children and the permission of their parents or guardians, as set forth in 45 CFR 46.408 and 21 CFR 50.55.

HHS has received a request on behalf of the Washington University Medical Center IRB to review under 45 CFR 46.407 the protocol entitled ''Precursor Preference in Surfactant Synthesis of Newborns.'' The principal investigator proposes to administer to preterm and full-term newborns simultaneous 24-hour infusions of palmitate and acetate labeled with the stable (nonradioactive) isotope carbon-13, then measure the incorporation of each into surfactant, collected by tracheal aspiration. Subjects of the study would include approximately 10 full-term, intubated infants with normal lungs and 15 to 20 preterm (24 to 28 weeks gestational age), intubated infants with respiratory distress syndrome.

The overall goal of the proposed study is to better understand the potential differences in precursor preferences in surfactant synthesis between preterm infants with immature lungs (requiring mechanical ventilation) and full-term infants with normal lung function. The three specific aims of the study are to: (1) Determine the rate of surfactant synthesis using de novo synthesized fatty acids (acetate), (2) determine the rate of surfactant synthesis using preformed fatty acids (palmitate), and (3) compare the rates of incorporation in preterm infants versus full-term infants with normal lungs.

The Washington University Medical Center IRB determined that the protocol was not approvable under 45 CFR 46.404, 46.405, or 46.406 because the 24-hour isotope infusion and extra blood draws pose more than minimal risks to the subjects, there is no prospect of direct benefit to the individual subjects, the interventions or procedures do not present an experience to the control group that are reasonably commensurate with those inherent in their expected medical situation, and the control group does not have the condition or disorder under study. Accordingly, the Washington University Medical Center IRB forwarded the protocol to OHRP under 45 CFR 46.407 for consideration. Because this clinical investigation is regulated by FDA, FDA's regulations in part 50, subpart D, specifically § 50.54, apply as well.

In accordance with 45 CFR 46.407(b) and 21 CFR 50.54(b), OHRP and FDA are soliciting public review and comment on this proposed clinical investigation. In particular, comments are solicited on the following questions: (1) What are the potential benefits, if any, to the subjects and to children in general; (2) what are the types and degrees of risk that this research presents to the subjects; (3) are the risks to the subjects reasonable in relation to the anticipated benefits, and is the research likely to result in knowledge that can be generalized about the subjects' disorder or condition; and (4) does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

To facilitate the public review and comment process, FDA has established a public docket and placed in that docket information relating to the proposed clinical investigation, including the following: Correspondence from Washington University Medical Center referring the proposed research protocol to HHS for consideration under 45 CFR 46.407; correspondence from FDA and OHRP to Washington University Medical Center regarding the proposed protocol; the research protocol; NIH's grant funding the protocol; IRB's deliberations on the proposed research; the drug preparation protocol; certificate of analysis of the test compounds; the data safety monitoring plan; and the parental permission documents. Electronic copies of these documents can be viewed at the Pediatric Advisory Committee (PAC) Docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Pediatric Ethics Subcommittee meetings.) These materials are also available on OHRP's website at *http://www.hhs.gov/ohrp/children/*.

All written comments concerning this proposed research should be submitted to FDA's Division of Dockets Management under 21 CFR 10.20, no later than 4:30 p.m. on June 17, 2005. The background materials and received comments may be viewed on FDA's Web site at *http://www.fda.gov/ohrms/dockets/dockets/05n0184/05n0184.htm* or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. The background materials may also be viewed on OHRP's Web site at *http://www.hhs.gov/ohrp/children/*.

Dated: May 19, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–10438 Filed 5–24–05; 8:45 am]

BILLING CODE 4160–01–S

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, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) 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; (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 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 that schools know the history and staus of each loan account that schools 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 annual burden is 34,558 hours. The 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	547	1.17	640
57.208(a), Promissory Note	547	1.25	684
57.210((b)(1)(i), Documentation of Entrance Interview	547	1.25	684
57.210(b)(1)(ii), Documentation of Exit Interview	*576	0.33	190
57.215(a) & (d), Program Records	*576	10	5,760
57.215(b), Student Records	*576	10	5,760
57.215(c), Repayment Records	*576	18.75	10,800
HPSL Subtotal	576	.....	24,518
NSL Program:			
57.306(b)(2)(ii), Documentation of Cost of Attendance	315	0.3	95
57.308(a), Promissory Note	315	0.5	158
57.310(b)(1)(i), Documentation of Entrance Interview	315	0.5	158
57.310(b)(1)(ii), Documentation of Exit Interview	*502	0.17	85
57.315(a)(1) & (a)(4), Program Records	*502	5	2,510
57.315(a)(2), Student Records	*502	1	502
57.315(a)(3), Repayment Records	*502	2.51	1,255
NSL Subtotal	502		4,763

