recommendations on January 19, 2011 (*http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf*).

The second prong of the comprehensive assessment of the 510(k) process was an independent study by the IOM. At the request of FDA, IOM evaluated the 510(k) clearance process and made recommendations aimed at protecting the health of the public and making available a mechanism to achieve timely access of medical devices to the market. On July 29, 2011, IOM released the report ''Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years'' (report) (*http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA–510k-Clearance-Process-at-35–Years.aspx*). The report contains eight recommendations aimed at improving regulation of medical devices. The recommendations are the subject of this public meeting.

II. What are the specific issues for discussion and public comment at the public meeting?

FDA welcomes comments on the following recommendations provided in the IOM report:

1. The Food and Drug Administration should obtain adequate information to inform the design of a new medical device regulatory framework for class II devices so that the current 510(k) process, in which the standard for clearance is substantial equivalence to previously cleared devices, can be replaced with an integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle. Once adequate information is available to design an appropriate medical device regulatory framework, Congress should enact legislation to do so.

2. FDA should develop and implement a comprehensive strategy to collect, analyze, and act on medical device postmarket performance information.

3. FDA should review its postmarket regulatory authorities for medical devices to identify existing limitations on their use and to determine how the limitations can be addressed.

4. FDA should investigate the viability of a modified de novo process as a mechanism for evaluating the safety and effectiveness of class II devices.

5. FDA should develop and implement a program of continuous quality improvement to track regulatory decisions on medical devices, identify potential process improvements in the medical device regulatory framework, and address emerging issues that affect decisionmaking.

6. FDA should commission an assessment to determine the effect of its regulatory process for class II devices on facilitating or inhibiting innovation in the medical device industry.

7. FDA should develop procedures that ensure the safety and effectiveness of software used in devices, software used as devices, and software used as a tool in producing devices.

8. FDA should promptly call for PMA applications for or reclassify class III devices that remain eligible for 510(k) clearance.

III. Where can I find out more about this public meeting?

Background information on the public meeting, registration information, the agenda, information about lodging, transcripts, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.*

IV. Will there be transcripts of the meeting?

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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: August 9, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20575 Filed 8–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0530]

Mobile Medical Applications Draft Guidance; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Mobile Medical Applications Draft Guidance.'' The purpose of the workshop is to provide a forum for discussion with FDA and to encourage public comment on the following topics: FDA's recently issued draft guidance document entitled ''Mobile Medical Applications,'' how FDA should approach accessories and particularly mobile medical applications that are accessories to other medical devices, and standalone software that provides clinical decision support.

Date and Time: The public workshop will be held on September 12 and 13, 2011. Submit electronic and written comments by October 19, 2011.

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 20993–0002.

Contact Person: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5456, Silver Spring, MD 20993, 301–796–5528, *Bakul.Patel@fda.hhs.gov.*

Registration and Requests for Oral Presentations: Registration is free and will be on a first-come, first-served basis. Persons interested in attending this workshop must register online by 5 p.m. on September 9, 2011. For those without Internet access, please call the contact person to register.

Early registration is recommended because seating is 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 7:30 a.m. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible.

If you need special accommodations due to a disability, please contact Susan Monahan (e-mail: *Susan.Monahan@fda.hhs.gov* or phone: 301–796–5661) no later than September 9, 2011.

This workshop will also be provided via webcast. Persons interested in participating by webcast must register online by 5 p.m. on September 9, 2011. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Webcast participants will be sent connection

requirements. To register for the public workshop—whether attending in person or for the webcast—please visit *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (or go to the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, telephone, and FAX number. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist.

This workshop includes a public comment session. During online registration you may indicate if you wish to make an oral presentation during a public comment session at the public workshop, and which topic you wish to address in your presentation. FDA has included topics for comment in this document. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin. All requests to make oral presentations, as well as presentation materials, must be sent to the contact person by September 9, 2011.

Comments: Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments until October 19, 2011. Submit electronic comments 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. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

SUPPLEMENTARY INFORMATION:

I. What is the background and purpose for holding this public workshop?

The purpose of the workshop is to provide a forum for discussion with FDA and to encourage public comment from interested stakeholders on the following issues previously raised in the notice of availability for the draft guidance (76 FR 43689, July 21, 2011): FDA's recently-issued draft guidance document entitled ''Mobile Medical Applications,'' how FDA should approach accessories and particularly mobile medical applications that are accessories to other medical devices, and stand-alone software that provides clinical decision support.

Given the rapid expansion and broad applicability of mobile applications (mobile apps), FDA issued the draft guidance, ''Mobile Medical Applications'' on July 21, 2011, to clarify the types of mobile apps to which the FDA intends to apply its authority (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm*).

At this time, FDA intends to apply its regulatory requirements to a subset of mobile apps that the Agency is calling mobile medical applications (mobile medical apps). For purposes of the draft guidance and the public workshop discussion, a ''mobile medical app'' is a mobile application that meets the definition of ''device'' in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h)) [1]; and either:

- Is used as an accessory to a regulated medical device; or
- Transforms a mobile platform into a regulated medical device.

