

If you wish to make an oral presentation during the hearing, you must register by submitting a written or electronic request by close of business on February 8, 2013, to David Banks or Steve Morin (see **FOR FURTHER INFORMATION CONTACT**). You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, email address, and type of organization you represent (e.g., industry, consumer organization). You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Persons registered to make an oral presentation should check in before the hearing.

Participants should submit a copy of each presentation to David Banks or Steve Morin (see **FOR FURTHER INFORMATION CONTACT**). We will file the hearing schedule, indicating the order of presentation and the time allotted to each person, with the Division of Dockets Management (see **ADDRESSES**). We will mail, email, or fax the schedule to each participant before the hearing. Participants are encouraged to arrive early to ensure the designated order of presentation.

If you need special accommodations due to a disability, please contact David Banks or Steve Morin (see **FOR FURTHER INFORMATION CONTACT**) at least 14 days in advance.

#### IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner, and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)).

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media

may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

#### V. Request for Comments

Interested persons may submit either electronic comments for consideration to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific topics to which they refer. 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.

#### VI. Transcripts

The hearing will be transcribed as stipulated in § 15.30(b). Transcripts of the hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at <http://www.regulations.gov> approximately 45 days after the hearing. A transcript will also be available in either hard copy or on a 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.

Dated: January 24, 2013.

**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-1205]

#### Accessible Medical Device Labeling in a Standard Content and Format Public Workshop; Request for Comments; Correction

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

**ACTION:** Notice of public workshop; request for comments; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of January 7, 2013 (78 FR 951). The document announced a public workshop entitled "Accessible Standardized Medical Device Labeling." The document was published with the incorrect date for submission of presentation materials. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Mary Weick-Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5426, 301-796-6089, FAX: 301-847-8510, email: [Mary.Brady@fda.hhs.gov](mailto:Mary.Brady@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Correction

In the **Federal Register** of January 7, 2013, in FR Doc. 951-953, on page 952, the following correction is made:

Under *Requests for Oral Presentations*, on page 952, in the first column, the sentences that read "All requests to make oral presentations must be received by the close of registration on April 5, 2013, at 5 p.m. If selected for presentation, any presentation materials must be emailed to Mary Weick-Brady (see **FOR FURTHER INFORMATION CONTACT**) no later than March 29, 2013" is changed to read "All requests to make oral presentations must be received by the close of registration on April 5, 2013, at 5 p.m. If selected for presentation, any presentation materials must be emailed to Mary Weick-Brady (see **FOR FURTHER INFORMATION CONTACT**) no later than April 19, 2013."

Dated: January 25, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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