*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
HPSL Program:					
57.205(a)(2), Excess Cash	Burden included under 0915–0044				
57.206(a)(2), Student Financial Aid Transcript	4,679	1	4,679	.25	1,170
57.208(c), Loan Information Disclosure	547	68.73	37,595	.0833	3,132
57.210(a)(3), Deferment Eligibility	Burden included under 0915–0044				
57.210(b)(1)(i), Entrance Interview	547	68.73	37,595	0.167	6,278
57.210(b)(1)(ii), Exit Interview	*547	12	6,564	0.5	3,282
57.210(b)(1)(iii), Notification of Repayment	*547	30.83	16,864	0.167	2,816
57.210(b)(1)(iv), Notification During Deferment	*547	24.32	13,303	0.0833	1,108
57.210(b)(1)(vi), Notification of Delinquent Accounts	*547	10.28	5,623	0.167	518
57.210(b)(1)(x), Credit Bureau Notification	*547	8.03	4,392	0.6	2,635
57.210(b)(4)(i), Write-off of Uncollectible Loans	20	1.00	20	3.0	60
57.211(a) Disability Cancellation	8	1	8	.75	6
57.215(a) Reports	Burden included under 0915–0044				
57.215(a)(2), Administrative Hearings	0	0	0	0	0
57.215(a)(d), Administrative Hearings	0	0	0	0	0
HPSL Subtotal	8,681		109,779		16,703
NSL Program:					
57.305(a)(2), Excess Cash	Burden included under 0915–0044				
57.306(a)(2), Student Financial Aid Transcript	4,062	1	4,062	0.25	1,016

REPORTING REQUIREMENTS—Continued

Regulatory/section requirements	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total hour burden
57.310(b)(1)(i), Entrance Interview	315	23.51	7,406	0.167	1,237
57.310(b)(1)(ii), Exit Interview	*502	3.77	1,892	0.5	946
57.301(b)(1)(iii), Notification of Repayment	*502	6.18	3,102	0.167	518
57.310(b)(1)(iv), Notification During Deferment	*502	0.65	326	0.083	27
57.310(b)(1)(vi), Notification of Delinquent Accounts	*502	4.61	2,314	0.167	386
57.310(b)(1)(x), Credit Bureau Notification	*502	8.3	4,167	0.6	2,500
57.310(b)(4)(i), Write-off of Uncollectible Loans	20	1.0	20	3.5	70
57.311(a), Disability Cancellation	7	1.0	7	0.8	5.6
57.312(a)(3), Evidence of Educational Loans 57.315(a)(1), Reports	Inactive Provision Burden included under 0915–0044				
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	6,914		23,296		6,706

* Includes active and closing schools.

Send comments to Susan G. Queen, PhD, 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: May 18, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–10430 Filed 5–24–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; 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: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: July 7, 2005, 9 a.m.–5 p.m., July 8, 2005, 8:30 a.m.–3 p.m.

Place: The Wyndham Washington Hotel, 1400 M Street, NW., Washington, DC 20005, (202) 429–1700.

Status: The meeting is open to the public with attendance limited to space availability.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs that are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start program and Healthy People 2010 infant mortality objectives.

Agenda: Topics that will be discussed include the following: Maternal and Child Health (MCH) Services Financing, Health Disparities in the MCH Population, and Improving Data and Public Health Practice. Substantial time will be spent in Subcommittee and full Committee discussions aimed at formulating the ACIM issues agenda. Proposed agenda items are subject to change as priorities indicate.

Time will be provided for public comments limited to five minutes each; comments are to be submitted no later than June 22, 2005.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443–2170.

Individuals who are submitting public comments or who have questions regarding the meeting should contact Ann M. Koontz, C.N.M., Dr.P.H., HRSA, Maternal and Child Health Bureau, telephone: (301) 443–6327, e-mail: *akoontz@hrsa.gov.*

Dated: May 18, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–10429 Filed 5–24–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–21258]

National Boating Safety Advisory Council; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the National Boating Safety Advisory Council (NBSAC). NBSAC advises the Coast Guard on matters related to recreational boating safety.

DATES: Application forms should reach us on or before September 8, 2005.

ADDRESSES: You may request an application form by writing to Commandant, Office of Boating Safety