Public Workshop - Mobile Medical Applications Draft Guidance, September 12-13, 2011

U.S. Food & Drug Administration

The Food and Drug Administration (FDA) is announcing a public Workshop on Mobile Medical Applications Draft Guidance. The U.S. Food and Drug Administration on July 19, 2011 announced it is seeking input on its oversight approach for certain mobile applications specific to medicine or health care called mobile medical applications ("apps") that are designed for use on smartphones and other mobile computing devices. Through this draft guidance the FDA defined a small subset of mobile medical apps that may impact on the performance or functionality of currently regulated medical devices and as such, will require FDA oversight.

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 topics:

- aspects of draft guidance document entitled "Mobile Medical Applications"
- how the Agency should approach accessories and particularly mobile medical applications that are accessories to other medical devices; and
- Standalone software that provides clinical decision support.

The FDA encourages feedback from manufacturers, health care providers and others on how its proposal may support the balance between promoting innovation and assuring safety and effectiveness. Submit either electronic or written comments on the draft guidance by October 19, 2011.

Submit electronic comments on the draft guidance to http://www.regulations.gov [1].

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.Identify comments with the docket number [Docket No. FDA-2011-D-0530].

- Date, Time, and Location [2]
- Federal Register Notice [3]
- Agenda [4]
- Registration [5]
- Contact Us [6]

Date, Time and Location

This meeting will be held on one full day (8:00 am – 6:00 pm) on September 12, 2011, and one half day (8:00 am – 1:00 pm) on September 13, 2011 at the following

location:

FDA White Oak Campus
10903 New Hampshire Ave
The Great Room (Room 1503), White Oak Conference Center, Bldg 31
Silver Spring, MD, 20903

The meeting will be webcasted.

Agenda

Will be available soon.

Registration to Attend the Workshop

If you wish to attend this Workshop, you must register by close of business on September 9, 2011.

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 (see section II of the FR notice), you must indicate this at the time of registration. FDA requests that presentations focus on the areas defined in section III of this document. 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 need special accommodations due to a disability, or additional information regarding registration, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Silver Spring, MD 20993, 301-796-5661, susan.monahan@fda.hhs.gov [7].

Please use either the In-Person Workshop Attendance **[8]** registration form, or the Online Webcast Viewing **[9]** registration form.

Registration for In Person Workshop Attendance

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)
Affiliation *	

Request to Speak * Would you like to speak? ❍ Yes ☐ No
Proposed Title If you would like to make a presentation, what is the proposed title of your presentation?

Submit Clear Form

Registration for Viewing the Online 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)
Affiliation *

Submit Clear Form

Contact Us

For information regarding the program, contact:

Bakul Patel
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue, Bldg 66
Silver Spring, MD 20993
Phone: 301-796-5528
Email: Bakul.patel@fda.hhs.gov [10]

SOURCE [11]

Source URL (retrieved on *04/26/2015 - 2:58am*):
http://www.mdtmag.com/news/2011/08/public-workshop-mobile-medical-applications-draft-guidance-september-12-13-2011

Links:
[1] http://www.regulations.gov/
[2] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/#date
[3] http://www.gpo.gov/fdsys/pkg/FR-2011-08-12/html/2011-20574.htm
[4] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/#agenda
[5] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/#registration
[6] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/#contact

[7] mailto://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/susan.monahan@fda.hhs.gov
[8] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/#inperson
[9] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/#webcast
[10] mailto://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/Raquel.Peat@fda.hhs.gov
[11] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm