AnimalDrugUserFeeActADUFA/ucm042891.htm. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be made available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24082 Filed 9–19–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0640]

Magnetic Resonance Imaging Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Magnetic Resonance Imaging (MRI) Safety Public Workshop.'' The purpose of the public workshop is to discuss factors affecting the safe use of magnetic resonance imaging (MRI) and approaches to mitigate risks. The overall goal is to discuss strategies to minimize patient and staff risk in the MRI environment.

DATES: The public workshop will be held on October 25, 2011, from 8:30 a.m. to 5 p.m. EDT and on October 26, 2011, from 8:30 a.m. to 5 p.m. EDT.

ADDRESSES: The public workshop will be held in the Great Room at the FDA White Oak Conference Center, Bldg 31, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD, 20993.

FOR FURTHER INFORMATION CONTACT: Carol Krueger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5437, Silver Spring, MD 20993, 301–796–3241, FAX: 301–847–8510, or e-mail: *Carol.Krueger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this workshop must register online by 5 p.m. on October 4, 2011. Early registration is recommended because facilities are limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, on-site registration on the day of the public workshop will be provided beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Cynthia Garris, e-mail: *Cynthia.Garris@fda.hhs.gov* or phone: 301 796–5861 no later than October 11, 2011.

To register for the public workshop, please visit the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm270720.htm* (or go the ''FDA Medical Devices News & Events—Workshops and Conferences'' calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. For those without Internet access, please call the Contact Person to register. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist.

Streaming Webcast of the Public Workshop: This workshop will also be webcast. Persons interested in viewing the webcast must register online by 5 p.m. on October 4, 2011. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Webcast participants will be sent technical system requirements after registration, and will be sent connection access information after October 20, 2011. If you have never attended a Connect Pro event before, test your connection at: *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit: *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This workshop includes public comment and topic-focused roundtable sessions. During on-line registration you may indicate if you wish to present during a public comment session or participate in a roundtable session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comment and participate in the roundtable sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the roundtable. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify roundtable participants. All requests to make oral presentations must be received by the close of registration on October 4, 2011. If selected for presentation, any presentation materials must be sent by email to the Contact Person no later than October 11, 2011. No commercial promotional material will be permitted to be presented or distributed at the workshop.

Comments: FDA is holding this public workshop to obtain information on a number of questions regarding factors affecting MRI safe use. The deadline for submitting written comments related to this public workshop is November 22, 2011. Regardless of attendance at the public workshop, interested persons may submit written or electronic comments. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* It is necessary to send only one set of comments. Please identify written comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at *http://www.regulations.gov.*

I. Background

The number of MRI procedures performed each year continues to rise. At the same time, MRI technology, implanted medical devices and medical device accessories (non-implanted) are becoming more complex. There is increasing demand to scan patients with implanted or accessory medical devices, and the presence of these devices are becoming commonplace in the MRI suite during imaging procedures. While MRI procedures are relatively safe, there are hazards inherent to the MRI environment that must be considered to ensure the safety of patients, healthcare providers, and others who enter the MRI suite. The Agency recognizes the need to work with stakeholders to identify

hazard reduction strategies that minimize risk in the MRI environment.

Through this effort, FDA and stakeholder groups will take steps to promote the safe use of MRI by increasing awareness of safety issues that may occur in the MRI environment and by identifying regulatory, policy and system-oriented solutions to mitigate risk. FDA can advance these goals by collaborating with medical device and health care industries, and the healthcare provider and consumer communities.

II. Topics for Discussion at the Public Workshop

The public workshop will be organized to discuss the following topic areas:

A. General MRI Safety

- Multiple professional organizations, patient safety groups and accrediting bodies, i.e. the American College of Radiology (ACR), the International Society for Magnetic Resonance in Medicine (ISMRM), Emergency Care Research Institute (ECRI Institute), and the Joint Commission (TJC), have sponsored MRI safety conferences and published recommendations and strategies for MRI safe practices. FDA would like public comment on the extent these practices have been adopted, and if they have not, what are the reasons for not adopting/implementing these practices, and given that FDA does not regulate the practice of medicine, what can FDA do to improve adoption.
- FDA would like public comment on the policies and procedures individual sites have in place governing the use of non-implanted medical devices entering the MRI suite.

B. Ferromagnetic Detectors (FD)

- FDA would like public comment on the user experience with ferromagnetic detectors (FD) and to gather information on whether these devices improve MRI safety. FDA would also like to understand any drawbacks to the use of FD and other risk/benefit/cost considerations by sites that are considering adopting the technology.
- FDA would also like public comment on the reasons for not adopting/implementing use of FD.

C. Scanning Subjects Known To Have Medical Implants

- FDA would like public comment on the clinical scenario and the challenges (technical and otherwise) involved in the scanning of patients with implanted medical devices. FDA is particularly interested in hearing how individual sites make the decision of whether or not to scan a patient with an implanted medical device, or any special monitoring of the patient's condition or the implanted medical device's performance.
- Safely scanning patients with implanted medical devices requires coordination between any MRI system and the implanted medical device, as not all implants can be safely scanned in all MRI systems. Current FDA labeling requirements for ''MR Conditional'' implants include the static magnetic field, maximum spatial gradient, and maximum specific absorption rate (SAR) under which the device can be safely scanned. FDA would like public comment on whether this information is or is not sufficient to make an informed decision about whether it is safe or is not safe to scan a patient.
- FDA would like public comment on the challenges sites face in obtaining the specific conditions of use (i.e. the ''MR Conditional'' labeling) for medical implants and what is done when information about MRI compatibility is unavailable. For example, when presented with a patient with an implanted medical device, how is the identity of the implant definitively determined and how is MR labeling information obtained to make a decision of whether or not to scan the patient? If ''MR Conditional'' labeling cannot be found or the device cannot be identified, how is the decision of whether or not to scan a patient determined?

D. The Impact of Innovation on MRI Safety Concerns

- FDA would like comment from stakeholders on future technical developments and changing clinical practice scenarios that may affect the safety profile of MRI.

III. Transcripts

As soon as the transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: September 13, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: National Survey of Organ Donation Attitudes and Practices (OMB No. 0915–New)

The Division of Transplantation (DoT), Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), is planning to conduct a telephone survey of public knowledge, perceptions, opinion, and behaviors related to organ donation. Two key missions of the DoT are (1) to provide oversight for the Organ Procurement and Transplantation Network and policy development related to organ donation and transplantation, and (2) to implement efforts to increase public knowledge, attitudes, and behaviors related to organ donation. With a constantly growing deficit between the number of Americans needing donor organs (currently nearly 112,000) and the annual number of donors (14,505 in 2010), increasing the American public's willingness to donate becomes increasingly critical. Effective education and outreach campaigns need to be based on knowledge of the public's