Public Workshop - Accessible Medical Device Labeling in a Standard Content and Format, April 29-30, 2013

U.S. Food & Drug Administration

The purpose of the workshop is to discuss the growing need for medical device labeling to be delivered in a clear, concise, and readily accessible format so that patients, caregivers, and healthcare providers may access and utilize device labeling as efficiently and effectively as possible. This public workshop aims to engage stakeholders in active discussion with FDA and to encourage public comments regarding standard content and format for medical device labeling and the use of a repository containing medical device labeling.

- Date, Time and Location [1]
- Federal Register Notice [2]
- Agenda [3]
- Registration [4]
- Contact Us [5]

Date, Time and Location

This workshop will be held April 29, 2013 from 8:00 am to 5:00 pm and April-30, 2013, from **8:00 am- 4:00 pm EST** at the following location:

FDA White Oak Campus
10903 New Hampshire Avenue,
Building 31, Conference Center (Great Room 1503A)
Silver Spring, MD 20993

- Link for FDA Campus Information [6]

The workshop will be webcast.

Agenda

Day 1

- Morning introductions and expectations followed by main address
- Summary of surveys from health care professionals and National Family Caregivers Association on medical device labeling

- CRADA with Kwikpoint and the development of a visual language
- CDER-measures of success with electronic submission of drug labeling
- Development of a standard content and format
- The use of a shortened or quick guide version of labeling

Day 2

- Clinical perspectives panel to discuss medical device labeling. Including: ER physician, staff nurse, caregiver, patient, home health professional
- Regulatory perspectives panel. Including: analyst, pre-market staff, industry representative
- Results from a pilot conducted for the electronic submission of labeling
- Medical device labeling repository and ways of accessing labeling.

Registration to Attend the Workshop

If you wish to attend this Workshop, you must register by close of business on April 7, 2013. If you wish to view this Workshop by Webcast you must also register by close of business on April 7, 2013.

There is no fee to register for the Workshop and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you wish to make an oral presentation during any of the open comment sessions at the meeting you must indicate this at the time of registration. FDA requests that presentations focus on the areas defined in the Federal Register Notice. You should also identify which discussion topic you wish to address in your presentation and you must submit a brief statement that describes your experience and/or expertise relevant to your proposed presentation. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. FDA will do its best to accommodate requests to speak .

If you require special accommodations due to a disability, or need additional information regarding registration, please contact Joyce Raines, Office of Communications, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Silver Spring, MD 20993, 301-796-5709, FAX: 301-847-8142, email: joyce.raines@fda.hhs.gov [7].

Attendance	❍ In-Person ❍ Webcast
Title	❍ Mr. ❍ Mrs. ❍ Ms. ❍ None
First Name *	
Last Name *	M.D.❑ Ph.D.❑
Email*	
	Please enter Email again for verification :
Phone Number*	(No dashes or spaces in phone numbers please)

Company or Organization *
Request to Speak Do you wish to make a presentation? ❍
Yes ❍ No
If so, please provide...
Proposed title of presentation:
And select a topic: (not presenting)
Submit Clear Form

Contact Us

For questions regarding workshop content please contact:

Mary Weick-Brady, MSN, RN,
Center for Devices and Radiological Health
Food and Drug Administration
WO66 Room 5426
Phone:301-796-6089
FAX: 301-847-8510
email: Mary.Brady@fda.hhs.gov [8].

Source URL (retrieved on *07/10/2014 - 3:58pm*):
http://www.mdtmag.com/news/2013/01/public-workshop-accessible-medical-device-labeling-standard-content-and-format-april-29-30-2013

Links:
[1] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#date
[2] http://www.gpo.gov/fdsys/pkg/FR-2013-01-07/html/2013-00003.htm
[3] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#agenda
[4] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#registration
[5] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#contact
[6] http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm
[7] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:joyce.raines@fda.hhs.gov
[8] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:Mary.Brady@fda.hhs.gov