Public Meeting: Converged Communications and Health Care Devices Impact on Regulation, June 26-27, 2010

U.S. Food & Drug Administration

The public meeting is scheduled for July 26 and 27, 2010, from 8 a.m. to 5:30 p.m. at the following location:

FCC Commission Meeting Room
445 12th St., SW
Washington, DC 20554

The meeting will not be videotaped or webcast.

Registration requests must be received by 5 p.m. on July 19, 2010. Interested persons may register by e-mailing FCC-FDAMeeting@fcc.gov [1]. Registrants must provide the following information: (1) name, (2) title, (3) company or organization, (4) mailing address, (5) telephone number, and (6) e-mail address. Registrants will receive confirmation once they have been accepted. Registration will be required for all speakers.

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. You should also identify which discussion topic you wish to address in your presentation. In order to keep each open comment session focused on the topic at hand, each oral presentation should address only the topic specified for that session. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA and FCC will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you need special accommodations due to a disability, please send an e-mail to fcc504@fcc.gov [2] or call the Consumer and Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (TTY) at least 7 days in advance of the meeting.

Background

There have been significant developments in recent years in medical and healthcare devices using radio technology to monitor various body functions and conditions, including critical elements, and to deliver treatment and therapy. There has also been an increasing proliferation of devices using established commercial communications networks such as Internet connectivity to communicate with care providers. Mobile devices like smartphones and personal digital assistants (PDAs) are transforming the transmission of information used by physicians to help

manage patient care, including communication networks to relay information for patient health monitoring and decision support.

At one end, general-purpose communications devices such as smartphones, wireless routers and certain video-conferencing equipment are regulated by FCC. At the other end, medical devices that critically monitor patient health or provide treatment or therapy are regulated by FDA. Devices that do provide critical care and also use communications, such as life-critical wireless devices like remotely controlled drug-release mechanisms, are regulated by both agencies. In addition, device applications that would not be governed by FCC but transmit over wireless networks might warrant FDA oversight, while FCC might have better capability to assess the reliability of their communications capability.

Public Meeting

The objective of this meeting is to gather information and to better understand issues and perspectives from various stakeholders so the agencies can identify potential areas where each agencyÃ¢??s jurisdiction can be identified and clarified for affected parties, collection and assessment of each agencyÃ¢??s respectively appropriate information can be improved, expertise can be shared, and regulatory approval can be coordinated and simplified. These concerns relate both to devices operating on designated frequencies and to convergent medical device and information technology. This includes challenges faced by manufacturers and innovators in ensuring compliance with various regulatory requirements and risks associated with medical device systems using spectrum shared by other medical devices, using spectrum shared by other types of devices and services, and using broadband communication capabilities.

The information gathered during the meeting will be used to enhance the coordination between FDA and FCC for such devices and applications, and clarify and delineate the respective areas of expertise and jurisdiction between the agencies.

Agenda

During each session, members of the public may present oral comments related to the topic of that session. Individuals who are interested in giving an oral presentation during any of the sessions must indicate this interest at the time of registration and must also identify the session(s) at which they would like to present. In order to keep each session focused on the topic at hand, each oral presentation should address only the topic specified for that session. Commenters are free to submit written comments on any topic(s) to the open docket (see Public Comments). FDA and FCC will schedule speakers for each session as time permits.

Questions for Comment

FDA and FCC are planning to focus the public meeting on the following topics:

A. Data integrity and reliability issues arising from the use of allocated spectrum, the use of unlicensed devices, and the use of commercial networks and applications, and n eeds, uses, and risks for Ã¢??medical-gradeÃ¢?? wireless technology and communications.
B. Medical device and system security issues Ã¢?? inadvertent and intentional intrusion Ã¢?? nonfunction and malfunction.
C. Trends in medical devices using allocated spectrum and using unlicensed operation, and medical devices and applications using commercial networks. Consideration of various wireless networking scenarios and use cases.
D. Risks Management:
    a. The need to define levels of Ã¢??criticalityÃ¢?□ of device function that can be used for determining reliability requirements.
    b. Environmental factors and delivery setting Ã¢?? hospitals, users, clinics, home, travel, *etc.*
E. Views on current FDA and FCC regulatory requirements:
    a. Relationship between FDA approval/clearance and FCC certification of applications, post market and compliance requirements.

Each of the above topics will cover

1. Defining topics and scope
2. Identifying the needs, goals and stakeholders
3. Recommendations

In advance of the meeting, additional information, including a meeting agenda with a speakersÃ¢?? schedule for each session, will be made available on the Internet. This information will be placed on file in the public docket FDA-2010-N-0291, which is available at http://www.regulations.gov [3] and in the FDA and FCC public reference rooms listed below.

Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857 or at the Federal Communications Commission, Reference Information Center, 445 12th Street SW, rm. CY-A257, Washington, DC 20554 , Monday through Thursday, between the hours of 8 a.m. and 4:30 p.m. and on Fridays between the hours of 8 a.m. and 12:00 noon, approximately 15 working days after the public meeting at a cost of 10 cents per page. A transcript of the public meeting will be available on the Internet at http://www.regulations.gov [3].

Public Comments

Refer to the Federal Register Notice for instructions on how to submit comments about the topics discussed at this meeting

To view the comments go to http://www.regulations.gov [4] and search by the key word: "FDA2010-N-0291." If you have questions about the posted comments please

call the Dockets Management Public Room at (301) 827-6860.

For further information about this meeting, contact:

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SOURCE [6]

Links:
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