April 2007 MOU FDA and AAFCO

FDA Record # 225-07-7001

PERIOD OF AGREEMENT

This agreement, when accepted by both parties, will have an effective period of performance from date of signature until 9/1/2012 (if no expiration date, so state), and may be modified by mutual consent by both parties or may be extended or terminated as agreed upon by FDA and AAFCO. Any notice of termination will be published in the Federal Register.

APPROVED AND ACCEPTED FOR THE AAFCO

By Ricky Schroeder

Printed Name Ricky Schroeder

Title President

Date 8/21/2007

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By SFS/M

Printed Name Stephen F. Sundlof

Title Director, FDA/CVM

Date 8/30/07

[FR Doc. 07–5748 Filed 11–16–07; 8:45 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0449]

Draft Guidance for Food and Drug Administration Advisory Committee Members and Food and Drug Administration Staff: Voting Procedures for Advisory Committee Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document for FDA advisory committee members and FDA staff entitled, ''Voting Procedures for Advisory Committee Meetings.'' This draft document is intended to provide guidance on advisory committee voting procedures that can be used for the voting process when votes are taken during advisory committee meetings. It does not to define when votes should be taken.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comment on the draft guidance by January 18, 2007.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jill Hartzler Warner, Office of Policy, Planning, and Preparedness (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3370.

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]

BILLING CODE 4160–01–S

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