

Dated: March 18, 2015.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-06601 Filed 3-23-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0663]

#### **Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products; Guidance for Industry: Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products; Guidance for Industry” dated March 2015. The guidance document provides investigational new drug application (IND) sponsors and applicants for a biologics license application (BLA) or a supplement to a BLA (BLA supplement), with recommendations on considerations when assessing whether to submit an Environmental Assessment (EA) for gene therapies, vectored vaccines, and related recombinant viral or microbial products (GTVVs). The guidance also contains recommendations as to what information should be included in an EA and what you can expect once an EA is filed. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2014.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the **SUPPLEMENTARY INFORMATION** section

for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### **FOR FURTHER INFORMATION CONTACT:**

Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled “Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products; Guidance for Industry” dated March 2015. The guidance document provides IND sponsors and applicants for a BLA or a BLA supplement, with recommendations on considerations when assessing whether to submit an EA for GTVVs. The guidance also contains recommendations as to what information should be included in an EA and what you can expect once an EA is filed. The guidance supplements the guidance entitled “Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications” dated July 1998 (July 27, 1998, 63 FR 40127) (1998 Guidance) and supersedes the recommendations for GTVVs in section IV.B.1 “Assessing Toxicity to Environmental Organisms” in the 1998 Guidance. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2014.

In the **Federal Register** of June 20, 2014 (79 FR 35361), FDA announced the availability of the draft guidance of the same title dated June 2014. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. There were no changes to the guidance except for one correction to a technical error regarding influenza taxonomy. The guidance announced in this notice finalizes the draft guidance dated June 2014.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. 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. Paperwork Reduction Act of 1995**

This 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 25 have been approved under OMB control number 0910-0322; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; and the collections of information for 21 CFR part 601 have been approved under OMB control number 0910-0338.

##### **III. 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>.

##### **IV. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 19, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-06686 Filed 3-23-15; 8:45 am]

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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): Initial Review**

The meeting announced below concerns Economic Studies of Immunization Policies and Practices, Funding Opportunity Announcement (FOA) IP15-001 and US Platform to Measure Influenza Vaccine

Effectiveness against Laboratory-Confirmed Influenza-Associated Hospitalizations, FOA IP15-002, initial review.

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 aforementioned meeting:

*Time And Date:* 10:00 a.m.–4:00 p.m., April 15, 2015 (Closed).

*Place:* Teleconference.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters For Discussion:* The meeting will include the initial review, discussion, and evaluation of applications received in response to “Economic Studies of Immunization Policies and Practices”, FOA IP15-001 and “US Platform to Measure Influenza Vaccine Effectiveness against Laboratory-confirmed Influenza-associated Hospitalizations”, FOA IP15-002.

*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) 718-8833.

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.

**Elaine L. Baker,**

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

[FR Doc. 2015-06651 Filed 3-23-15; 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): Initial Review

The meeting announced below concerns Detection and Characterization of Emerging Vector-Borne Zoonotic Pathogens in Indonesia, CK15-001; Sentinel Enhanced Dengue Surveillance

System (SEDSS) Sites to Evaluate the Epidemiology and Prevention of Dengue and other Acute Febrile Illnesses in Puerto Rico, CK15-002, and Capacity Building to Prevent, Detect, and Respond to Emerging Infectious Disease Threats and Strengthen Global Health Security in Uganda, CK15-003, Funding Opportunity Announcement (FOA), initial review.

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 aforementioned meeting:

*Time And Date:* 11:00 a.m.–3:00 p.m., April 21, 2015 (Closed).

*Place:* Teleconference.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters For Discussion:* The meeting will include the initial review, discussion, and evaluation of applications received in response to “Detection and Characterization of Emerging Vector-Borne Zoonotic Pathogens in Indonesia”, FOA CK15-001 and “Sentinel Enhanced Dengue Surveillance System (SEDSS) Sites to Evaluate the Epidemiology and Prevention of Dengue and other Acute Febrile Illnesses in Puerto Rico”, FOA CK15-002, and “Capacity Building to Prevent, Detect, and Respond to Emerging Infectious Disease Threats and Strengthen Global Health Security in Uganda”, FOA CK15-003.

*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) 718-8833

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.

**Elaine L. Baker,**

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

[FR Doc. 2015-06652 Filed 3-23-15; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-15-15GD]

#### Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

#### Proposed Project

Emergency Self Escape for Coal Miners—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).