submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 77 manufacturers submitted samples and protocols in fiscal year (FY) 2011, under the regulations cited previously in this document. FDA estimates that approximately 73 manufacturers submitted protocols under § 610.2 and 2 manufacturers submitted protocols under the regulation (§ 660.6) for the other specific product. FDA received no submissions under § 660.36 or § 660.46; however, FDA is using the estimate of one protocol submission under each regulation in the event that protocols are submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2011 for the various submission requirements of samples and protocols for the licensed biological products. The average burden per response is based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the average burden per response is based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the average burden per response is based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the other protocols than under § 610.2.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
610.2	73	92.9	6,782	3	20,346
660.6(b)	2	21.5	43	5	215
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	1	1	1	5	5
Total	77		6,827		20,572

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 10, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3743 Filed 2–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Funds for Leadership Training in Pediatric Dentistry's Current Grantees; One-Year Extension

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of a Non-competitive One-Year Extension with Funds for Leadership Training in Pediatric Dentistry's (T17) Current Grantees.

SUMMARY: The Health Resources and Services Administration (HRSA) will be issuing a non-competitive one-year extension with funds for the Leadership Training in Pediatric Dentistry awards to Columbia University, The Regents of the University of California and the University of Washington. Up to $196,506 per grantee will be awarded over a one-year extended project period. The Leadership Training in Pediatric Dentistry program supports a national focus on leadership training in pediatric dentistry through the support of: (1) The postdoctoral training of dentists in the primary care specialty of pediatric dentistry for leadership roles in education, research, public health, advocacy, and public service related to oral health programs for populations of mothers and children (infants through adolescents), particularly children with special health care needs; (2) the development and dissemination of curricula, teaching models, and other educational resources to enhance maternal and child health (MCH) oral health programs; and (3) the continuing education, consultation, and technical assistance in pediatric oral health which address the needs of the MCH community. This extension with funds will allow HRSA's Maternal and Child Health Bureau (MCHB) to align its leadership training initiatives in oral health with HRSA's other oral health training investments.

SUPPLEMENTARY INFORMATION: Grantees of record and intended award amounts are:

Grantee/organization name	Grant number	State	FY2011 Authorized funding level	FY2012 Estimated funding level
Columbia University	T17MC06359	NY	$196,506	$196,506
The Regents of the University of California, Los Angeles	T17MC08055	CA	196,506	196,506
University of Washington	T17MC00020	WA	196,506	196,506

Amount of the Award(s): Up to $196,506 per grantee over a one-year project period.

CFDA Number: 93.110.

Current Project Period: 7/1/2007 through 6/30/2012.

Period of Supplemental Funding: 7/1/2012 through 6/30/2013.

Authority: Title V of the Social Security Act, Section 501(a)(2) (42 U.S.C. 701(a)(2)).

Justification

HRSA is extending funding for the Leadership Training in Pediatric Dentistry grants by one year for the following reason: MCHB has been working with leaders within HRSA involved in oral health, the Bureau of Health Professions (BHPr) on oral health training investments, and other oral health leaders in the field to align its leadership training in oral health with HRSA's other oral health training investments. With HRSA prioritizing oral health integration in primary care, MCHB is focusing on the best possible use of its funds to continue to promote oral health training in a coordinated way related to efforts and initiatives within HRSA and the field.

HRSA's BHPr plans to hold a stakeholders meeting on oral health training in 2012 that would impact the scope and nature of all HRSA's oral health training initiatives. To ensure coordinated and non-duplicative HRSA program planning and future oral health grant funding, it is crucial to fund MCHB's current training program for one year to sustain MCH oral health leadership training, while developing the next MCH oral health leadership training initiative in a systemically coordinated way with other HRSA oral health training initiatives.

FOR FURTHER INFORMATION CONTACT: Christopher Dykton, Health Resources and Services Administration, Maternal and Child Health Bureau, 5600 Fishers Lane, Room 18A–55, Rockville, Maryland 20857 or email *cdykton@hrsa.gov*.

Dated: February 10, 2012.

Mary K. Wakefield,

Administrator.

[FR Doc. 2012–3792 Filed 2–16–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Emergency Review; Comment Request: A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI)

Summary: In accordance with Section 3507(j) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for emergency review and processing this information collection by March 5, 2012. NCI is requesting emergency processing of this information collection, pursuant to 5 CFR 1320.13, because NCI cannot reasonably comply with the normal clearance procedures which would cause a delay and likely prevent or substantially disrupt the collection of information. A delay in starting the information collection would hinder the agency in accomplishing its mission to the detriment of the public good. Public harm could result through the loss of critically needed information to understand and reduce the cancer burden from lymphoid malignancies in the Asian population. 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 currently valid OMB control number.

Proposed Collection: Title: A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI). *Type of Information Collection Request:* Emergency. *Need and Use of Information Collection:* Incidence rates of certain lymphomas have increased in several centers in Asia thereby increasing the cancer burden in these populations, but the causes remain unknown. AsiaLymph is a multi-disciplinary case-control study that will confirm and extend previous findings and yield novel insights into the causes of lymphoma in both Asia and the West. The major postulated risk factors for evaluation in this study are chemical exposures (i.e., organochlorines, trichloroethylene, and benzene) and genetic susceptibility. Other factors potentially related to lymphoma, such as viral infections, ultraviolet radiation exposure, medical conditions, and other lifestyle factors will also be studied. Patterns of key risk factors, including range of exposures, prevalence of exposures, correlations between exposures, and variation in gene regions are of particular interest. Patients from 19 participating hospitals will be screened and enrolled. There will be a one-time computer-administered interview, and patients will also be asked to provide a one-time blood and buccal cell mouth wash sample and lymphoma cases will be asked to make available a portion of their pathology sample. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Newly diagnosed patients with lymphoma or patients undergoing surgery or other treatment for non-cancer related medical issues who live in Hong Kong, Taiwan, and Chengdu and Tianjin, China will be enrolled at treating hospitals. The annual reporting burden is estimated at 3,377 hours (see Table below). There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

ESTIMATES OF ANNUAL BURDEN HOURS

Category of respondents	Types of respondents	Number of respondents	Frequency of response	Average time per response (Hours)	Annual burden hours
Individuals	Patients to be Screened	3,100	1	5/60	258
	Patients with Lymphoma	1,100	1	105/60	963
	Other Patients	1,100	1	105/60	963
	Study Pathologists	19	58	5/60	92
	Interviewers	19	116	30/60	1102
Total					3,377

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