SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for FDA advisory committee members and FDA staff entitled, ''Voting Procedures for Advisory Committee Meetings,'' dated November 2007.

FDA's advisory committees provide independent, expert advice to the agency on a range of complex scientific, technical, and policy issues, including questions related to the development and evaluation of products regulated by FDA. Advisory committees are a valuable resource to FDA, and they make an important contribution to the agency's decision-making processes. Although advisory committees provide recommendations to FDA, FDA makes the final decisions.

Advisory committees typically communicate advice or recommendations to the agency in two ways. First, committee members routinely share their individual thoughts and recommendations during the discussion of a particular matter at an advisory committee meeting. Second, advisory committees often vote on a question or series of questions posed to the committee during a committee meeting.

Votes can be an effective means of communicating with FDA because they provide feedback on discrete questions. These questions are generally scientific in nature and can involve a range of subjects, including evaluation of post-market safety data or pre-market assessment of a product's risk/benefit profile. Since all members vote on the same question, the results help FDA gauge a committee's collective view on complex, multi-faceted issues. This view helps inform the agency's own deliberations on scientific and regulatory matters.

This draft guidance recommends adopting uniform voting procedures to help maximize the integrity and meaning of voting results. In developing these recommendations, FDA is mindful of the legal requirements of the Federal Advisory Committee Act, other relevant statutes (e.g., the Federal Food, Drug, and Cosmetic Act), regulations (e.g., 21 CFR Part 14) , guidance, and policies, and the goals of FDA's of advisory committee program.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on recommended uniform procedures that can be used for the voting process when votes are taken during advisory committee meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: November 14, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. 07–5751 Filed 11–15–07; 9:06 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Proposed Collection; Comment Request; Formative Research and Pilot Studies 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: Formative Research and Pilot Studies for the National Children's Study. *Type of Information Collection Request:* NEW. *Need and use of information collection:* The NICHD seeks to obtain OMB's generic approval to conduct pilot and formative research to be used in the development of instruments, materials, and procedures for the National Children's Study (NCS). The NCS is a long-term cohort study of environmental influences on child health and development authorized under the Children's Health Act of 2000. The Act specifies a broad definition of environment, including biologic, chemical, physical, and psycho-social factors and authorizes the NICHD to plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of those exposures on child health and human development. Further details pertaining to the NCS background and planning, including the NCS Research Plan, can be found at: *http://nationalchildrensstudy.gov*. The proposed data collection program will include community outreach materials, medical provider and participant materials, questionnaires and measures, use of technology such as Interactive Voice Recognition (IVR), and other aspects related to data collection. Activities will include small focused studies to test data collection items and methods on a specific or targeted population, validation of questionnaires for targeted populations, focus groups within the NCS communities to test forms and procedures, cognitive interviews to test data items, and the use of materials on targeted populations such as medical providers and hospitals, and materials translated into other languages. These activities will be conducted over the life of the study to develop procedures and materials for each stage of data collection. The results of these pilot tests will be used to maximize the efficiency of study procedures, materials, and methods for community outreach, engagement of the medical community, for recruiting and retaining study subjects prospectively across study visits and to ensure that data collection methodologies are efficient and valid for all potential participants. Without this information, NCS will be hampered in its efforts to effectively publicize the NCS, gain public and professional support, and effectively recruit and retain respondents and collect data over the life of the Study. *Affected entities:* Individuals. *Types of respondents:* People potentially affected by this action are pregnant women or women of childbearing age, their husbands or partners, health care professionals, and community leaders. The annual

reporting burden is as follows: *Estimated Number of Respondents:* 3,150. *Frequency of Response:* On occasion (see Burden table). *The Estimated Number of Responses per Respondent:* 1. *Average Burden Hours Per Response:* Varies with study type. *Estimated Total Annual Burden Hours Requested:* 5,825. The estimated annualized cost to respondents is $114,250 (based on rates listed in the burden table). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents (estimated hourly rate)	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours
Small focused studies ($10)	1,250	1	1.5	1,875
Focus groups with potential participants ($10)	350	1	3.0	1,050
Focus groups with health care professionals ($50)	350	1	3.0	1,050
Focus groups with community leaders ($10)	350	1	3.0	1,050
Medical provider feedback on materials through informal in-person contacts ($50)	700	1	0.5	350
Cognitive interviews ($10)	150	1	3.0	450
Total	3,150	.....	.....	5,825

Requests 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 enhance the quality, utility, and clarity of the information to be collected; and (4) 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 Ruth A. Brenner, MD, MPH, National Institute of Child Health and Human Development, Building 6100, 5C01, 6100 Executive Blvd, Bethesda, Maryland 20892, or call non-toll free number (301) 594–9147, or e-mail your request, including your address to *ncsinfo@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.

Paul Johnson,

NICHD Project Clearance Liaison, National Institutes of Health.

[FR Doc. E7–22592 Filed 11–16–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Division of Extramural Research and Training; Submission for OMB Review; Comment Request; Program Assessment and Evaluations for NIEHS—Asthma Research

Summary: Under the provision of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 9, 2007, page 26399 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. 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: Program Assessment and Evaluations for NIEHS—Asthma Research. *Type of Information Collection Request:* NEW. *New and Use of Information Collection:* National Institute of Environmental Health Sciences, Division of Extramural Research and Training (DERT). DERT, with contract support from Battelle Centers for Public Health Research and Evaluation, is examining the impact of its research portfolio. Focusing specifically on one portion of the research portfolio—asthma research—DERT proposes to supplement extant data sources with a primary data collection activity. The purpose of the proposed primary data collection is to obtain information from grantees regarding the impact of their funded asthma research in the short-, intermediate-, and long-term. This will be done through a survey of grantees that includes questions about the impact of funding on career development, the field of asthma research, public attitudes, commercial product development, clinical practice, business and industry practices, and long-term human and environmental health. *Frequency of Response:* One time. *Affected Public:* Individuals. *Type of Respondents:* Individuals receiving asthma funding. A 15-minute, close-ended, multi-mode (web and paper) survey will be administered to the universe of NIEHS-funded asthma researchers (N=179) and comparison agency asthma researchers (N=1371). Comparison agencies include other NIH institutes (NICHD, NIAID, NIA, NHLBI), the CDC, AHRQ, and the EPA. The survey development process included formative interviews with a small sample of NIEHS asthma researchers. The annual reporting burden is as follows: *Estimated Number of Respondents:* 1550; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response: 15 minutes;* and *Estimated Total Annual Burden Hours Requested:* 387.5. The annualized cost to respondents is estimated at $13,039.38. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.