TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Waivers—812.10	1	1	1	1	1
IDE Application—812.20, 812.25, and 812.27	219	1	219	80	17,520
Supplements—812.35 and 812.150	579	6	3,474	6	20,844
Treatment IDE Applications—812.36(c)	1	1	1	120	120
Treatment IDE Reporting—812.36(f)	1	1	1	20	20
Total					38,505

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Original—812.140	219	1	219	10	2,190
Supplemental—812.140	579	6	3,747	1	3,474
Nonsignificant—812.140	356	1	356	6	2,136
Total					7,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Reports for Nonsignificant Risk Studies—812.150	1	1	1	6	6

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated annual reporting burden for this extension has decreased to 38,505 hours (previously 54,253 hours) as the result of a decrease in the average number of applications and supplements submitted. For the same reason, the recordkeeping burden has decreased to 7,800 hours (previously 9,968). The previous approved total burden hours of 64,227, have therefore decreased by 17,916 to 46,311.

Dated: March 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05385 Filed 3–9–16; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing the 2016 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 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.

DATES: Submit either an electronic or written request for participation in the ELP by April 11, 2016.

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 requests with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christian Hussong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5261, Silver Spring, MD 20993–0002, 240–402–2246, FAX: 301–827–3079, *Christian.Hussong@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 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

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
Usability testing	Observe usability testing throughout a device's life cycle and complex clinical simulations.
Reprocessing and reuse of single-use devices (SUDs)	Observe reprocessing and reuse of SUDs in a major health system (*i.e.* Hospital Reprocessor).
Transcatheter heart valves	Observe design, development, and testing of transcatheter heart valves, including pulmonic and aortic valve prostheses and related technology.
Cardiac electrophysiology (EP) diagnostic, mapping, and ablation devices.	Observe clinical EP catheter laboratory and observe catheter ablation procedures (manual and potentially robotic); including EP Lab manager and practicing EP physicians.
Neurological medical devices—early feasibility clinical trials	Design, development, and testing of novel neurological medical devices qualified under early feasibility clinical trials.
Neurostimulators and neuroprosthetics including brain-to-computer interface (BCI).	Design, development, and testing of neurostimulators and neuroprosthetics including BCI technologies.
Non-clinical testing—animal model	Observe non-clinical animal model testing demonstrating the performance of bone void fillers in the posterolateral spine.
Patient matched orthopaedic implants	Observe the patient matched process from the surgeon's decision to utilize patient matched technology through surgery.
Auditory brainstem implants (ABI)	Design, development, and testing of ABI and observe the surgical procedure and a post-implant programming session.
Contact lens care products	Design, development, and testing of contact lens care products and observe non-clinical testing for these devices.
Surgical mesh devices	Design, development, and testing of surgical mesh indicated for gynecologic and urologic indications.
Feeding tubes	Design, development, and testing of nasogastric tubes, nasojejunal tubes, and percutaneous endoscopic gastrostomy tubes.
Robotically-assisted surgical devices (RASD) and surgical simulators in robotic surgery.	Design, development, testing, and validation of emerging RASD and mechanized laparoscopic technologies adopted from other specialties and new-area specific; and surgical simulators incorporating tissue models and force feedback mechanism or haptic technology to reduce learning curve in robotic surgery.
Biological evaluation (*i.e.,* biocompatibility) and viral inactivation of medical devices.	Observe all implanted, surface contacting, and external communicating devices.

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

Focus area	Specific areas of interest
Continuous glucose monitoring systems and insulin pumps	Design and development in-process, and finished device testing of continuous glucose monitoring systems and insulin pumps.
Urine test strips and readers	Design and development in-process, and finished device testing of urine test strips and readers.
Prothrombin (PT)/international normalized ratio (INR) devices	Design and development in-process, and finished device testing of PT/INR devices.
Direct anticoagulants (detection)	Observe the detection of direct anticoagulants.
Antimicrobial susceptibility testing (phenotypic, biochemical, and molecular detection).	Observe clinical microbiology laboratory, contract research organization (CRO), and/or industrial setting where antimicrobial susceptibility testing is being applied.
Next generation sequencing (NGS)	Observe clinical microbiology laboratory, CRO, and/or industrial setting where NGS is being applied.
Immunohistochemistry (IHC) reagents or digital pathology devices	Design, development, and testing of IHC reagents or digital pathology devices that are commonly used in pathology labs.
Cell-free DNA/RNA biomarker technology	Observe Clinical Laboratory Improvement Amendments labs involved with cfDNA, ctDNA, or miRNA for clinical diagnostics.
Radiological imaging equipment testing	Observe radiological imaging equipment (*e.g.* CT, MR, PET, fluoroscopy, etc.) testing and evaluation of particular consensus standards.

TABLE 2—AREAS OF INTEREST—OFFICE OF IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH—Continued

Focus area	Specific areas of interest
Radiation therapy equipment	Observe radiation therapy equipment (*e.g.,* linear accelerator, proton beam therapy, brachytherapy) testing and evaluation.

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 the 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 To Participate

Submit requests 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 request should include a description of your facility relative to focus areas described in table 1 or 2. Please include the Area of Interest (see table 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. Requests submitted without this minimum information will not be considered.

Additional information regarding the CDRH ELP, including a sample request and an example of the site visit agenda, is available on CDRH's Web site at: *http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.*

Dated: March 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05387 Filed 3–9–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0976]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance: Emergency Use Authorization of Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 11, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0595. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Public Health Stakeholders OMB Control Number 0910–0595–Extension

The guidance describes the Agency's general recommendations and procedures for issuance of emergency use authorizations (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb–3), which was amended by the Project BioShield Act of 2004 (Pub. L. 108–276). The FD&C Act permits the Commissioner to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the FD&C Act, the FDA Commissioner may establish conditions on the authorization. Section 564(e) requires the FDA Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the FDA Commissioner to establish other conditions that she finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the FD&C Act include, for example: Requirements for information dissemination to health care providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and