TABLE 1—LIST OF THE CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE—Continued

| Constituent | Carcinogen (CA), respiratory toxicant (RT), cardiovascular toxicant (CT), reproductive or developmental toxicant (RDT), addictive (AD) |
|---|---|
| Uranium-235 | CA, RT |
| Uranium-238 | CA, RT |
| Vinyl acetate | CA, RT |
| Vinyl chloride | CA |

Dated: August 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–20502 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–N–0556]**

### Center for Devices and Radiological Health 510(k) Clearance Process; Recommendations Proposed in Institute of Medicine Report: ''Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years;'' Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled: ''Recommendations Proposed in Institute of Medicine Report: 'Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years.' '' The purpose of the public meeting is to encourage public comment on the recommendations proposed in the Institute of Medicine (IOM) report.

*Date and Time:* The public meeting will be held on September 16, 2011, from 8:30 a.m. to 5 p.m. Submit electronic and written comments by September 30, 2011.

*Location:* The public meeting will be held at the Silver Spring Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910.

*Contact Person:* Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993, 301–796–5678, *philip.desjardins@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 meeting must register online by 5 p.m. on September 15, 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 meeting will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan (email: *Susan.Monahan@fda.hhs.gov* or phone: 301–796–5661) no later than September 15, 2011.

To register for the public meeting, 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 meeting from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone, and FAX number. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist.

This meeting 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 meeting, 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 15, 2011.

*Comments:* Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments until September 30, 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 meeting?

In September 2009, FDA's Center for Devices and Radiological Health (CDRH) convened an internal 510(k) Working Group as part of a two-pronged, comprehensive assessment of the premarket notification (510(k)) process. The first prong of this evaluation consisted of an internal evaluation of the 510(k) process, resulting in the publication of the CDRH preliminary internal evaluation entitled ''510(k) Working Group Preliminary Report and Recommendations'' (*http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf*). This preliminary report was intended to communicate preliminary findings and recommendations regarding the 510(k) program and actions CDRH might take to address identified areas of concern. The report was issued on August 5, 2010 (75 FR 47307). After reviewing public comment, CDRH issued a plan of action for implementation of the previously announced

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