well as cases where available therapies do not directly impact the aspects of disease that matter most to patients. The extent of public comment for specific disease areas was one of many factors used to select the disease areas for Patient-Focused Drug Development during FY 2013–2015. In selecting the disease areas of focus, FDA carefully considered the public comments received, the perspectives of reviewing divisions at FDA, and the following selection criteria, which were published in the September 24, 2012, **Federal Register** notice:

- Disease areas that are chronic, symptomatic, or affect functioning and activities of daily living;
- disease areas for which aspects of the disease are not formally captured in clinical trials; and
- disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how a patient feels or functions.

FDA's selection also reflects the Agency's desire to include a diverse set of disease areas that represent the wide range of diseases the Agency encounters in its regulatory decision-making. These criteria, also published in the September 24, 2012, **Federal Register** notice, were overarching considerations that the Agency took into account in selecting the set of disease areas:

- Disease areas that reflect a range of severity, from diseases that are life-threatening to those that are mild and symptomatic;
- disease areas that have a severe impact on identifiable subpopulations, such as children or the elderly; and
- disease areas that represent a broad range in terms of size of the affected population, including common conditions experienced by large numbers of patients and rare diseases that affect much smaller patient populations.

Patient-Focused Drug Development was conceived as a mechanism to learn more from patients where their perspectives could be helpful to drug development and FDA's review of applications for new drugs in certain disease areas. For FDA's review divisions, this kind of input is most helpful when the impact of a disease on patients is not well understood or endpoints for studying drugs for a disease are not clearly defined or established. The potential to fill these information gaps by hearing from patients was also a key consideration in identifying the initial 12 disease areas.

FDA has selected the following diseases to be addressed in FY 2013–2015:

- Alpha-1 antitrypsin deficiency;
- breast cancer;
- chronic Chagas disease;
- female sexual dysfunction;
- fibromyalgia;
- hemophilia A, hemophilia B, von Willebrand disease, and other heritable bleeding disorders;
- HIV;
- idiopathic pulmonary fibrosis;
- irritable bowel syndrome, gastroparesis, and gastroesophageal reflux disease with persistent regurgitation symptoms on proton-pump inhibitors;
- lung cancer;
- myalgic encephalomyelitis/chronic fatigue syndrome;
- narcolepsy;
- neurological manifestations of inborn errors of metabolism;
- Parkinson's disease and Huntington's disease;
- pulmonary arterial hypertension; and
- sickle cell disease.

A schedule of the meetings planned for each year can be found at the FDA Patient-Focused Drug Development Web site described in the following section of this notice.

FDA will initiate a second public process to determine the list of disease areas for FY 2016–2017. The Agency recognizes that there are many more disease areas than can be addressed in the planned FDA meetings under PDUFA V, and FDA will seek other opportunities to gather public input on disease areas not addressed through this PDUFA V commitment. FDA also encourages stakeholders to identify and organize patient-focused collaborations to generate public input on other disease areas with regard to the types of questions addressed through this PDUFA commitment, using the process established through Patient-Focused Drug Development as a model. More information on other opportunities for gathering patient input can be found on the Patient-Focused Drug Development Web site.

III. Patient-Focused Drug Development Web site

FDA has a Web site on Patient-Focused Drug Development: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.* This Web site contains the general schedule of upcoming meetings for FY 2013–2015, information on how stakeholders can prepare for upcoming meetings, and information on how stakeholders may leverage Patient-Focused Drug Development to generate input on disease areas not addressed through the Patient-Focused Drug Development PDUFA V commitment. The Web site will be updated as new information becomes available.

