Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–08028 Filed 4–7–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0986]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH or Center) is announcing the 2015 Experiential Learning Program (ELP). This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities to apply to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the ELP.

DATES: Submit either an electronic or written request for participation in the ELP by May 8, 2015. The proposal should include a description of your facility relative to focus areas described in tables 1or 2). Please include the Area of Interest (see tables 1or 2) that the site visit will demonstrate to CDRH staff, a contact person, site visit location(s), length of site visit, proposed dates, and maximum number of CDRH staff that can be accommodated during a site visit. Proposals submitted without this minimum information will not be considered. In addition, please include an agenda outlining the proposed training for the site visit. A sample request and agenda are available on the ELP Web site at *http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf* and *http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.*

ADDRESSES: Submit either electronic requests to *http://www.regulations.gov* or written requests to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify proposals with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Latonya Powell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5232, Silver Spring, MD 20993–0002, 301–796–6965, FAX: 301–827–3079, *Latonya.powell@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to high-quality, safe, and effective medical devices. In support of this mission, the Center launched various training and development initiatives to enhance performance of its staff involved in regulatory review and in the premarket review process. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (78 FR 19711). CDRH is committed to advancing regulatory science; providing industry with predictable, consistent, transparent, and efficient regulatory pathways; and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. This is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, regulatory impacts, and regulatory needs.

These formal training visits are not intended for FDA to inspect, assess, judge, or perform a regulatory function (*e.g.,* compliance inspection), but rather, they are an opportunity to provide CDRH review staff a better understanding of the products they review. Through this notice, CDRH is formally requesting participation from companies, academia, and clinical facilities, including those that have previously participated in the ELP or other FDA site visit programs.

II. ELP

A. ELP Training Component

In this training program, groups of CDRH staff will observe operations at research, manufacturing, academia, and health care facilities. The focus areas and specific areas of interest for visits may include the following:

TABLE 1—AREAS OF INTEREST—MEDICAL DEVICES/TECHNOLOGY

Focus area	Specific areas of interest
Failure analysis of orthopedic devices.	Methods for retrieval and preservation of failed implants for analysis; understanding how retrieved implants may be analyzed; methods for identifying failure modes; understanding how analysis of failed implants influences device design modifications.
Radiologic analysis of orthopedic devices.	Methods of radiologic analysis and associated data analyses; radiologic imaging core laboratories.
Automated external defibrillators (AEDs).	Manufacturing process; incoming component inspection; design verification testing; human factors testing; returned product testing (as available).
Diagnostic imaging catheters for cardiovascular diseases.	Manufacturing process; design verification testing; returned product testing (as available); ultrasound, optical coherence tomography (OCT), and near infrared spectroscopy (NIS) catheters.
Endovascular grafts for treatment of aortic aneurysms.	Physician-sponsored clinical studies; observation of endovascular grafting surgical procedure; surgical planning process; factors that influence device modifications (e.g., patient anatomy, patient pathology).
Animal models for evaluation of hemostatic devices.	Models of traumatic injury and severe hemorrhage; limitations of the model; understanding the relevance of the data generated from these models in evaluating hemostatic devices.
Hyaluronic acid in dermal tissue fillers.	Manufacturing process; source materials; performance testing (e.g., material characterization, biocompatibility, residence time).
Minimally invasive glaucoma surgery (MIGS) devices.	Observation of a MIGS procedure; surgical planning; surgical challenges.

TABLE 1—AREAS OF INTEREST—MEDICAL DEVICES/TECHNOLOGY—Continued

Focus area	Specific areas of interest
Neurointerventional devices	Stents, flow-diverters, mesh balls, coils, and other related devices; observation of surgical procedures; understanding of clinical decision making for relevant patient populations; manufacturing; performance testing.
Implantable functional electrical stimulation devices.	Observation of implantation procedure; surgical challenges.
Male condoms	Manufacturing process; lot release testing (e.g., airburst, water leak, dimensional analysis).
Solid organ preservation devices	Observation of organ preservation procedures; pulsatile perfusion (for either cold storage or normothermia).
Infusion pumps	Manufacturing process; device design considerations; patch pumps; insulin pumps; implantable infusion pumps; implantable ports.
Bone grafting materials for dental applications.	Manufacturing process; sourcing process; viral inactivation testing; animal testing.

