(2), Student Financial Aid Transcript .....					
57.310(b)(1)(i), Entrance Interview .....	282	17.5	4,935	0.42	2,048
57.310(b)(1)(ii), Exit Interview .....	348	9.0	3,132	0.42	1,300
57.301(b)(1)(iii), Notification of Repayment .....	348	9.0	3,132	0.27	830
57.310(b)(1)(iv), Notification During Deferment .....	348	1.5	522	0.29	151
57.310(b)(1)(vi), Notification of Delinquent Accounts ...	348	42.5	14,790	0.04	592
57.310(b)(1)(x), Credit Bureau Notification .....	348	709.0	246,732	0.00	86
57.310(b)(4)(i), Write-off of Uncollectible Loans .....	23	1.0	23	3.00	69
57.311(a), Disability Cancellation .....	16	1.0	16	1.00	16
57.315(a)(1)(ii), Administrative Hearings .....	0	0	0	0	0
57.316(a)(d), Administrative Hearings .....	0	0	0	0	0
<b>NSL Subtotal</b> .....					<b>5,092</b>

\*Includes active and closing schools.

**Jackie Painter,**

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014-28555 Filed 12-4-14; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; 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 Cancer Institute Special Emphasis Panel; Outstanding Investigator Award 2.  
*Date:* March 24–26, 2015.  
*Time:* 6:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

*Contact Person:* Peter J. Wirth, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W154, Rockville, MD 20850, 240-276-6434, *pw2q@nih.gov*.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Outstanding Investigator Award 1.

*Date:* March 24–26, 2015.

*Time:* 6:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

*Contact Person:* Michael B. Small, Ph.D., Chief, Program and Review Extramural Staff Training Office, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W412, Rockville, MD 20850, 240-276-6438, *smallm@mail.nih.gov*.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Outstanding Investigator Award 3.

*Date:* March 24–26, 2015.

*Time:* 6:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

*Contact Person:* Shamala K. Srinivas, Ph.D., Scientific Review Officer, Office of

Referral, Review, and Program Coordination, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W530, Rockville, MD 20850, 240-276-6442, *ss537t@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/sep/sep.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 1, 2014.

**Melanie J. Gray,**

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-28530 Filed 12-4-14; 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 Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as