Dated: April 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08441 Filed 4–10–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Lentiviral Vectors with Dual Fluorescence/Luminescence Reporters

Description of Technology: Twelve lentiviral vectors that express both fluorescent and luminescent markers as a single fusion protein under various gene promoters were constructed. Vectors have been developed previously to monitor tumors or tumor cells via bioluminescence or fluorescence alone. However, bioluminescence is not sensitive enough to sort individual tumor cells and fluorescence cannot be used effectively to view internal tumors. By combining the two reporters into a single fusion protein, the tumor can be effectively visualized within the animal as well as sorted from non-tumor cells for post-necropsy experiments. The added advantage of bioluminescent visualization allows for *in vivo*

experiments that more closely simulate the biological development of tumors in organs rather than at the surface of the skin. Additionally, since twelve different vectors with different gene promoters were developed, they can be tested in individual tumor models to find the best vector for visualizing that particular tumor cell line. The vectors are able to sustain long-term expression of both visualization markers, depending on the cell type and promoter in each vector.

Potential Commercial Applications:

- The vectors will be extremely useful for experiments in which both *in vivo* and *in vitro* analysis is desired.
- The vectors can also be used for screening cancer cell lines and in tumor models for reporter gene activity.
- The vectors can be useful in drug development.

Competitive Advantages:

- The bioluminescent marker allows for effective visualization of deep (non-surface) tumors in mice.
- The fluorescence label permits efficient sorting of tumor cells from normal (non-labeled) cells after tumors are excised from the mice.
- The vectors allow *in vivo* experiments that more closely simulate the biological development of tumors in organs rather than at surface of skin.
- The vectors sustain long-term expression.

Development Stage:

- Early-stage
- Pre-clinical
- *In vitro* data available
- *In vivo* data available (animal)

Inventors: Dominic Esposito, Chi-Ping Day, Glenn Y. Merlino (NCI)

Publication: Day CP, *et al.* Lentivirus-mediated bifunctional cell labeling for *in vivo* melanoma study. Pigment Cell Melanoma Res. 2009 Jun;22(3):283–95. [PMID 19175523]

Intellectual Property: HHS Reference No. E–132–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Sury Vepa, J.D., Ph.D.; 301–435–5020; *vepas@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize dual luminescent/fluorescent vectors. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Epigenetic Factors Associated with the Development of Age-related Macular Degeneration

Description of Technology: Recent studies have demonstrated genetic associations between Age-related Macular Degeneration (AMD) and specific genes. In the case of identical twins in which only one twin develops AMD, a direct genetic cause seems unlikely. NIH researchers explored the epigenetic mechanisms that control the pathogenesis of AMD. A DNA methylation study identified sites on selected gene promoters that can potentially serve as markers to distinguish patients likely to develop AMD from those less likely to develop the disease. The strongest association was found in the IL17RC gene and later studies confirmed this association, first in siblings that were discordant for AMD and then in AMD patients as compared with age-matched controls.

Potential Commercial Applications: Diagnosis of Age-related Macular Degeneration.

Competitive Advantages: This technology is potentially a more sensitive means of diagnosing patients with AMD.

Development Stage: In vitro data available.

Inventors: Lai Wei, Robert Nussenblatt, Baoying Liu, Chi-Chao Chan (NEI).

Publication: Wei L, *et al.* Hypomethylation of the IL17RC promoter associates with age-related macular degeneration. Cell Rep. 2012 Nov 29;2(5):1151–8. [PMID 23177625]

Intellectual Property: HHS Reference No. E–075–2011/0—

- US Application No. 61/435,989 filed 25 Jan 2011
- PCT Application No. PCT/US2012/022511 filed 25 Jan 2011

Licensing Contact: Jaime M. Greene; 301–435–5559; *greenejaime@mail.nih.gov*.

Dated: April 5, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–08414 Filed 4–10–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

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 meeting.

The meeting 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 materials, 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 Institute of Neurological Disorders and Stroke Special Emphasis Panel; Epilepsy Genetics Review.

Date: May 1, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS, NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–0660, *benzingw@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 5, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–08416 Filed 4–10–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

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 meeting.

The meeting 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 Institute on Alcohol Abuse and Alcoholism Initial