at least 21 days in advance of the conference.

Registration Instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to ''AFDO''. Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register online, please visit *http://indy.afdo.org/register.html.* (FDA has verified the Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the conference, or for questions about registration, please contact AFDO at 717–757–2888, FAX: 717–650–3650, or email: *afdo@afdo.org.*

SUPPLEMENTARY INFORMATION: The conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The conference will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include, but are not limited to, the following:

- Medical Device Single Audit Program
- Contract Manufacturing Arrangements for Drugs: Quality Agreements
- Compliance Question and Answer Panel
- Draft Guidance: Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements
- Compounding Pharmacies
- Overview of Global Device/Drug Requirements v. U.S. System
- Case for Quality Initiative Update
- Unique Device Identifier (UDI) Implementation Update
- Metric, Data, and Analysis; Biometrics
- Pharmaceutical Inspection Cooperation Scheme
- Biosimilar Regulations

FDA has made education of the food, feed, drug, and device manufacturing community a high priority to help ensure the quality of FDA-regulated products. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03115 Filed 2–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0824]

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 March 19, 2015. 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: Loni Warren Henderson, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, 240–402–7800, FAX: 301–595–1243, *Industry.Biologics@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 that those firms that have previously applied and are still interested in participating reaffirm their interest. CBER is also requesting that new interested parties 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 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 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: *February 10, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03117 Filed 2–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Start-up Evaluation License for the Development of Theranostic Kits for Taxane-based Chemotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Taxor Diagnostics, LLC of an exclusive evaluation option license to practice the inventions embodied in the following US Patent, US Patent Application, and International Patent Application (and all foreign counterparts): US Patent No. 8,546,091, issued 01 October 2013, entitled, ''Akt Phosphorylation at SER473 as an Indicator for Taxane-based Chemotherapy'' [HHS Ref. E–191–2009/0–US–07]; US Patent Application serial no. 14/031,699, of the same name, filed 19 September 2013 [HHS Ref. E–191–2009/0–US–08]; and International (PCT) Patent Application no. PCT/US2010/035816, of the same name, filed 21 May 2010 [HHS Ref. E–191–2009/0–PCT–02]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

1. Exclusive use of the Licensed Patent Rights to develop a test kit approved by the FDA as a Class III medical device under the Premarket approval (PMA) process, such test kit to be distributed in commerce for the purpose of identifying subgroups of breast cancer, colorectal cancer, and non-small cell lung cancer patients that may benefit from treatment with a taxane therapy; and

2. Non-exclusive use of the Licensed Patent Rights to develop a test kit for which the FDA issues an order, in the form of a letter, which finds Licensee's device to be substantially equivalent to one or more similar legally marketed devices, and states that the Licensee's device can be marketed in the U.S. (*i.e.,* 510(k) cleared), such test kit to be distributed in commerce for the purpose of identifying subgroups of breast cancer, colorectal cancer, and non-small cell lung cancer patients that may benefit from treatment with a taxane therapy.

Upon the expiration or termination of the exclusive evaluation option license, Taxor Diagnostics, LLC will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before March 4, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; Email: *mccuepat@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology describes a method of identifying cancer patients that will respond favorably to and benefit from treatment with taxane-based therapy depending on the phosphorylation status of protein Akt-Serine 473 in patient's tumor biopsy sample.

The prospective exclusive evaluation license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 9, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–03088 Filed 2–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 of Environmental Health Sciences Special Emphasis Panel; Worker Health and Safety Training Review.

Date: March 9–10, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Sheraton Chapel Hill Hotel, One Europa Drive, Chapel Hill, NC 27517.