

B. Earlier Stakeholder Involvement in Guidance Development

CDRH has received feedback that stakeholders desire earlier involvement in the guidance process and has taken steps to create a mechanism to address this request. In FY 2016, in anticipation of guidance documents expected to be developed, CDRH sought stakeholder input regarding electromagnetic compatibility of electrically powered medical devices and regarding utilizing animal studies to evaluate the safety of organ preservation devices and solutions. FDA appreciated the feedback received and considered it in the development of these guidances. Demonstrating commitment to incorporating stakeholder input, CDRH has included these guidances topics on the FY 2017 B-List as we progress toward issuance of draft policies reflecting early stakeholder input as appropriate.

We also welcome any additional feedback for improving the guidance program and the quality of CDRH guidance documents.

C. Applicability of Previously Issued Final Guidance

CDRH has issued over 500 final guidance documents to provide stakeholders with the Agency's thinking on numerous topics. Each guidance reflected the Agency's current position at the time that it was issued. However, the guidance program has issued these guidances over a period of 30 years, raising the question of how current previously issued final guidances remain. CDRH has resolved to address this concern through a staged review of previously issued final guidances in collaboration with stakeholders. At the Web site where CDRH has posted the "A-list" and "B-list" for FY 2017, CDRH has also posted a list of final guidance documents that issued in 2007, 1997, 1987, and 1977.¹ CDRH is interested in external feedback on whether any of these final guidances should be revised or withdrawn. In addition, for guidances that are recommended for revision, information explaining the need for revision, such as, the impact and risk to public health associated with not revising the guidance, would also be helpful as the Center considers potential action with respect to these guidances. CDRH intends to provide these lists of previously issued final guidances

¹ The retrospective list of final guidances does not include the following: (1) Documents that are not guidances but were inadvertently categorized as guidance such as scientific publications, advisory opinions, and interagency agreements; (2) guidances actively being revised by CDRH; and (3) special controls documents.

annually through FY 2025 so that by 2025, FDA and stakeholders will have assessed the applicability of all guidances older than 10 years. For instance, in the annual notice for FY 2018, CDRH expects to provide a list of the final guidance documents that issued in 2008, 1998, 1988, and 1978; the annual notice for FY 2019 is expected to provide a list of the final guidance documents that issued in 2009, 1999, 1989, and 1979, and so on. CDRH will consider the comments received from this retrospective review when determining priorities for updating guidance documents and will revise these as resources permit.

In FY 2016, CDRH received comments regarding guidances issued in 2006, 1996, and 1986, and has withdrawn 12 guidance documents in response to comments received and because these guidance documents were determined to no longer represent the Agency's current thinking. One guidance on this retrospective review list was revised, and revision of several guidance documents is also being considered as resources permit.

Consistent with Good Guidance Practices regulation at 21 CFR 10.115(f)(4), CDRH would appreciate suggestions that CDRH revise or withdraw an already existing guidance document. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. While we are requesting feedback on the list of previously issued final guidances located in the annual agenda Web site, feedback on any guidance is appreciated and will be considered.

III. Web Site Location of Guidance Lists

This notice announces the Web site location of the document that provides the A and B lists of guidance documents, which CDRH is intending to publish during FY 2017. To access these two lists, visit FDA's Web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm529396.htm>. We note that the topics on this and past guidance priority lists may be removed or modified based on current priorities, as well as comments received regarding these lists. Furthermore, FDA and CDRH priorities are subject to change at any time (e.g., newly identified safety issues). Topics on this and past guidance priority lists may be removed or modified based on current priorities. The Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative

review timelines and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.

Stakeholder feedback on guidance priorities is important to ensure that the CDRH guidance program meets the needs of stakeholders. The feedback received on the FY 2016 list was mostly in agreement, and CDRH continued to work toward issuing the guidances on this list. In FY 2016, CDRH issued 20 of 33 guidances on the FY 2016 list (14 from the A-list, 6 from the B-list). In addition, for the guidances that were on the FY 2016 A or B list but could not be published within FY 2016, and for which we received feedback that these guidances were of high priority, CDRH has recommitted to publish these guidances by placing them on the annual agenda for FY 2017, as appropriate.

Dated: December 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4342]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Food and Drug Administration Regulatory Science Student Internship Program

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 the application for participation in FDA's Regulatory Science Student Internship Program (RSIP).

DATES: Submit either electronic or written comments on the collection of information by February 21, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-4342 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the FDA Regulatory Science Student Internship Program." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the 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 FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@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 provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for Participation in the FDA Regulatory Science Student Internship Program—OMB Control Number 0910–New

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code, authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the RSIP will allow FDA's Office of the Commissioner to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application	600	1	600	1.33	798

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

Dated: December 19, 2016.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Unique Device Identification System

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 January 23, 2017.

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 0910-0720. 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, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Unique Device Identification System OMB Control Number 0910-0720—Extension

In accordance with the collection of information entitled “Unique Device Identification System (UDI),” medical device labelers, unless excepted, are required to design and use medical device labels and device packages that bear a UDI, present dates on labels in a particular format, and submit data concerning each version or model of a device to the Global Unique Device Identification Database (GUDID) no later than the date the label of the device must bear a UDI. Once a device becomes subject to UDI requirements, respondents will be required to update the information reported whenever the information changes.

The recordkeeping, reporting, and third-party disclosure requirements referenced in this document are imposed on any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but other types of labelers include a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler. Respondents may also include any private organization that applies for accreditation by FDA as an issuing agency.

FDA has identified the following requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the table that follows:

Section 801.18 requires that whenever a labeler of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the labeler must present the date on the label in a format that meets the requirements of this section.

Section 801.20 requires every medical device label and package to bear a UDI.

Under § 801.35, any labeler of a device that is not required to bear a UDI on its label may include a UDI on the

label of that device and utilize the GUDID.

Under § 801.45, any device that has to be labeled with a UDI also has to bear a permanent marking providing the UDI on the device itself if the device is intended for more than one use and intended to be reprocessed before each use.

Section 801.50 requires stand-alone software to comply with specific labeling requirements that identify the software.

Section 801.55 authorizes additional, case-by-case, labeling exceptions and alternatives to standard UDI labeling requirements.

If a labeler relabels or modifies a label of a device that is required to bear a UDI, under § 830.60 it has to keep a record showing the relationship of the original device identifier to the new device identifier.

Section 830.110 requires an applicant seeking initial FDA accreditation as a UDI-issuing agency to furnish FDA an application containing certain information, materials, and supporting documentation.

Under § 830.120, an FDA-accredited issuing agency is required to disclose information concerning its system for the assignment of UDIs; maintain a list of labelers that use its system for the assignment of UDIs, and provide FDA a copy of such list; and upon request, provide FDA with information concerning a labeler that is employing the issuing agency’s system for assignment of UDIs.

Sections 830.310 and 830.320 require the labeler to provide certain information to the GUDID concerning the labeler and each version or model of a device required to be labeled with a UDI, unless the labeler obtains a waiver.

Section 830.360 requires each labeler to retain records showing all UDIs used to identify devices that must be labeled with a UDI and the particular version or model associated with each device identifier, until 3 years after it ceases to market a version or model of a device.

Respondents who are required to submit data to the Agency under certain other approved information collections (listed below) are required to include UDI data elements for the device that is the subject of such information