This narrowly-tailored approach focuses on a subset of mobile apps that either have traditionally been considered medical devices or affect the performance or functionality of a currently regulated medical device.

Although some mobile apps that do not meet the definition of a mobile medical app may meet the FD&C Act's definition of a device, FDA intends to exercise enforcement discretion [2] towards those mobile apps.

[1] Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act. That provision defines a device as ''* * * an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent * * *'', that is ''* * * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man * * * '' or ''* * * intended to affect the structure or any function of the body of man or other animals * * *''.

[2] This means that FDA intends to exercise its discretion to decline to pursue enforcement actions for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile medical app, as specified in the draft guidance, ''Mobile Medical Applications.'' This does not constitute a change in the requirements of the FD&C Act or any applicable regulations.

II. What are the specific issues for discussion and public comment at the public workshop?

We welcome comments on all aspects of the draft guidance as well as the following specific issues:

1. FDA generally considers extensions of medical devices as accessories to those medical devices. Accessories have been typically regulated under the same classification as the connected medical device. However, we recognize potential limitations to this policy for mobile medical apps. FDA seeks comment on how the Agency should approach accessories and particularly mobile medical apps that are accessories to other medical devices so safety and effectiveness can be reasonably assured. For example, one possible approach could be the following:

- An accessory that does not change the intended use of the connected device, but aids in the use of the connected medical device could be regulated as class I. For example, such an accessory would be similar to an infusion pump stand, which is currently classified as a class I device because it supports the intended use of an infusion pump (class II medical device). A mobile medical app that simply supports the intended use of a regulated medical device could be classified as class I with design controls as part of the quality systems requirements;
- An accessory that extends the intended use of the connected medical device could be classified with the connected device. For example, if a mobile medical app that performs more detailed analysis than the connected medical device while maintaining the original intended use, which is data analysis, could be classified in the same classification as the connected medical device; and
- An accessory that creates a new intended use from that of the connected device(s) could be classified according to the risk posed to patient safety by the new intended use, for example, if the intended use of a mobile medical app is to provide prognosis relating to a certain disease or condition and the mobile medical app is connected to a device that does not have that intended use, the mobile medical app may have a different level of risk than the connected device, resulting in a different classification to assure safety and effectiveness of the mobile medical app.

2. FDA has not addressed in its draft guidance, ''Mobile Medical Applications,'' stand-alone software (mobile or traditional workstation) that analyzes, processes, or interprets medical device data (collected

electronically or through manual entry of the device data) for purposes of automatically assessing patient specific data or for providing support in making clinical decisions. FDA plans to address such stand-alone software in a separate guidance. In order to provide a reasonable assurance of the safety and effectiveness of such software, and to ensure consistency between the draft guidance, ''Mobile Medical Applications,'' and the planned guidance on stand-alone software that provides clinical decision support (CDS), FDA is seeking comment on the following issues:

- What factors should FDA consider in determining the risk classification of different types of software that provide CDS functionality? Please provide examples of how those factors would be applied for such software that you believe should be in class I, class II, and class III;
- How should the FDA assess stand-alone software that provides CDS functionality, to assure reasonable safety and effectiveness? For example, to what extent can FDA rely on a manufacturer's demonstration that it has a robust quality system with appropriate quality assurance and design controls? Under what circumstances should the submission of clinical data be required?; and
- Are there specific controls that manufacturers should implement that could change the risk classification or reduce the premarket data requirements for particular types of stand-alone software that provide CDS functionality?

III. Where can I find out more about this public workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, transcripts, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.*

IV. Will there be transcripts of the meeting?

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Dated: August 9, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Web-Based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 24, 2011, Vol 76, #100, page 30177–30178, and allowed 60 days for public comment. One request for the draft instruments was received from the public. These were provided to the requestor. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Web-based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment).

Type of Information Collection Request: NEW.

Need and Use of Information Collection: The project aims to increase the provision of screening, brief intervention, and referral to treatment (SBIRT) for substance use in primary care by developing an engaging, interactive case-based training program that will be delivered over the Internet, providing convenient access to screening and brief intervention skills training and resources for busy PCPs. The goal of this study is to evaluate the effectiveness of this training on provider behavior and/or patient outcome and the program's utility as a training tool in a real-world medical setting. The training is named SBIRT–PC. Study participants will be randomly assigned to complete SBIRT–PC or a control training, consisting of online reading materials. Effectiveness will be evaluated in terms of differential SBIRT-related knowledge, attitudes, self-efficacy, self-reported clinical practices, skills as measured by virtual standardized patient evaluations (VSPE) and a telephone-based standardized patient (SP) interaction. Participants in each condition will also complete a training satisfaction questionnaire.

Frequency of Response: On occasion.

Affected Public: Private sector; businesses or other for-profit.

Type of Respondents: Primary Care Providers.

The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per set of responses	Estimated total annual burden hours requested
Primary Care Providers	94	1	2.0	188

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the