Group 3 will receive a mailing about the registry, whereas Group 4 the comparison group will not receive any outreach component. To analyze the change in ALS registry self-enrollment, ATSDR will compare, on a monthly basis, enrollment rates between Groups 1, 2, and 3, and 4, as well as with the 44-state Group 4.

Study activities include, but are not limited to, initial and follow-up phone calls, mailings, train-the-trainer sessions, and key informant interviews. The initial phone call will: (1) determine if the neurologist(s) diagnose/care for patients with ALS; (2) determine how many ALS patients are seen on an annual basis, and (3) confirm contact information for neurologists. Providers who do or would diagnose/care for patients with ALS will receive a targeted mailing about the registry. Follow-up phone calls and faxes, as needed, will confirm the receipt of mailings (including posters, provider guide pamphlet, Persons with ALS Quick Start Guide etc.). Key informant interviews with neurologists will allow for better understanding of their knowledge, attitudes, and beliefs about the Registry, and for gathering additional information about the currently deployed Registry materials. As neurologists may not be familiar with the self-enrollment process of the Registry, the project includes train-the-trainer site visits that will provide neurologists and staff (if requested to attend by the neurologist) with information to educate persons with ALS about the National ALS Registry self-enrollment process. The train-the-trainer module activities do not involve information collections.

Participation is voluntary. For the duration (2 years), the project staff will conduct 3,800 initial phone calls, 1,900 follow-up #1 calls at one week post-mailing, 1,900 follow-up #2 calls at three months post-mailing, 30 train-the-trainer presentations, and 32 key-informant interviews.

There are no costs to respondents other than their time. The estimated annualized burden hours for this data collection activity are 326.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Neurologist Support Staff	Initial Phone Call Checklist	1,900	1	6/60	190
Neurologist Support Staff	Fax to Determine Provider Status	380	1	1/60	6
Neurologist Support Staff	Follow-up Phone Call #1 (One Week Post-Mailing).	950	1	3/60	48
Neurologist Support Staff	Follow-up Phone Call #2 (Three Months Post-Mailing).	950	1	3/60	48
Neurologist Support Staff	Fax to Determine if Mailing Was Received.	190	1	1/60	3
Neurologist	Train-the-Trainer	15	1	1	15
Neurologist	Key Informant Interview	16	1	1	16
Total					326

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–06654 Filed 3–23–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Basic Research in HIV-Related Heart, Lung and Blood Diseases.

Time: April 16, 2015.

Time: 8:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Susan Wohler Sunnarborg, Ph.D. Scientific Review Officer, Office of Scientific Review/DERA National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, *sunnarborgsw@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Translational Programs in Lung Diseases.

Date: April 16, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924, 301–435–0725, *johnsonwj@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Basic Research in HIV-Related Heart, Lung and Blood Diseases (R21).

Date: April 16, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Susan Wohler Sunnarborg, Ph.D. Scientific Review Officer, Office of Scientific Review/DERA National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, *sunnarborgsw@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

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]

BILLING CODE 4140–01–P

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]

BILLING CODE 4164–01–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 Economic Studies of Immunization Policies and Practices, Funding Opportunity Announcement (FOA) IP15–001 and US Platform to Measure Influenza Vaccine