on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Criteria for Members

Persons nominated for membership as consumer representatives on the committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committee on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Potential candidates will be required to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

All nominations should include: A cover letter; a curriculum vitae or resume that includes the nominee's office address, telephone number, and email address; and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations also should specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination and is willing to serve as a member of the advisory committee or panel if selected.

The term of office is up to 4 years. FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

Dated: June 17, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–14889 Filed 6–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal Health Town Hall Listening Session; Notice of Meeting

Name: Maternal Health Town Hall Listening Session.

Date and Time: August 27, 2013, 2:00 p.m.–3:30 p.m. (EST).

Place: Virtual via Webinar.

Status: The meeting is open to the public. The meeting will be hosted virtually through webinar and by phone. Participants will have an opportunity to interact with presenters via the chat function in the public comment section of the webinar system. In addition, there will be up to 100 phone lines available to individuals who choose to participate by phone. The phone lines will be made available on a first-come, first-served basis. To register for this meeting please go to: *http://learning.mchb.hrsa.gov/LiveWebcastDetail.asp?leid=333*. Registrations will be accepted through 5:00 p.m. EST on August 19, 2013. Call information for this meeting will be provided upon registration.

Purpose: The purpose of the meeting is to share and discuss proposed strategies and to solicit ideas in support of the National Maternal Health Initiative. The Town Hall Listening Session will serve as a platform to engage and obtain feedback from the public on HRSA's strategic thinking around a national strategy to reduce maternal morbidity and mortality, and improve the quality and safety of maternity care in the United States.

The desired outcomes of the meeting are:

I. To share with the public the Health Resources and Services Administration, Maternal and Child Health Bureau's (HRSA/MCHB): (1) Vision for promoting maternal health in the United States; (2) strategic direction for the National Maternal Health Initiative including mission, goals and objectives; and (3) identified priority areas to focus efforts to improve maternal health;

II. Enhance, guide, and strengthen HRSA's strategic thinking related to maternal health using input from maternal health experts, representatives of professional organizations, and the public at large.

Agenda: Topics that will be discussed include the following: Maternal health in the United States; current efforts to improve maternal health; gaps in the field; opportunities for collaborative efforts; and an overview of the National Maternal Health Initiative. 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. Registered attendees for this meeting are encouraged to submit comments prior to the meeting. Comments are to be submitted in writing no later than 5:00 p.m. ET on August 19, 2013.

For Further Information Contact: Individuals who are submitting public comments or who have questions regarding the meeting should contact Keisher Highsmith, Dr.P.H., Director of Special Initiatives and Program Planning and Evaluation, Health Resources and Services Administration, Maternal and Child Health Bureau, telephone: (301) 443–0543; or email: *khighsmith@hrsa.gov*.

Dated: June 14, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–14837 Filed 6–20–13; 8:45 am]

BILLING CODE 4165–15–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.

GPR116 Knockout and Conditional Knockout Mice

Description of Technology: Pulmonary surfactant plays a critical role in preventing alveolar collapse by decreasing surface tension at the alveolar air-liquid interface. Surfactant deficiency contributes to the pathogenesis of acute lung injury (ALI) and acute respiratory distress syndrome (ARDS), common disorders that can afflict patients of all ages and carry a mortality rate greater than 25%. Excess surfactant leads to pulmonary alveolar proteinosis. The NCI investigators created a G-protein coupled receptor GPR116 mutant mouse model and showed that GPR116 plays a previously unexpected, essential role in maintaining normal surfactant levels in the lung.

The mouse model could aid in the development of drug screens to identify agents that can modulate surfactant levels. Alveolar type II cells have also been isolated from the GPR116 wildtype and knockout mice that could be directly used in such assays. The identification of surfactant modulating agents could be important to a number of lung surfactant disorders.

Potential Commercial Applications: Research materials to study lung surfactant homeostasis and disorders.

Competitive Advantages: Not available elsewhere.

Development Stage:

- Prototype.
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Bradley Dean St. Croix and Mi Young Yang (NCI).

Publication: Yang MY, et al. Essential Regulation of Lung Surfactant Homeostasis by the Orphan G Protein-Coupled Receptor GPR116. Cell Rep. 2013 May 30;3(5):1457–64. [PMID 23684610]

Intellectual Property: HHS Reference No. E–269–2012/0—Research Tool. Patent prosecution is not being pursued for this technology.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov*.

Collaborative Research Opportunity: The Center for Cancer Research Mouse Cancer Genetics Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize GPR116 Knockout and Conditional Knockout Mice. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Engineered Anthrax Toxin Variants That Target Cancer

Description of Technology: This technology describes the use of novel mutated anthrax protective antigen (PA) protein variants to target tumor cells and tumor vasculature. NIH scientists have engineered two PA variants that selectively complement one another and combine to form active octamers that target tumor cells. This controlled oligomeric activation of the PA proteins makes the likelihood of toxicity to non-tumor cells very low since non-tumor tissue does not express certain cell-surface proteases required to activate the PA variants. Using proteases that are highly expressed in tumor cells, e.g., matrix metalloproteases (MMP) and urokinase plasminogen activator (uPA), the scientists have shown significant tumor growth suppression with the oligomer in a mouse model. Furthermore, other tumor-specific proteases could also be used to control formation of the targeted octameric anthrax toxin structures. Moreover, the structures can be expanded to include several PA variants. In summary, this technology provides a unique, expandable platform that reduces toxicity to normal tissues compared to other systems and can be used to treat cancers more effectively.

Potential Commercial Applications: Therapeutic treatment for solid tumors, cancers, and infectious diseases.

Competitive Advantages:

- Specificity in targeting tumors while eliminating side effects associated with non-specific targeting of normal cells.
- Method can be expanded to include different proteases and up to eight PA variants.

Development Stage:

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Clinton E. Leysath, Stephen H. Leppla, Damilola D. Phillips (NIAID).

Publication: Phillips DD, et al. Engineering anthrax toxin variants that exclusively form octamers and their application to targeting tumors. J Biol Chem. 2013 Mar 29;288(13):9058–65. [PMID 23393143]

Intellectual Property: HHS Reference No. E–246–2012/0—U.S. Provisional Application No. 61/692,143 filed 22 Aug 2012.

Related Technologies:

- HHS Reference No. E–293–1999—Mutated Anthrax Toxin Protective Antigen Proteins That Specifically Target Cells Containing High Amounts of Cell-Surface Metalloproteinases or Plasminogen Activator Receptors (Leppla/NIAID).