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.

cure and (2) the number of affected pediatric patients.

The purpose of this guidance document is to describe the type of information that FDA believes is readily-available to the applicant, and the information FDA believes should be included in a submission to meet the requirements of section 515A(a) of the FD&C Act. The draft version of this guidance was issued on February 19, 2013 (78 FR 11654).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Providing Information about Pediatric Uses of Medical Devices,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1801 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

On January 9, 2014, the Agency submitted a proposed collection of information entitled ''Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug and Cosmetic Act'' 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 0910–0762. 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.*

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 814, subpart B have been approved under OMB control number 0910–0231 and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332.

V. Comments

Interested persons may submit either written comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09897 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–2014–N–0366]

Pilot Program for Center for Devices and Radiological Health Electronic Submission of Premarket Notification Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) is announcing the availability of a CDRH eSubmissions Pilot Program (eSubmissions Pilot), which will be a new pathway that will guide the user through constructing and submitting their 510(k) submissions electronically without the requirement for submitting a hard copy or a compact disc. Participation in the eSubmissions Pilot is open to applicants whose device submissions would be reviewed in either of two branches in CDRH's Office of Device Evaluation (ODE), the Cardiac Diagnostic Devices Branch and the Peripheral Interventional Devices Branch, and is limited to unbundled, traditional 510(k) submissions for classified devices only. The eSubmissions Pilot will use the existing eSubmitter software for data acquisition and the existing Electronic Submission Gateway (ESG) for submitting (the eSubmissions Pilot is not intended to evaluate the existing eSubmitter software or the existing ESG). The eSubmissions Pilot is intended to provide industry and CDRH staff the opportunity to evaluate the 510(k) eSubmission with regards to the content (wording of questions, help text and guides), layout, and flow of the questions.

DATES: FDA will begin accepting requests to participate in the eSubmissions Pilot immediately. See the ''Procedures'' section for instructions on how to submit a request.

FOR FURTHER INFORMATION CONTACT: Patrick Axtell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1566, Silver Spring, MD 20993–0002, *eSubpilot@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has been moving toward transforming all regulatory submissions from paper to electronic methods. Since January 1999, FDA has accepted voluntary electronic submissions for certain types of regulatory submissions. FDA presently utilizes eSubmitter as a platform for submitting many types of submissions across several Centers. The eSubmitter platform contains templates for many types of submissions specific to those Centers and any template can be chosen by the user for constructing and submitting the appropriate type of submission. The 510(k) eSubmission program introduces a new template in eSubmitter for use in submitting 510(k)s to ODE.

FDA presently utilizes the ESG for the receipt and processing of many types of electronic regulatory submissions (*http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*). The ESG automates the receipt, acknowledgment, routing and notification of electronic submissions via the Internet and meets FDAs standards of electronic information exchange.

The benefits to industry of this pilot program include, but are not limited to: