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]

BILLING CODE 4164–01–P

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

sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to speak during the public comment session and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Following the close of registration, FDA will determine the amount of time allotted to each speaker and will select and notify participants by November 10, 2014. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain input on insulin bolus calculators. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments regarding the public workshop topics that pertain to insulin bolus calculators. The deadline for submitting comments related to this public workshop is December 11, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question number you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the workshop.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is seeking to foster greater stakeholder collaboration in the area of diabetes device interoperability. To that end, the Agency requests 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 calculator design and use.

The first topic of discussion is the interoperability between diabetes devices. The Agency recognizes that the diabetes community possesses an interest in patients having greater flexibility to pair device components, e.g., continuous glucose meters with insulin pumps from different manufacturers. Pairing would allow those devices to communicate with each other and enable patients to interact with a single interface platform. Achieving this goal would improve data tracking and access, thereby facilitating more productive patient interactions with their healthcare providers. In order to realize the objective of effective diabetes device interoperability, developers and manufacturers should discuss technical, safety, and regulatory challenges that lay before this goal. A forum that elicits opinions from physicians and patients regarding their desires and needs will help inform those discussions. FDA is committed to fostering a collaborative environment to promote these interactions.

The second topic of discussion is insulin bolus calculators. These devices are intended to calculate insulin boluses for patients who manage their diabetes with insulin-intensive therapy. FDA currently regulates insulin bolus calculators as class II devices, often clearing them in combination with insulin pumps or blood glucose meters. Devices that calculate insulin boluses are increasingly available on the market, including those devices that use novel dosing algorithms and new user interface formats. Although these devices can benefit patient care, they could also jeopardize patient safety without proper regulation guarding against the serious health consequences of miscalculating insulin dosages. The Agency will host a public dialogue about insulin bolus calculators to help realize the aim of ensuring continued access to safe and effective technological innovations, regardless of interface format.

The public workshop will include two sessions, one for each of the topics noted previously. Each session will include presentations from physicians, FDA, and other experts in the field. A panel discussion will follow the session addressing insulin bolus calculators, and the panel will address questions from the audience. In addition, Agency representatives will update the diabetes community on relevant FDA news.

II. Topics for Discussion at the Public Workshop

Among other topics, the workshop will include discussion of the following questions.

1. How can patients and providers be confident that the insulin bolus values obtained from the calculators are accurate and appropriate for their use?
2. What information do patients and providers need about how a particular calculator works so that they may appropriately use the calculator for diabetes management?
3. How can FDA foster both innovation and safety of insulin dose calculators intended for use by healthcare practitioners?
4. How can FDA foster both innovation and safety of insulin dose calculators intended for use by patients?

Dated: October 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24451 Filed 10–14–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.