sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to speak during the public comment session and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Following the close of registration, FDA will determine the amount of time allotted to each speaker and will select and notify participants by November 10, 2014. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain input on insulin bolus calculators. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments regarding the public workshop topics that pertain to insulin bolus calculators. The deadline for submitting comments related to this public workshop is December 11, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question number you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the workshop.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is seeking to foster greater stakeholder collaboration in the area of diabetes device interoperability. To that end, the Agency requests input from the clinical community, academia, government, industry, and other stakeholders regarding usability considerations for appropriate information consumption (e.g., notifications, indicators, data, and displays) based on user skill and knowledge. The Agency also requests input regarding the technical considerations for calculator design and use.

The first topic of discussion is the interoperability between diabetes devices. The Agency recognizes that the diabetes community possesses an interest in patients having greater flexibility to pair device components, e.g., continuous glucose meters with insulin pumps from different manufacturers. Pairing would allow those devices to communicate with each other and enable patients to interact with a single interface platform. Achieving this goal would improve data tracking and access, thereby facilitating more productive patient interactions with their healthcare providers. In order to realize the objective of effective diabetes device interoperability, developers and manufacturers should discuss technical, safety, and regulatory challenges that lay before this goal. A forum that elicits opinions from physicians and patients regarding their desires and needs will help inform those discussions. FDA is committed to fostering a collaborative environment to promote these interactions.

The second topic of discussion is insulin bolus calculators. These devices are intended to calculate insulin boluses for patients who manage their diabetes with insulin-intensive therapy. FDA currently regulates insulin bolus calculators as class II devices, often clearing them in combination with insulin pumps or blood glucose meters. Devices that calculate insulin boluses are increasingly available on the market, including those devices that use novel dosing algorithms and new user interface formats. Although these devices can benefit patient care, they could also jeopardize patient safety without proper regulation guarding against the serious health consequences of miscalculating insulin dosages. The Agency will host a public dialogue about insulin bolus calculators to help realize the aim of ensuring continued access to safe and effective technological innovations, regardless of interface format.

The public workshop will include two sessions, one for each of the topics noted previously. Each session will include presentations from physicians, FDA, and other experts in the field. A panel discussion will follow the session addressing insulin bolus calculators, and the panel will address questions from the audience. In addition, Agency representatives will update the diabetes community on relevant FDA news.

II. Topics for Discussion at the Public Workshop

Among other topics, the workshop will include discussion of the following questions.

1. How can patients and providers be confident that the insulin bolus values obtained from the calculators are accurate and appropriate for their use?
2. What information do patients and providers need about how a particular calculator works so that they may appropriately use the calculator for diabetes management?
3. How can FDA foster both innovation and safety of insulin dose calculators intended for use by healthcare practitioners?
4. How can FDA foster both innovation and safety of insulin dose calculators intended for use by patients?

Dated: October 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24451 Filed 10–14–14; 8:45 am]

BILLING CODE 4164–01–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. 209 and 37 CFR Part 404 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

The Use of Chimeric Antigen Receptor To Control HIV Infection

Description of Technology: Chimeric Antigen Receptors (CARs) are engineered proteins expressed by transduction on autologous CD8 T cells; after adoptive transfer, they promote targeted killing of specific cell types. CARs are showing great promise for treating cancer. The present invention (CD4–CRD CAR) is a novel bifunctional targeting motif for an anti-HIV CAR, consisting of a region of human CD4 linked to a carbohydrate recognition domain (CRD) from one of several human C-type lectins known to interact with high-mannose glycans on HIV gp120. Compared to a ''standard'' CD4 CAR, the CD4–CRD CAR displays two major enhancements: (1) Increased potency for suppression of HIV–1 infection by selective killing of productively infected cells, and (2) complete absence of CD4-mediated entry receptor activity that would otherwise render the transduced CD8 T cells susceptible to HIV infection. Compared to antibody-based anti-HIV CARs, the CD4–CRD CAR of the present invention is predicted to have two major advantages: (1) Lower escape potential, due to the universality of HIV CD4-dependence and high-mannose glycan display on gp120, and (2) reduced immunogenicity, since the all-human CD4–CRD CAR sequences are devoid of variable regions that would likely elicit anti-idiotypic antibody responses against scFv-based targeting motifs.

