

### III. Oral Comments

In addition to formal oral presentations, which are limited to 5 minutes total per presentation, there will be an opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

### IV. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Priority will be given to those who pre-register, and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on Federal property, must register by following the instructions in the "Meeting Registration Timeframe" section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

### V. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present valid photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.

### VI. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must include the request for these services during registration.

### VII. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our Web site after the meeting.

### VIII. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 14, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-1021]

### Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2013 Proposed Guidance Development

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the Web site location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH) is intending to publish in Fiscal Year (FY) 2013. In addition, FDA has established a docket where stakeholders may provide comments and/or propose draft language for those topics, suggest new or different guidance documents, and comment on the priority of topics for guidance.

**DATES:** Submit either electronic or written comments at any time.

**ADDRESSES:** Submit electronic comments on the proposed 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.

**FOR FURTHER INFORMATION CONTACT:** Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993-0002, 301-796-5678.

### SUPPLEMENTARY INFORMATION:

#### I. Background

During negotiations over the Medical Device User Fee Amendments of 2012 (MDUFA III), Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112-114), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of prioritized medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the "A-list") and a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the "B-list"). In addition to posting lists of prioritized device guidance documents, FDA has committed to updating its Web site in a timely manner to reflect the Agency's review of previously published guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency. Fulfillment of this commitment will be reflected through the issuance of updated guidance on existing topics, removal of guidances that that no longer reflect FDA's current thinking on a particular topic, and annual updates to A-list and B-list announced in this notice.

This notice announces the Web site location of the two lists of guidance documents which CDRH is intending to publish during FY 2013. We note that 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. The Agency is not precluded from issuing guidance documents that are not on either list.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current

priorities. CDRH's experience in guidance development has shown that there are many reasons that CDRH staff may not complete the entire agenda of guidance documents it undertakes. Staff are frequently diverted from guidance development to other priority activities. In addition, at any time new issues may arise to be addressed in guidance that could not have been anticipated at the time the annual list is generated. These issues may involve newly identified public health issues as well as special control documents that are necessary for the classification of de novo devices.

FDA anticipates that feedback from stakeholders, including draft language for guidance documents, will allow CDRH to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the lists. FDA has established a docket where comments on the FY 2013 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual Agency-wide notice issued under its good guidance practices (21 CFR 10.115(f)(5)). The CDRH lists, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site at the beginning of each fiscal year from 2013 to 2017. To access the lists of guidance documents CDRH is intending to publish in FY 2013, visit FDA's Web site <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm>

## II. Request for Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. 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: November 7, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

### Risk Communication Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Risk Communication Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 12, 2013, from 8 a.m. to 3 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Lee L. Zwanziger, Risk Communication Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3278, Silver Spring, MD 20993, 301-796-9151, FAX: 301-847-8611, email: [RCAC@fda.hhs.gov](mailto:RCAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line

to learn about possible modifications before coming to the meeting.

*Agenda:* On February 12, 2013, the Committee will discuss general factors in risk communication about FDA regulated products, including approaches to avoid message fatigue and related communication barriers such as prevention or warning fatigue or inaccurate risk perception.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 28, 2013. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. on February 12, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 17, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 18, 2013. Interested persons can also log on to <https://collaboration.fda.gov/rcac/> to hear and see the proceedings.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to