FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2011, through December 31, 2011. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2011, THROUGH DECEMBER 31, 2011

PMA No., Docket No.	Applicant	Trade name	Approval date
P110003, FDA–2011–M–0746	Pluromed, Inc	LEGOO	September 28, 2011.
P090024, FDA–2011–M–0737	Siemens Healthcare Diagnostics	ADVIA CENTAUR HBEAG assay and quality control material.	October 11, 2011.
P040024 (S51), FDA–2011–M–0735	Medicis Aesthetics, Inc	RESTYLANE injectable gel	October 11, 2011.
P010029 (S8), FDA–2011–M–0736	Ferring Pharmaceuticals, Inc	EUFLEXXA (1% sodium hyaluronate)	October 11, 2011.
P110022, FDA–2011–M–0786	Roche Diagnostics Corp	ELECSYS anti-HBC IGM immunoassay and ELECSYS PRECICONTROL anti-HBC IGM.	October 26, 2011.
P110011, FDA–2011–M–0791	Medtronic Ireland	ASSURANT COBALT iliac balloon-expandable stent system.	October 26, 2011.
P100042, FDA–2011–M–0792	Gen-Probe Incorporated	APTIMA HPV assay	October 28, 2011.
P110019, FDA–2011–M–0796	Abbott Vascular	XIENCE PRIME and XIENCE PRIME LL EVEROLIMUS-eluting coronary stent system.	November 1, 2011.
P100041, FDA–2011–M–0837	Edwards Lifesciences, LLC	EDWARDS SAPIEN transcatheter heart valve and RETROFLEX 3 delivery system, RETROFLEX balloon catheter and crimper.	November 2, 2011.
P090016, FDA–2011–M–0832	Merz Aesthetics, Inc	BELOTERO balance	November 14, 2011.
H090002, FDA–2011–M–0848	BSD Medical Corp	BSD–2000 hyperthermia system	November 18, 2011.
P110010, FDA–2011–M–0865	Boston Scientific Corp	PROMUS ELEMENT PLUS EVEROLIMUS-eluting platinum chromium coronary stent system.	November 22, 2011.
P100024, FDA–2011–M–0866	Dako Denmark A/S	*HER2* CISH PHARMDX kit	November 30, 2011.
P110025, FDA–2011–M–0917	Roche Diagnostics Corp	ELECSYS anti-HBC IGM immunoassay and ELECSYS PRECICONTROL anti-HBC IGM for use on the MODULAR ANALYTICS E170 immunoassay analyze.	December 14, 2011.
P100046, FDA–2011–M–0910	AtriCure Inc	ATRICURE SYNERGY ablation system.	December 14, 2011.

II. Electronic Access

Persons with access to the Internet may obtain the documents at:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm; and

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm.

Dated: March 12, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6390 Filed 3–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request: Child Health Disparities Measurement for the National Children's Study

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 National Institute of Child Health and Human Development (NICHD), the

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: Child Health Disparities Substudy for the National Children's Study (NCS). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) Investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) REQUIREMENT.—The study under subsection (b) shall—

(1) Incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) Consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the Child Health Disparities Substudy will validate measures needed for studying health disparities and selected biomarkers. Utilizing cognitive interview techniques and components of standardized questionnaires, responses will be used to assess and validate measures of health literacy, discrimination, parenting self-efficacy, and health care accessibility.

Acceptability and feasibility of saliva collection from a subsample of women and young children will also be evaluated. The incorporation of saliva measurements will increase understanding of biological responses to environmental factors and how these may be correlated with health disparities within this population.

Background: The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines ''environment'' broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study is led by a consortium of federal partners: the U.S. Department of Health and Human Services (including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention), and the U.S. Environmental Protection Agency.

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

In this information collection request, the NCS requests approval from OMB to perform a multi-center substudy called the Child Health Disparity Substudy. This substudy aims to validate measures needed for studying health disparities and selected biomarkers. Developing optimum measures for studying health disparities is of particular interest to the NCS because studies have shown that health literacy, discrimination, parenting self-efficacy, health care (access, utilization, and quality) contribute to health disparities. Additionally, aspects of the social environment such as social isolation, lack of control and contingency and social support, violence, discrimination, challenging and changing social relationships, and restricted access to health care are thought to interact with biological processes. Variation in these processes has been associated with negative emotional states, cognitive deficits, problem behavior, and a variety of metabolic and immune-related processes. Alone, or particularly in combination with other commonly collected measures of social forces and family relationships, salivary analytes have the potential to advance our understanding of maternal and child health and development. This project will make its contribution to the NCS Main Study and to the health disparities field as a whole by constructing a validated set of questionnaire measures and biomarker analyses that can be used among pregnant women and mothers of young children for the purpose of investigating disparities.

Frequency of Response: One-time data collection conducted in multiple phases.

Affected Public: Pregnant women, mothers with young children, and their children.

Type of Respondents: Pregnant women, mothers with young children, and their children who are not geographically eligible to enroll in the NCS Vanguard Study.

Annual Reporting Burden: See Table 1. The annualized cost to respondents is estimated at $24,600 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY, CHILD HEALTH DISPARITIES SUBSTUDY

Data collection activity		Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours
Consent	Pregnant Women/ Mothers of children ages 0–5.	Members of NCS target population (not NCS participants).	1,260	1	0.08	105
Cognitive Interview	Mothers of children ages 0–5.	Members of NCS target population (not NCS participants).	60	1	1.33	80
Primary Data Collection	Pregnant Women/ Mothers of children ages 0–5. Mothers of children ages 0–5.	Members of NCS target population (not NCS participants).	600 600	2 1	1.08 1.08	1,300 650
Saliva Collection	Pregnant Women/ Mothers of children ages 0–5. Additional mothers of children ages 0–5. Children ages 0–5	Members of NCS target population (not NCS participants).	260 260 520	2 1 1	0.25 0.25 0.25	130 65 130
Total			1,780			2,460

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 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 Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call non-toll free number (301) 496–1877 or email your request, including your address to *glavins@mail.nih.gov.*

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

Dated: March 12, 2012.

Sarah L. Glavin,

Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

[FR Doc. 2012–6354 Filed 3–15–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, April 18, 2012, 1 p.m. to April 18, 2012, 5 p.m., National Institutes of Health, 6116 Executive Boulevard, 8055B, Rockville, MD 20852 which was published in the Federal Register on March 1, 2012, 77 FR 12600.

This notice is being amended to change the times of the meeting from 1 p.m.–5 p.m. to 12 p.m.–3 p.m. The meeting is closed to the public.

Dated: March 9, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–6352 Filed 3–15–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.