Radiological Devices Panel of the Medical Devices Advisory Committee Meeting Announcement (April 11-12, 2012)

U.S. Food & Drug Administration

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Radiological Devices Panel of the Medical Devices 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: Radiological Devices Panel of the Medical Devices Advisory Committee.

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

Contact Person: Shanika Craig, Shanika.Craig@fda.hhs.gov [1] , Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, Silver Spring, MD 20993, 301-796-6639, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 11, 2012, the committee will discuss, make recommendations, and vote on information related to a premarket approval application for the Automated Breast Ultrasound (ABUS) scanning device, sponsored by U-Systems, Inc. The ABUS scanning device is intended to increase breast cancer detection in asymptomatic dense-breasted women following a negative screening mammogram.

On April 12, 2012, during session I, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 (74 FR 16214), for breast transilluminators, one of the remaining preamendments class III devices. On July 18, 1995 (60 FR 36639), FDA published a Final Rule that misbranded breast transilluminators and effectively placed them in class III based on the recommendation of the Obstetrics and Gynecology Devices Panel, which concluded there were no published studies or clinical data demonstrating the safety and effectiveness of this device. The committee discussion will include a review of the present literature to assess the current knowledge of breast transilluminators and determine if sufficient safety and effectiveness data are available to support reclassification of breast transilluminators.

During session II on April 12, 2012, the committee will discuss and make recommendations regarding the classification of blood irradiators. Blood irradiators have been found to be substantially equivalent to predicate devices marketed in interstate commerce prior to May 28, 1976, and are subject to the general controls provisions of the Federal Food, Drug and Cosmetic Act. These devices have never been formally classified. There is an agreement between the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) that outlines which FDA center will regulate these devices. CDRH regulates irradiators intended for use in the immunologically active cells in blood and other tissues and CBER regulates irradiators intended for use in the in-process inactivation of HIV viruses or other pathogens. The committee discussion will focus on whether these devices should be classified in class I, II, or III.

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 [2]. Scroll down to the appropriate advisory committee 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 April 3, 2012. On April 11, 2012, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m.; on April 12, 2012, oral presentations will be scheduled between approximately 9 a.m. and 10 a.m. for session I and between 1:30 p.m. and 2:30 p.m. for session II. 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 appropriate meeting topic, the names and addresses of proposed participants, and an indication of the

approximate time requested to make their presentation on or before March 26, 2012. 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 March 27, 2012.

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 a disability, please contact James Clark, Committee Management Staff, 301-796-5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm [3]for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 23, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

SOURCE [4]

Source URL (retrieved on *07/30/2014 - 7:23pm*):
http://www.mdtmag.com/news/2012/02/radiological-devices-panel-medical-devices-advisory-committee-meeting-announcement-april-11-12-2012

Links:
[1] http://www.fda.gov/AdvisoryCommittees/Calendar/mailto:Shanika.Craig@fda.hhs.gov
[2] http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm
[3] http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm
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