TABLE 2—AREAS OF INTEREST—IN VITRO DIAGNOSTIC AND RADIOLOGICAL DEVICES/TECHNOLOGY

Focus area	Specific areas of interest
Manufacturing of glucose test strips and meters.	Observation of the manufacturing and in-process and finished device testing of glucose monitoring devices.
Manufacturing of continuous glucose monitoring systems and insulin pumps.	Observation of the manufacturing and in-process and finished device testing of glucose monitors and insulin pumps.
Manufacturing of chemistry devices	Observation of the manufacturing and in-process and finished device testing of point of care chemistry cassettes/cartridges/strips for smaller chemistry analyzers used in clinical and point of care settings.
Manufacturing of chemistry reagent, controls and calibrators.	Observation of the manufacturing and in-process and finished device testing of chemistry reagents, calibrators, and controls for common chemistry analytes used in a clinical laboratory setting.
Manufacturing of urine test strips and readers.	Manufacturing and observation of in process or finished device testing for urine test strips and meters in clinical laboratory and point of care testing settings.
Manufacturing and development of IHC (immunohistochemistry) devices.	Observation of manufacturing, in-process testing, and/or finished device testing of IHC devices (used in the diagnostic evaluation of cancer, classification of tumors, or companion diagnostic testing).
Manufacturing and development of ISH (in situ hybridization) devices.	Observation of the manufacturing, in-process testing, or finished device testing of colorimetric in situ hybridization (CISH) and/or fluorescent in situ hybridization (FISH) assays used in identifying specific nucleic acid sequences within tissue sections (for diagnostic and/or treatment decisions).
Manufacturing and development of NGS (next gen sequencing) platforms and devices.	Observation of NGS sequencing platforms, bioinformatic analysis of the resulting sequence information, and types of interpretative software for potential clinical purposes.
Manufacturing, development and observation of CTC (circulating tumor cells) devices.	Observation of the manufacturing, in-process testing, or finished device testing of CTC devices that assess the prognosis of patients with metastatic breast, colorectal, or prostate cancer (manufacturing site or research site or clinical setting).
Manufacturing, development and/or observation of clinical mass spectrometers and high performance liquid chromatography (HPLC) devices.	Observe the manufacturing, development and/or demonstration of clinical mass spectrometers and HPLC as part of laboratory workflow including sample preparation, equipment usage, and data analysis.
Manufacturing, development and research of flow cytometry devices and components.	Manufacturing, research, and development of in-process testing, or finished device testing of cytometry analyzers and accompanying components.
Manufacturing of immunoassays for autoimmune diseases.	Manufacturing and development of in-process testing, or finished device testing, for diagnostic evaluation and research.
Manufacturing and development of coagulation—point of care devices.	Manufacturing and development of in-process or finished device testing for point of care devices such as Prothrombin Time and International Normalized Ratio (PT/INR) meters.
Manufacturing and product development of global hemostasis testing devices.	Manufacturing of global hemostasis testing for anti-coagulants and anti-platelet drugs for new molecular targets to assess the level of drug-induced inhibition for qualitative and quantitative evaluation.
Manufacturing and product development of direct anticoagulants assays/controls/calibrators.	Manufacturing and development of assays, controls, and calibrators for the detection of direct anticoagulants.
Observation of testing of sequencing technologies in large sequencing centers.	Visit a sequencing center where various sequencing methods are used for different applications other than in vitro diagnostic devices (IVD) manufacturing.
Manufacturing, and product evaluation of IVDs using next generation sequencing (NGS) technology.	Visit a manufacturer of IVD designed for sequencing of microorganisms for identification purposes.
Clinical applications-NGS in practice.	Visit a clinical laboratory that uses NGS as a diagnostic/screening tool.
Antimicrobial susceptibility testing (AST).	Visit to a manufacturer of antimicrobial susceptibility test platforms intended for use in clinical laboratory settings.

TABLE 2—AREAS OF INTEREST—IN VITRO DIAGNOSTIC AND RADIOLOGICAL DEVICES/TECHNOLOGY—Continued

Focus area	Specific areas of interest
Antimicrobial susceptibility testing (AST).	Visit to a clinical laboratory that employs various AST methodologies for identification of antibiotic resistance.

B. Site Selection

CDRH will be responsible for CDRH staff travel expenses associated with the site visits. CDRH will not provide funds to support the training provided by the site to this ELP. Selection of potential facilities will be based on CDRH's priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history.

III. Request for Participation

Submit proposals for participation with the docket number found in the brackets in the heading of this document. Received requests may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08017 Filed 4–7–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENT OF AGRICULTURE

Solicitation of Written Comments on the Scientific Report of the 2015 Dietary Guidelines Advisory Committee; Extension of Comment Period

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services; and Food, Nutrition and Consumer Services and Research, Education, and Economics. U.S. Department of Agriculture.

ACTION: Notice.

SUMMARY: A notice was published in the **Federal Register** on Monday, February 23, 2015, Vol. 80, No. 35, pages 9465–9466 to announce the availability of the Scientific Report of the 2015 Dietary Guidelines Advisory Committee (Advisory Report) and to solicit written comments on the Advisory Report (among other things). In the notice dated February 23, 2015, it was announced that the due date for providing comments was April 8, 2015. This notice is to announce the extension of the solicitation period to allow for additional time for written comments to be submitted for consideration.

DATES: The comment period is extended and thus will end at 11:59 p.m., E.D.T. on May 8, 2015.

ADDRESSES: The Advisory Report is available on the Internet at *www.DietaryGuidelines.gov*. Written public comments on the Advisory Report can be submitted and/or viewed at *www.DietaryGuidelines.gov* using the ''Submit Comments'' and ''Read Comments'' links, respectively.

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer (DFO), 2015 DGAC, Richard D. Olson, M.D., M.P.H.; Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852: Telephone: (240) 453–8280; Fax: (240) 453–8281; Alternate DFO, 2015 DGAC, Kellie (O'Connell) Casavale, Ph.D., R.D., Nutrition Advisor; Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852: Telephone: (240) 453–8280; Fax: (240) 453–8281; Lead USDA Co-Executive Secretary, Colette I. Rihane, M.S., R.D., Director, Office of Nutrition Guidance and Analysis, Center for Nutrition Policy and Promotion, USDA; 3101 Park Center Drive, Room 1034; Alexandria, VA 22302; Telephone: (703) 305–7600; Fax: (703) 305–3300; and/or USDA Co-Executive Secretary, Shanthy A. Bowman, Ph.D., Nutritionist, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, USDA; 10300 Baltimore Avenue, BARC-West Bldg. 005, Room 125; Beltsville, MD 20705–2350; Telephone: (301) 504–0619.

Dated: March 24, 2015.

Don Wright,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

Dated: March 24, 2015.

Angela Tagtow,

Executive Director, Center for Nutrition Policy and Promotion, U.S. Department of Agriculture.

Dated: March 23, 2015.

Steven R. Shafer,

Associate Administrator, Agricultural Research Service, U.S. Department of Agriculture.

[FR Doc. 2015–08049 Filed 4–7–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, Office of Science Policy, Office of Biotechnology Activities; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.

Date: May 5, 2015.

Time: 8:30 a.m.—3:30 p.m. Eastern.

Agenda: Presentations and discussions regarding: (1) NSABB's proposed framework for guiding risk and benefit assessments of gain-of-function (GOF) studies involving pathogens with pandemic potential; (2) overview of conducting the risk and benefit assessments; (3) planning for future NSABB deliberations on the GOF issue; and (4) other business of the Board.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor Conference 10, Bethesda, Maryland 20892.

Contact Person: Carolyn Mosby, NSABB Program Assistant, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 435–5504, *carolyn.mosby@nih.gov.*

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the National Science Advisory Board for Biosecurity (NSABB) to provide advice regarding federal oversight of dual use research, defined as