Remaining Operating Rules; and (3) A letter emphasizing NCVHS's long-standing position on the adoption of ICD–10 code sets in the US.

Contact Person for More Information: Debbie Jackson, Interim Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4614; Written comments should be sent directly to Terri Deutsch, lead staff for the Standards Subcommittee, NCVHS, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Mailstop S2–26–17, Baltimore, Maryland 21244, email *Terri.Deutsch@cms.hhs.gov,* phone (410) 786–9462.

Program information as well as summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Dated: April 23, 2014.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and, Evaluation.

[FR Doc. 2014–09903 Filed 4–30–14; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0575]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 31, 2013, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0765. The approval expires on March 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09914 Filed 4–30–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1394]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Special Protocol Assessment'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 19, 2014, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on Special Protocol Assessment'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0470. The approval expires on March 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09913 Filed 4–30–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0338]

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 an invitation for participation in its Experiential Learning Program (ELP). The ELP provides a formal training mechanism for regulatory review staff to visit research, clinical, manufacturing, and health care facilities to observe firsthand how medical devices are designed, developed, and utilized. This training is intended to provide CDRH staff with an opportunity to observe the device development life cycle and provide a better understanding of the medical devices they review and the challenges faced throughout development, testing, manufacturing, and clinical use. The purpose of this document is to invite medical device industry, academia, and health care facilities to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the program.

DATES: Submit either an electronic or written request for participation in this program by June 2, 2014. The request should include a description of your facility relative to product areas regulated by CDRH. 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, length of site visit, proposed dates, and maximum number of CDRH staff that can be accommodated during a site visit. Submitted proposals without this 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: *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 comments 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. 66, Rm. 4448, Silver Spring, MD 20993–0002, 301–796–6965, FAX: 301–827–3079, *Latonya.powell@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH launched the ELP Pilot in 2012 and fully implemented the program (78 FR 19711, April 2, 2013) in 2013. The Center 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 and safe radiation-emitting products. 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. 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. This program is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, and regulatory impacts and needs.

These formal training visits are not a mechanism for FDA to inspect, assess, judge, or perform a regulatory function (i.e., compliance inspection), but rather, are an opportunity to provide the 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; other FDA site visit programs; and new interested parties.

II. ELP

A. Experiential Learning Program

In this program, groups of CDRH staff will observe operations of medical device establishments, including research, manufacturing, academia, and health care facilities. The areas of focus 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
Advanced simulation testing of mechanical ventilators	Performance testing of closed loop controlled ventilators using advanced physiologic simulation and computational modeling of the system (patient, ventilator, and sensor).
Assisted reproductive technology (ART) clinic setting	Structure and organization of an ART clinic; understanding the necessary specifications for ART devices (incubators, microscopes, media, micromanipulation, assisted reproduction lasers, and lab ware); cleaning and disinfection of reprocessed instruments in the ART clinic; aseptic techniques used in ART clinic.
Clinical use of orthopedic bone void filler devices	Observation of surgical procedures (posterolateral spine fusion, foot, ankle) utilizing bone void fillers.
Clinical use of physical medicine devices	Rehabilitation hospitals and programs; devices for treatment of pain (transcutaneous electrical nerve stimulator, diathermy), devices for muscle rehabilitation (powered muscle stimulators), devices intended to help restore function to patients (prosthetic limbs, functional electrical stimulators, orthoses).
Design and development of ablation devices, including electrosurgical units and accessories, electrosurgical/ultrasonic devices, microwave ablation devices.	Tumor ablation devices.
Electrophysiology (EP) catheters for diagnostic (mapping) and therapeutic (ablation) indications.	Observe manufacturing and testing of EP devices, with inclusion of design verification and returned product testing, as available.
Emerging manufacturing methods for orthopedic devices	3D printing, rapid manufacturing.
Endosseous implants	Computer Aided Design/Computer Aided Manufacturers produced elements, titanium bases, and various software programs utilized for forming abutments.
Hemodialysis devices used in the home environment	Home hemodialysis training program, hemodialysis machines, ''wetness'' detectors, hemodialysis blood access devices, water treatment.
Interface between the brain thought processes and the movement of medical devices to assist mobility.	Brain-computer interface manufacturer or laboratory.
Intraocular lenses (IOLs) and injectors	Development and manufacture of IOLs and injectors.
Manufacturing of polymeric sealants	Vascular surgical sealants.
Refractive lasers	Manufacturing; preclinical testing; femtosecond lasers.
Robotic surgery	Manufacturing of robotic surgical devices.

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

Focus area	Specific areas of interest
Artificial pancreas related devices	Manufacturing of continuous glucose monitoring devices and insulin pumps.
Manufacturing of different types of human antibodies for the use of immunoassays.	Manufacturing of antibodies (monoclonal and polyclonal) for immunoassay tests.
Coagulation point of care and home use devices	Coagulation devices for point of care and home use (COUMADIN self-monitoring) utilizing whole blood and/or citrated plasma.
Immunohistochemistry for the diagnostic evaluation for cancer	Immunohistochemistry as an important tool in biomarkers detection and clinical practice.
Systems capable of running multiple analytes composed of a specimen collection and processing unit at satellite locations and data transmittal to a central location for analysis and quality control oversight.	Systems maintaining quality oversight of data generated at a distant location and transmitted digitally to another location for analysis.
Antimicrobial resistance detection and characterization	Observation and hands-on experience with reference methods and assays for phenotypic and non-phenotypic-based methods for determining antimicrobial resistance.
Diagnostic x-ray imaging devices	Site visits to user facilities.
Next generation sequencing/single-nucleotide polymorphism (SNP) arrays and clinical genomics.	Next generation sequencing and/or SNP array devices in the clinical laboratory setting for molecular diagnostics used.

B. Site Selection

CDRH will be responsible for all CDRH staff travel expenses associated with the site visits. CDRH cannot provide funds to support the proposed training provided by the applicants to this 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 to the applicant, that firm must agree to participate in the program and must also have a satisfactory compliance history.

III. Request for Participation

Identify 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.

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09916 Filed 4–30–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0458]

Providing Information About Pediatric Uses of Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Providing Information about Pediatric Uses of Medical Devices.'' FDA is issuing this guidance document to describe how to compile and submit the readily available pediatric use information required under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Providing Information About Pediatric Uses of Medical Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request.

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

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1651, Silver Spring, MD 20993–0002, 301–796–6563; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

I. Background

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) [1] (Pub. L. 110–85) amended the FD&C Act by adding, among other things, a new section 515A (21 U.S.C. 360e–1) of the FD&C Act. Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications to include, if readily available: (1) A description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or

[1] Title III of FDAAA, which includes new section 515A, is also known as the Pediatric Medical Device Safety and Improvement Act of 2007.