Potential Commercial Applications:

- Therapy for HIV infection
- Research on antiretroviral infection

Competitive Advantages: Enhanced potency for HIV inhibition and does not render transduced CD8T cells susceptible to HIV infection.

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors: Mustafa H. Ghanem, Bama Dey, Edward Berger (all of NIAID)

Publications:

1. Scholler J, et al. Decade-long safety and function of retroviral-modified chimeric antigen receptor T cells. Sci Transl Med. 2012 May 2;4(132):132ra53. [PMID 22553251]

2. Du T, et al. Bifunctional CD4–DC–SIGN fusion proteins demonstrate enhanced avidity to gp120 and inhibit HIV–1 infection and dissemination. Antimicrob Agents Chemother. 2012 Sep;56(9):4640–9. [PMID 22687513]

3. Lamers CH, et al. Immune responses to transgene and retroviral vector in patients treated with ex vivo-engineered T cells. Blood. 2011 Jan 6;117(1):72–82. [PMID 20889925]

Intellectual Property: HHS Reference No. E–212–2014/0—US Provisional Application No. 62/040,398 filed 21 August 2014

Licensing Contact: John Stansberry, Ph.D.; 301–435–5236; *stansbej@mail.nih.gov*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Chris Kornak at *chris.kornak@nih.gov.*

Photo-Controlled Removal of Targets In Vitro and In Vivo

Description of Technology: The invention relates to a novel technology for separation, isolation and removal of target molecules or cells from a complex mixture. The technology can be used for both in vitro and in vivo applications. It comprises a conjugate of a biomolecule with specific binding activity (e.g. antibody, hapten, protein, nucleic acid) and the fluorescence dye IR700. When the conjugate is allowed to contact with a sample, it binds to the target molecule in the sample to form a biological complex. Upon exposure to near infrared light (NIR) of approximately 700 nm the biological complex becomes hydrophobic due to cleavage of a part of the fluorescent dye. Such hydrophobic complex can aggregate and readily be separated and removed from the biological mixture. The technology can be used in a broad range of applications, such as environmental or food (removal of contaminants from samples), or in vivo removal of toxins, pathogens or drugs from a subject, where the latter may provide a photo-controlled way to control the pharmacokinetics of a drug in vivo. The technology can also be applied in the therapeutic field, for example in cancer therapy, by killing and removal of tumor cells in a subject with the aid of wearable NIR device. In such treatment, the aggregated target cells may be removed from the subject via the liver and/or spleen.

Potential Commercial Applications:

- Environmental or food (removal of contaminants from samples)
- In vivo removal of toxins, pathogens or drugs from a subject
- Cancer therapy

Competitive Advantages: Simple and versatile way to separate and remove molecules or cells from a complex mixture.

Development Stage: Early-stage

Inventors: Hisataka Kobayashi, et al. (NCI)

Intellectual Property: HHS Reference No. E–209–2014/0—US Provisional Application No. 62/034,990 filed 08 August 2014

Licensing Contact: Uri Reichman, Ph.D., MBA; 301–435–4616; *ur7a@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 this technology. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Human Monoclonal Antibodies Against 5T4 as Therapeutic Agents

Description of Technology: 5T4 is an antigen expressed in a number of carcinomas. Its expression is limited in normal tissue, but is prevalent in malignant tumors throughout their development. This confined expression makes it an attractive target for cancer immunotherapy. 5T4 is often found in colorectal, ovarian, and gastric tumors and thus has been used as a prognostic aid for these cancers. In addition, its role in antibody-directed immunotherapy for delivering response modifiers to tumors has been studied using murine monoclonal antibodies (mAbs) and the cancer vaccine TroVax (currently in clinical trials for multiple solid tumors) targets 5T4.

The present invention describes the identification and characterization of two fully human mAbs (m1001 and m1002) that bind to 5T4. Since the mAbs are fully human, they could have less immunogenicity and better safety profiles than the existing mouse and humanized antibodies. These mAbs have the potential to be cancer therapeutics as naked mAbs, Chimerica Antigen Receptors (CARs) and/or Antibody-Drug Conjugates (ADCs).

