B. Is there a fee and how do I register for the conference?

A registration fee will be charged to attendees other than invited speakers to help defray the costs of rental of the meeting spaces, meals and snacks provided, and if possible, to cover travel costs incurred by invited academic (but not Government or industry) speakers, and other costs. The fee for the 2-day meeting is $500 for industry registrants and $250 for Federal Government and academic registrants. Registration fees will be waived for invited speakers and moderators.

The registration process will be handled by AASLD, a not-for-profit organization with extensive experience in planning, organizing, and executing educational meetings.

Additional information on the conference, program, and registration procedures is available on the Internet at *http://www.aasld.org* (go to Conferences and Education, Meetings and Conferences), and also at *http://www.fda.gov* by typing into the search box "liver toxicity." (FDA has verified the AASLD Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Transcripts: The presentations and discussions will be transcribed and published on the Internet at *http://www.aasld.org* for public availability after minor editing by the organizers of the meeting (Lana Pauls and John Senior). Please be advised that as soon as a transcript is available, it will also be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. 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 Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the guidance and the issues and questions presented at the conference. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. Monday through 4 p.m. Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1759 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0046]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing an invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. The purpose of this document is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit either an electronic or written request for participation in this program by February 28, 2011. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address(es) of the site(s) you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit, submit either an electronic request to *http://www.regulations.gov* or a written request to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. If you previously responded to earlier requests to participate in this program and you continue to be interested in participating, please renew your request through a submission to the Division of Dockets Management.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Henderson, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, *e-mail: matt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and availability of biological products to patients. To support this primary goal, CBER has initiated various training and development programs, including programs to further enhance performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to enhance: (1) Its understanding of current industry practices and regulatory impacts and needs and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005. Through these annual notices, CBER is requesting those firms that have previously applied and are still interested in participating, to reaffirm their interest. CBER is also requesting new interested parties to apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example, blood and tissue establishments. The visits may include the following: (1) Packaging facilities, (2) quality control and pathology/toxicology laboratories, and (3) regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an

avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

CBER will be responsible for all travel expenses associated with the site visits. Therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with FDA or another Agency with which we have a memorandum of understanding. If a site visit also involves a visit to a separate physical location of another firm under contract to the applicant, the other firm also needs to agree to participate in the program, as well as have a satisfactory compliance history.

III. Requests for Participation

Identify requests for participation with the docket number found in the brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (*see* **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 24, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1753 Filed 1–26–11; 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, Public Health Service, 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.

ADDRESSES: 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.

Allele Specific shRNA for Nanog, and Its Use To Treat Cancer

Description of Technology: Cancer stem cells are currently thought to be major participants in resistance to radiation therapy and chemotherapy; they are also thought to drive the spread of cancer through metastasis. It has been postulated that genes involved in early embryogenesis, primarily transcription factor Nanog but also Oct4 and SOX2, may be reactivated to maintain the properties of cancer stem cells, any treatment that inhibits such genes may therefore inhibit the progression of cancer and lead to improved survival and other clinical outcomes.

The NIH investigators discovered that the expression of NanogP8, a pseudogene of Nanog, is upregulated in human colorectal cancer spheroids formed in serum-free medium. NanogP8 has also been reported to be upregulated in human prostate cancer and glioblastomas. An inhibitory RNA molecule was identified by the investigators to knock down expression of NanogP8, without interfering with expression of Nanog. The discovery may improve the safety of a shRNA-based gene therapy and improve its chances for acceptance as a clinical therapy.

Applications and Market:

• This invention may provide a new therapy to target colorectal cancer as well as a few other cancers for treatment.

• Cancer is the second leading cause of death, and colorectal cancer is the fourth most common form of cancer in the U.S. Development of more effective cancer therapies is always in need.

Development Status: Pre-clinical stage of development.

Inventors: John M. Jessup and Jingyu Zhang (NCI).

Patent Status: U.S. Provisional Application No. 61/420,214 filed 06 Dec 2010 (HHS Reference No. E–294–2010/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Experimental Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this specific gene therapy to target colorectal and other human carcinomas. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Compositions and Methods for Controlling Neurotropic Viral Pathogenesis by Micro-RNA Targeting

Description of Technology: There are more than seventy (70) single-stranded, positive-sense RNA viruses in the arthropod-borne flavivirus genus of the Flaviviridae family, many of which are important human pathogens that cause a devastating and often fatal neuroinfection. Flaviviruses are transmitted in nature to various mammals and birds through the bite of an infected mosquito or tick; they are endemic in many regions of the world and include mosquito-borne yellow fever (YFV), Japanese encephalitis (JEV), West Nile (WNV), St. Louis encephalitis (SLEV), dengue viruses (DEN) and the tick-borne encephalitis viruses (TBEV). During the past two decades, both mosquito-borne and tick-borne flaviviruses have emerged in new geographic areas of the world where previously they were not endemic and have caused outbreaks of diseases in humans and domestic animals.

Long-term experience with the only two successful live attenuated flavivirus vaccines has demonstrated that live attenuated virus vaccines are an efficient approach to prevent diseases caused by virulent flaviviruses because, in most cases, just a single dose of the vaccine provides a long-lasting protective immunity in humans that mimics the immune response following natural infection.

This application claims recombinant attenuated neurotropic flaviviruses comprising nucleic acid sequences complementary to the target sequences of microRNAs. The application also claims live attenuated chimeric flaviviruses, where the first flavivirus is a different flavivirus from the second flavivirus.

Applications:

• Vaccines for the prevention of multiple flavivirus infections.

• Use of human clinically-tested live attenuated dengue vector.

Advantages:

• Novel vaccine candidate.

• Rapid production time.

• Low manufacturing cost.

Development Status: Preclinical studies have been conducted by the inventors.

Inventors: Alexander Pletnev and Brian Heiss (NIAID).