• improve the standards-based technology solution to encourage widespread adoption.

II. Questions to Stakeholders

1. What other potential benefits to stakeholders can be achieved through the use of a standards-based technology solution focusing on EHR and EDC integration?

2. What are the challenges to the implementation of a standards-based technology solution focusing on EHR and EDC integration?

3. What are the gaps between the data collected in a healthcare setting by EHRs vs. clinical research data required for regulated drug development?

4. Are there any perceived regulatory obstacles to the implementation of a standards-based technology solution focusing on EHR and EDC integration? (Examples include: Source data verification, remote monitoring, 21 CFR part 11, patient privacy, access control and confidentiality safeguards.) If yes, what approach(es) would you recommend to overcome these obstacles?

5. Are there any obstacles to the implementation of a standards-based technology solution focusing on EHR and EDC integration?

6. What standards-based solutions may exist?

III. Requests for Response

Comments, proposed approaches, interest to participate, and responses to the questions are to be identified with the docket number found in brackets in the heading of this document. Interested parties should include the following information in the request: Contact name, contact phone number, email address, name of the stakeholder, and address. Once requests for participation are received, FDA will contact interested stakeholders to discuss demonstration projects. The elapsed time duration of any project is expected to be approximately 12 months but may be extended as needed.

Dated: June 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15644 Filed 6–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2245]

Unique Device Identification: Direct Marking of Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Unique Device Identification: Direct Marking of Devices.'' Direct marking is an important feature of FDA's unique device identification system. This document is intended to assist industry and FDA staff to understand FDA's requirements for direct marking of devices with a unique device identifier (UDI). In addition, FDA is seeking information on what processes should be considered to meet the definition of ''reprocessing'' for purposes of UDI direct marking requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 24, 2015.

ADDRESSES: An electronic copy of the draft guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Unique Device Identification: Direct Marking of Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft 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: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993–0002, 301–796–5995, email: *GUDIDSupport@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 and section 614 of the Food and Drug Administration Safety and Innovation Act amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The unique device identification system final rule was published on September 24, 2013 (78 FR 58786) (the UDI Rule).

21 CFR 801.45 requires a device bear a permanent UDI marking if the device is intended to be used more than once and intended to be reprocessed before each use. It details the UDI format when provided as a direct marking, and provides criteria for exceptions to this UDI direct marking requirement. As explained in the preamble of the UDI Rule, UDI direct marking requirements apply to devices that are intended to be used for months or years, sometimes many years. Because such devices are intended to be reprocessed and reused, they will inevitably be separated from their original labels and device packages. UDI direct marking helps to ensure the adequate identification of such devices through their distribution and use. However, the UDI Rule does not define ''intended to be used more than once'' and ''reprocessed.'' FDA's interpretation of these terms is included in this draft guidance, but FDA seeks additional information on its current definition of ''reprocessing'' for purposes of UDI direct marking requirements.

FDA guidance entitled ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling; Guidance for Industry and Food and Drug Administration Staff'' issued on March 17, 2015 (available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf*) (the Reprocessing Guidance), indicates that reprocessing of reusable devices

generally encompasses three steps—point-of-use processing, thorough cleaning, and disinfection or sterilization. The Reprocessing Guidance makes clear, however, that certain devices may be suitably reprocessed after cleaning alone and may not require further disinfection or sterilization. It is important to note that the Reprocessing Guidance is intended, among other things, to provide guidance in crafting and validating reprocessing instructions to be included in the labeling of reusable devices generally, and it may not be applicable for determining whether a UDI direct marking should be required on a specific device intended to be reused. For purposes of UDI direct marking requirements, FDA considers a device that is intended to be cleaned and either sterilized or disinfected to be intended to be reprocessed. FDA has some concern about whether cleaning alone, without subsequent sterilization and/or disinfection, should fit within the definition of ''reprocessing'' for purposes of UDI direct marking requirements. Therefore, FDA is seeking additional information on this issue. FDA is particularly interested in receiving information relating to the following questions:

- FDA is concerned that devices intended to be used more than once tend to be separated from its original label during reprocessing, making accurate identification of devices difficult or impossible. Should the definition of ''reprocessing'' for purposes of UDI direct marking requirements include cleaning alone without subsequent disinfection and/or sterilization of the device?
- What public health benefits would be served by requiring a UDI direct marking to be affixed to devices intended to be reused for which reprocessing instructions include cleaning only and not disinfection and/or sterilization?

This draft guidance, when finalized, is intended to assist industry, particularly labelers, as defined under 21 CFR 801.3, and FDA staff understand FDA's requirements for UDI direct marking of devices, and the criteria for exceptions.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on ''Unique Device Identification: Direct Marking of Devices.'' 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 draft 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.* Persons unable to download an electronic copy of ''Unique Device Identification: Direct Marking of 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 1400031 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information described in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 830 pertaining to GUDID labeler accounts and data submissions addressed in this draft guidance document have been approved under OMB control number 0910–0720.

V. Comments

Interested persons may submit either electronic 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: June 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15719 Filed 6–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1837]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic User Fee Payment Request Forms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on Electronic User Fee Payment Request Forms.

DATES: Submit either electronic or written comments on the collection of information by August 25, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or