claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR MORE INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–3714, FAX: 301–796–9832, email: *SentinelInitiative@fda.hhs.gov.*

Registration: To attend the public workshop, you must register before February 3, 2016, by visiting *http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.* You may also register for the live webcast by visiting this Web page. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. Those without Internet access should contact Carlos Bell to register (see **FOR MORE INFORMATION CONTACT**). There is no registration fee for the public workshop. However, registration will be on a first-come, first-served basis because seating is limited. Therefore, early registration is recommended. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Renaissance Washington, DC Dupont Circle Hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (phone: 813–586–1201, email: *jklatzman@brookings.edu*) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast (archived video footage will be available following the workshop). Persons interested in viewing the live webcast must register online by February 2, 2016, at 5 p.m. EST. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements.

Meeting Materials: All event materials will be available to registered attendees via email before the workshop at the Eventbrite Web site at *http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.*

Transcripts: Please be advised that transcripts will not be available.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28851 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–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; General Training 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) General Training Program. 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 request to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the ELP General Training Program.

DATES: Submit either an electronic or written request for participation in the ELP General Training Program by December 16, 2015.

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 helping to ensure 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 General Training Program 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. This component 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. CDRH ELP General Training Program

A. Areas of Interest

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—OFFICE OF DEVICE EVALUATION

Focus area	Specific areas of interest
Biocompatibility testing	Decision making process for biocompatibility evaluation and test selection (if needed); considerations for use of animal testing vs. in vitro testing; sample preparation of nanoscale, bioabsorbable, and in situ polymerized materials; evaluation of color additives.
Combination products	Devices coated with drug(s) or biologic(s); drug/biologic delivery products.
Emerging manufacturing methods	3-D printing; additive manufacturing; additional or unique validation and verification activities.
Management of clinical trials for medical devices.	Conducting clinical trials, overcoming common obstacles to starting and completing clinical trials, and interacting with various other stakeholders; preparing applications to request approval to conduct Investigational Device Exemption (IDE) clinical studies and responding to feedback received from FDA.
Reprocessing and sterilization	Reprocessing challenges in clinical environment, including techniques for understanding and incorporating these challenges from the clinical environment to labeling and validation studies; techniques for validating cleaning, disinfection, or sterilization instructions; challenges in validating cleaning, disinfection, or sterilization instructions; simulated use testing, particularly for validating sterilization methods and instructions; unique sterilization methods (*e.g.*, use of flexible bags, mixed sterilants sound waves, ultraviolet light, microwave radiation).

TABLE 2—AREAS OF INTEREST—OFFICE OF IN VITRO DIAGNOSTIC DEVICES AND RADIOLOGICAL HEALTH

Focus area	Specific areas of interest
Manufacturing of in vitro diagnostic devices.	Pre-analytical devices (*i.e.*, blood tubes), pathogen collection devices, micro collection/transport devices; general reagents, manual reagents; general assays, common point-of-care devices.
Instrument training of medical devices (manufacturer or clinical laboratory).	Hands-on instrument and system training; clinical implication of common laboratory testing; hands on familiarization of medical imaging equipment in a hospital setting.
Quality system in manufacturing environments based on 21 CFR part 820.	Observation of implemented quality systems practices based on current Good Manufacturing Practices; the manufacturing of medical imaging or therapeutic radiology technologies.

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 General Training Program. 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 General Training program and must also have a satisfactory compliance history.

III. Request To Participate

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.

The proposal should include a description of your facility relative to focus areas described in tables 1 or 2. Please include the Area of Interest (see tables 1 or 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.*

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28857 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1977–N–0356 (Formerly 77N–0240); DESI 1786]

Drugs for Human Use; Drug Efficacy Study Implementation; Nitroglycerin Transdermal Systems; Withdrawal of Hearing Request; Withdrawal of Applications; Final Resolution of Hearing Requests Regarding Transdermal Systems Under Docket

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that all outstanding hearing requests regarding nitroglycerin drug