

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Meeting**

Studies at the Animal-Human Interface of Influenza and Other Zoonotic Diseases in Vietnam, Funding Opportunity Announcement (FOA) IP11-005, The Incidence and Etiology of Influenza-Associated Community-Acquired Pneumonia in Hospitalized Persons Study; FOA IP11-011, Spectrum of Respiratory Pathogens in Acute Respiratory Tract Infection Among Children and Adults in India; FOA IP11-012, Influenza Vaccine Efficacy in Tropical and Developing Countries; FOA IP11-013, Influenza and Other Respiratory Diseases in Southern Hemisphere; and FOA IP11-014, initial review.

*Correction:* The notice was published in the **Federal Register** on March 11, 2011, Volume 76, Number 48, Pages 13413-13414. The place should read as follows:

*Place:* Holiday Inn Decatur Conference Center, 130 Clairmont Avenue, Decatur, Georgia 30030, *Telephone:* (404) 371-0204.

*Contact Person For More Information:* Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road, NE., Mailstop E60, Atlanta, Georgia 30333, *Telephone:* (404) 498-2293.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 5, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011-11522 Filed 5-10-11; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Combining Subjective and Objective Methods for Quantifying Contact Rates and Mixing Pattern in School-Aged Children, Funding Opportunity Announcement, CK11-006, Initial Review**

*Correction:* The notice was published in the **Federal Register** on March 22, 2011, Volume 76, Number 55, Page 15984. The time, date, and place should read as follows:

*Time And Date:* 11 a.m.-2 p.m., May 3, 2011 (Closed).

*Place:* Teleconference.

*Contact Person For More Information:* Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road, NE., Mailstop E60, Atlanta, Georgia 30333, *Telephone:* (404) 498-2293.

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Dated: May 5, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Virologic Evaluation of the Modes of Influenza Virus Transmission Among Humans, Funding Opportunity Announcement, IP11-001**

*Correction:* The notice was published in the **Federal Register** on April 4, 2011, Volume 76, Number 64, Page 18555.

*The place should read as follows:*

*Place:* Holiday Inn Decatur Conference Plaza, 130 Clairmont Avenue, Decatur, Georgia 30030, *Telephone:* (404) 371-0204.

*Contact Person for More Information:* Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road, NE., Mailstop E60,

Atlanta, Georgia 30333, *Telephone:* (404) 498-2293.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 5, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011-11521 Filed 5-10-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****Advisory Council for the Elimination of Tuberculosis Meeting (ACET)**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

**Times and Dates**

11 a.m.-5 p.m., June 7, 2011.

8:30 a.m.-2:30 p.m., June 8, 2011.

*Place:* Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333, telephone (404) 639-8317.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

*Purpose:* This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

*Matters to be Discussed:* Agenda items include issues pertaining to TB Surveillance/Epidemiology/Outbreaks; Role of U.S. program in global TB control; Federal role in TB clinical and diagnostic research; Role of CDC in development of evidence-based policies; Forecasting the U.S. TB Trends and

Challenges; and other related tuberculosis issues. Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Margie Scott-Cseh, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., M/S E-07, Atlanta, Georgia 30333, telephone: (404) 639-8317.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 5, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011-11526 Filed 5-10-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0042]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 10, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0014. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and

Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792,

[Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Investigational New Drug (IND) Regulations—21 CFR Part 312—(OMB Control Number 0910-0014)—Extension

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in the FDA regulations “Investigational New Drug Application” in part 312 (21 CFR part 312). Part 312 implements provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

FDA is charged with implementing statutory requirements that drug products marketed in the United States be shown to be safe and effective, properly manufactured, and properly labeled for their intended uses. Section 505(a) of the FD&C Act provides that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product’s labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts. The IND regulations establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug’s safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year’s clinical experience. Submissions are reviewed by medical officers and other Agency scientific reviewers assigned responsibility for overseeing the specific study. The IND regulations also contain recordkeeping requirements that pertain to the responsibilities of sponsors and investigators. The detail and complexity of these requirements are dictated by the scientific procedures and human subject safeguards that must be followed in the clinical tests of INDs.

The IND information collection requirements provide the means by which FDA can do the following: (1) Monitor the safety of ongoing clinical investigations; (2) determine whether the clinical testing of a drug should be authorized; (3) ensure production of reliable data on the metabolism and pharmacological action of the drug in humans; (4) obtain timely information on adverse reactions to the drug; (5) obtain information on side effects associated with increasing doses; (6) obtain information on the drug’s effectiveness; (7) ensure the design of well-controlled, scientifically valid studies; and (8) obtain other information pertinent to determining whether clinical testing should be continued and information related to the protection of human subjects. Without the information provided by industry in response to the IND regulations, FDA cannot authorize or monitor the clinical investigations which must be conducted prior to authorizing the sale and general use of new drugs. These reports enable FDA to monitor a study’s progress, to assure subject safety, to assure that a study will be conducted ethically, and to increase the likelihood that the sponsor will conduct studies that will be useful in determining whether the drug should be marketed and available for use in medical practice.

There are two forms that are required under part 312:

Form FDA-1571—“Investigational New Drug Application”—A person who intends to conduct a clinical investigation submits this form to FDA. It includes the following information: (1) A cover sheet containing background information on the sponsor and investigator; (2) a table of contents; (3) an introductory statement and general investigational plan; (4) an investigator’s brochure describing the drug substance; (5) a protocol for each planned study; (6) chemistry, manufacturing, and control information for each investigation; (7) pharmacology and toxicology information for each investigation; and (8) previous human experience with the investigational drug.

Form FDA-1572—“Investigator Statement”—Before permitting an investigator to begin participation in an investigation, the sponsor must obtain and record this form. It includes background information on the investigator and the investigation, and a general outline of the planned investigation and the study protocol.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements in part 312: