The collection of information under § 801.437 does not constitute a ''collection of information'' under the PRA. Rather, it is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

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

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

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300	5	1	5	12	60

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

Dated: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24445 Filed 10–14–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0114]

Distinguishing Medical Device Recalls From Medical Device Enhancements; 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 a guidance entitled, ''Distinguishing Medical Device Recalls From Medical Device Enhancements.'' This guidance is intended to clarify when a potential change to a device is a medical device recall, distinguish those instances from product enhancements, and explain reporting requirements.

DATES: Submit either electronic or written comments on this guidance 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 single copies of the guidance document entitled, ''Distinguishing Medical Device Recalls From Medical Device Enhancements'' 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 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: Ronny Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2654, Silver Spring, MD 20993–0002, 301–796–6163.

I. Background

Defects or performance failures of marketed medical devices can pose serious risks to public health. The recall process serves both to correct the device defects and to notify users of potential risks and steps to minimize the impact of device failure or improper function. The recall process establishes a mechanism for firms that produce and market medical devices to take timely action to correct or remove violative devices.

When a firm's recall process is operating effectively, the firm identifies a device defect or failure, determines that a recall is appropriate, and triggers the initiation of the recall process. However, firms may have trouble identifying whether a change to a device meets the definition of a recall, the appropriate scope of a recall, and when FDA should be notified of a recall. These issues can result in delays in notifying the public about unsafe medical devices.

FDA also recognizes that continuous improvement activities, as part of an effective quality system, often have a favorable impact on medical device safety and are part of ongoing efforts to design and manufacture devices that meet the needs of the user and patient. When a new iteration of a device has improved design, for example, this does not necessarily mean that the prior version of the device should be recalled. Such changes may be appropriately characterized instead as product enhancements. In addition to determining whether a proposed change to a marketed device meets the definition of a device recall or a product enhancement, a firm must assess whether it is required to report the change to FDA.

In the **Federal Register** of February 22, 2013 (78 FR 12329), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by May 23, 2013. Multiple comments were received with recommendations pertaining to three main areas: (1) Clarification of definitions; (2) requests for more examples; and (3) clarification of reporting obligations pertaining to 21 CFR part 806. In response to these comments, FDA revised the guidance document to enhance clarity through the inclusion of multiple new examples. Some previously-included examples were deleted or reframed for improved clarity, and some content was removed since it did not enhance clarity and in some cases led to confusion. The guidance as revised provides more succinct information about the distinctions between medical device recalls and medical device enhancements and related reporting obligations. The guidance is organized in a question-and-answer format, providing responses to questions that FDA believes are helpful in properly identifying medical device recalls and applying reporting requirements.

II. Significance of Guidance

The 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 difference between a medical device recall and a

medical device enhancement. 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 using the Internet. A search capability for all CDRH 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 ''Distinguishing Medical Device Recalls From Medical Device Enhancements,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1819 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found 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 7, subpart C, have been approved under OMB control number 0910–0249; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR part 810 have been approved under OMB control number 0910–0432.

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: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24446 Filed 10–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1496]

Regulatory Science Considerations for Software Used in Diabetes Management; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Regulatory Science Considerations for Software Used in Diabetes Management.'' The goals of this public workshop are to foster greater stakeholder collaboration in the area of diabetes device interoperability and to seek input from the clinical community, academia, government, industry, and other stakeholders regarding usability considerations for appropriate information consumption (e.g., notifications, indicators, data, and displays) based on user skill and knowledge. The Agency also requests input regarding the technical considerations for insulin bolus calculator design and use.

Date and Time: The public workshop will be held on November 13, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Please arrive early to ensure time for parking and security screening. The public meeting will also be available to be viewed online via Webcast.

Contact Persons: James Mullally, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5613, Silver Spring, MD 20993, 240–402–5021, FAX: 301–847–8513, email: *james.mullally@fda.hhs.gov;* and Runa Musib, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5633, Silver Spring, MD 20993, 301–796–7014, FAX: 301–847–8513, email: *runa.musib@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. You must register online by 4 p.m., November 6, 2014. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7 a.m. If you need special accommodations due to a disability, please contact Susan Monahan, 301–796–5661, email: *susan.monahan@fda.hhs.gov,* no later than October 30, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see registration contact person). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 4 p.m., November 6, 2014. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after November 6, 2014. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web