animal safety studies to justify omission of specific biocompatibility tests; (5) assessment of known or potentially toxic chemical entities; and (6) contents of a biocompatibility test report.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the use of International Standard ISO–10993, ''Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.'' 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.*

To receive ''Use of International Standard ISO–10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,' '' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1811 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 812, have been approved under OMB control number 0910–0078.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: April 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09479 Filed 4–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0788]

Pilot Program for Early Feasibility Study Investigational Device Exemption Applications; Extending the Duration of the Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of the Early Feasibility Study Investigational Device Exemption (IDE) Applications pilot program to May 8, 2014, for sponsors who have already been accepted for the program.

DATES: This notice is effective April 23, 2013.

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–5640, *sheila.brown@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 10, 2011 (76 FR 70150), FDA announced the availability of a draft guidance entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.'' This guidance document is intended to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Concurrent with the publication of the draft guidance, FDA also announced an Early Feasibility Study IDE Pilot Program (76 FR 70152; November 10, 2011) intended to collect information and experience on the application of the draft guidance in order to inform the final guidance document.

In the pilot program notice, FDA stated its intention to accept nominations to participate in the pilot program until May 8, 2012, and stated that the pilot program would terminate on May 8, 2012. In the **Federal Register** notice announcing the pilot program, FDA also stated its intention to limit the pilot program to nine candidates.

FDA began accepting nominations for the pilot program on December 12, 2011. After reviewing the nominations received in response to the pilot program notice, FDA accepted nine appropriate candidates for the pilot program. In the **Federal Register** of March 6, 2012 (77 FR 13343), FDA terminated the acceptance of applications into the program and extended the pilot program for the nine accepted sponsors until May 8, 2013. The pilot program will be further extended for the nine accepted sponsors until May 8, 2014.

Dated: April 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09528 Filed 4–22–13; 8:45 am]

BILLING CODE 4160–01–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 (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: April 24, 2013, 8:00 a.m.–5:00 p.m., April 25, 2013, 8:00 a.m.–3:00 p.m.

Place: Virtual via Webinar.

Status: The meeting is open to the public. For more information on registration and webinar details, please visit the ACIM Web site: *http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality.*

Adobe Connect: *https://hrsa.connectsolutions.com/infantmortality/.*

Teleconference Number: (888) 790–1958. Participant passcode: 461–8352.

Purpose: The Committee provides advice and recommendations to the Secretary of

Health and Human Services (HHS) on the following: HHS programs that focus on reducing infant mortality and improving the health status of infants and pregnant women; and factors affecting the continuum of care with respect to maternal and child health care. ACIM accesses the outcomes following childbirth; strategies to coordinate the myriad 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 2020* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Updates from federal agencies including the Health Resources and Services Administration and Centers for Medicare and Medicaid Services; improving the health of women (Maternal Health Initiative); updates from partnering agencies and organizations; and, ACIM's recommendations for the HHS National Strategy to Address Infant Mortality.

Proposed agenda items are subject to change as priorities dictate. Time will be provided for public comments. Each public comment is limited to five minutes. Comments are to be submitted in writing no later than 5:00 p.m. ET on April 19, 2013.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Michael C. Lu, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration, 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 David S. de la Cruz, Ph.D., M.P.H., ACIM Designated Federal Official, Health Resources and Services Administration, Maternal and Child Health Bureau, telephone: (301) 443–0543, or email: *David.delaCruz@hrsa.hhs.gov*. The logistical challenges of scheduling the meeting hindered an earlier publication of this meeting notice.

Dated: April 16, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–09507 Filed 4–22–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)

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 Cancer Institute (NCI), 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.

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.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Jane Hoppin, Sc.D., Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3–05, Research Triangle Park, NC 27709, or call non-toll-free number 919–541–7622, or email your request, including your address to: *hoppin1@niehs.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment 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.

Proposed Collection: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture, 0925–0406, Expiration Date 5/31/2013, REVISION, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to request initiation of a new dust specimen component as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA) as well as continue and complete phase IV (2013–2015) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA dust component will include a brief paper-and-pen questionnaire mailed to the participant in advance of the home visit; at the home visit, the study phlebotomist will to collect and review the questionnaire, and collect the participant's disposable vacuum bag (or empty the dust from vacuums without disposable bags). The dust component will use similar procedures to ones that have been employed on other NCI studies to obtain information about the dust specimen and to collect and ship the dust specimen. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among Agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 10,679.