Potential Commercial Applications: A mAb, CAR, or ADC therapeutic for the

treatment of various human cancers expressing 5T4.

Competitive Advantages:

• The fully human antibodies may have better drugability, especially less immunogenicity and better safety.

• This antibodies could be used as naked mAbs, CARs and/or as ADCs.

• The confined expression of 5T4 makes it an attractive target for cancer immunotherapy.

• 5T4 mAbs could be used to treat several solid tumor cancers.

Development Stage: In vitro data available

Inventors: Dimiter Dimitrov, Tianlei Ying, Yang Feng (all of NCI)

Intellectual Property: HHS Reference No. E–158–2014/0—U.S. Provisional Application No. 62/034,995 filed 08 August 2014

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov*

Quantitative Multiplex Methods for Rapid Detection and Identification of Viral Nucleic Acids

Description of Technology: The subject technologies are quantitative multiplex loop mediated isothermal amplification assays that can detect and distinguish different viral pathogens, including HIV, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Hepatitis E Virus (HEV), Dengue Virus (DENV), Chikungunya virus (CHIKV) and West Nile Virus (WNV). The assay has the advantage of distinguishing between different genotypes of HCV. It has the potential to detect other pathogens. A quantitative multiplex variation of the assay can detect and identify all seven viruses using one reaction mixture. The detection-reaction is performed on a simple heat-source and viral quantitation can be measured using a simple fluorospectrophotometer. The entire detection process using these assays can be accomplished within 30 to 60 minutes in a doctor's office, laboratory setting, or in the field. Detection limits of as little as 1–10 International Units (viral copies) are possible with the use of fluorogenic oligonucleotides. The assays demonstrate very high specificity when tested with human clinical samples.

Potential Commercial Applications: Detection assays for viral pathogens such as HIV, HBV, HCV, HEV, Dengue Virus, Chikungunya, and West Nile Virus.

Competitive Advantages:

• Assays can be completed within 30 to 60 minutes and in a doctor's office, laboratory setting, or in the field.

• Assays can be performed without expensive instrumentation or specialized technical operators.

• Assays are highly specific and can distinguish between different viruses and between different genotypes of viruses.

Development Stage:

• Early-stage

• In vitro data available

• In vivo data available (human)

Inventors: Dougbeh-Chris Nyan (FDA), Deborah R. Taylor (FDA), Maria Rios (FDA), Kevin L. Swinson (Morgan State University), Laura E. Ulitzky (FDA)

Publication: Nyan DC, et al. Rapid Detection of Hepatitis B Virus in Blood Plasma by a Specific and Sensitive Loop-Mediated Isothermal Amplification Assay. Clin Infect Dis. 2014 July 1;59(1):16–23. [PMID 24704724]

Intellectual Property: HHS Reference No. E–135–2014/0—US Provisional Patent Application No. 61/979,446 filed 14 April 2014

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov*

Collaborative Research Opportunity: The Food and Drug Administration, Center for Biologics Evaluation and Research, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize blood screening test and/or diagnostic test for infectious diseases. For collaboration opportunities, please contact Nisha Narayan at *Nisha.Narayan@fda.hhs.gov* or 240–402–9770.

Dated: October 8, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–24403 Filed 10–14–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 27, 2014, 07:30 a.m. to October 28, 2014, 06:00 p.m., Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA, 90401 which was published in the **Federal Register** on October 06, 2014, 79 FR 60175.

The meeting will start on October 27, 2014. The meeting time and location remains the same.

The meeting is closed to the public.

Dated: October 7, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–24380 Filed 10–14–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

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

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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: Board of Regents of the National Library of Medicine; Extramural Programs Subcommittee.

Date: February 10, 2015.

Closed: 7:45 a.m. to 8:45 a.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Billings Conference Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Donald A.B. Lindberg, MD, Director, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892, 301–496–6221, *lindberg@mail.nih.gov*.

Name of Committee: Board of Regents of the National Library of Medicine; Subcommittee on Outreach and Public Information.

Date: February 10, 2015.

Open: 7:45 a.m. to 8:45 a.m.

Agenda: To review and discuss outreach activities.

Place: National Library of Medicine, Building 38, 2nd Floor, Conference Room B, 8600 Rockville Pike, Bethesda, MD 20892.