

Individuals requiring sign language interpretation or other special accommodations must contact the DFO via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

**Note:** Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

**Authority:** (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92-463 (5 U.S.C. App. 2, section 10(a)).)

Dated: February 18, 2010.

**Charlene Frizzera,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010-3693 Filed 2-19-10; 4:15 pm]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0080]

#### Device Improvements to Reduce Unnecessary Radiation Exposure From Medical Imaging; Public Meeting; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled: "Device Improvements to Reduce Unnecessary Radiation Exposure From Medical Imaging." The purpose of this meeting is to discuss steps that could be taken by manufacturers of devices used in computed tomography (CT) and in fluoroscopy that would help reduce unnecessary patient exposure to ionizing radiation during CT and fluoroscopic procedures. FDA is seeking input on this topic and requests comments on a number of related questions.

**Dates and Time:** The public meeting will be held on March 30 and 31, 2010, from 8 a.m. to 5 p.m. Persons interested in attending and/or participating in the meeting must register by 5 p.m. on March 15, 2010. Submit written or electronic comments by April 15, 2010.

**Location:** The public meeting will be held at the Holiday Inn Gaithersburg, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The meeting will not be videotaped or webcast.

**Contact Person:** Simon Choi, Food and Drug Administration, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5400, Silver Spring, MD 20993-0002, 301-796-5426, e-mail: [simon.choi@fda.hhs.gov](mailto:simon.choi@fda.hhs.gov).

**Registration:** If you wish to attend the public meeting, you must register by e-mailing [CDRHimaginginitiative@fda.hhs.gov](mailto:CDRHimaginginitiative@fda.hhs.gov). Provide complete contact information for each attendee, including name, title, company or organization, address, e-mail, and telephone number. Registration requests must be received by March 15, 2010.

If you wish to make an oral presentation during any of the sessions at the meeting (see section II of this document, Public Meeting), you must indicate this at the time of registration. FDA has included specific questions for comment in section III of this document, Questions for Comment. You should also identify the session(s) during which you would like to present, as well as the question(s) you would like to address in each session. In order to keep each session focused on the topic at hand, presentations given during each session should address only the topic specified for that session. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each

presenter and the approximate time that each oral presentation is scheduled to begin.

If you would like to participate in any of the four planned roundtable discussions (see section II of this document, Public Meeting), you must indicate this interest at the time of registration, and also submit a brief statement that describes your experience with CT or fluoroscopic devices. FDA is seeking participants interested in engaging in one of four wrap-up roundtable discussions related to the presentations given during each of the earlier sessions of the meeting. Each roundtable discussion will include no more than 10 nonFDA participants. Only one participant from an organization or company will be assigned to each discussion group. FDA will attempt to have a range of constituencies represented in each discussion group. Others in attendance at the public meeting will have an opportunity to listen to each roundtable discussion.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Simon Choi at 301-796-5426, [simon.choi@fda.hhs.gov](mailto:simon.choi@fda.hhs.gov) at least 7 days in advance of the meeting.

**Comments:** FDA is holding this public meeting to obtain information on a number of questions regarding steps manufacturers of CT and fluoroscopic devices could take to help reduce unnecessary patient exposure to ionizing radiation from these medical imaging modalities. The deadline for submitting comments related to this public meeting is April 15, 2010.

Regardless of attendance at the public meeting, 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>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. In addition, when

responding to specific questions as outlined in section III 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.

#### SUPPLEMENTARY INFORMATION:

### I. Background

Like all medical procedures, medical imaging that uses ionizing radiation presents both benefits and risks. Medical imaging has led to improvements in the diagnosis and treatment of numerous medical conditions. At the same time, exposure to ionizing radiation may elevate patients' lifetime risk of developing cancer. Overexposure to ionizing radiation can also cause injuries in the short-term such as skin burns and hair loss. In an effort to reduce these risks, FDA's Center for Devices and Radiological Health (CDRH) recently announced the Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging (see <http://www.fda.gov/Radiation-Emitting-Products/RadiationSafety/RadiationDoseReduction/UCM199904> for more information).

FDA is currently exploring steps that manufacturers of CT and fluoroscopic devices could take to reduce unnecessary radiation exposure through improved product design, enhanced labeling, or improved instructions and training for equipment use and quality assurance at medical imaging facilities.

### II. Public Meeting

The objective of this public meeting is to receive public input on steps manufacturers of CT and fluoroscopic devices should take to help reduce unnecessary patient exposure to ionizing radiation from these medical imaging modalities.

The meeting will be held over the course of 2 days. Each day will be divided into two sessions. Day 1 will focus on equipment features that manufacturers should incorporate into CT scanners (morning session) and fluoroscopes (afternoon session). Day 2 will focus on steps manufacturers should take to improve training of individuals who use these devices (morning session) and steps to improve quality assurance at medical imaging facilities with respect to these two modalities (afternoon session).

During each session, members of the public may present oral comments related to the topic of that session. Specific questions for comment are listed in section III of this document, Questions for Comment. 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 (see *Registration*). In order to keep each session focused on the topic at hand, each oral presentation should address only the topic specified for that session. Commentators are free to submit written comments on any topic(s) to the open docket (see *Comments*). FDA will schedule speakers for each session as time permits.

To close each of the four sessions, FDA will hold a roundtable discussion between FDA staff and selected participants representing a range of constituencies (for more information about participating in the roundtable discussion, see *Registration*). The participants in each roundtable discussion will remark on the presentations given during the session, engage in a dialogue with each other and FDA staff, and provide closing thoughts on the session. Roundtable participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the meeting will have an opportunity to listen to each roundtable discussion.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule for each session, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at <http://www.regulations.gov>. This information will also be available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

### III. Questions for Comment

#### A. Device-Specific Elements: Equipment Features, Labeling, and Premarket Submission Requirements

Note: The questions in the following paragraphs are relevant to both CT and fluoroscopic devices. Please clearly indicate in your response which modality you are discussing. Additionally, while the questions are worded broadly, please feel free to include elements in your response that are specific to particular types of procedures (e.g., multi-phase contrast-enhanced CT examinations, perfusion studies, etc.) or devices (e.g., multidetector CT devices that allow very thin slices, etc.).

1. What hardware and software features should manufacturers build into CT and fluoroscopic devices in order to reduce unnecessary exposure to ionizing radiation during each imaging exam, and in order to reduce what may be inappropriate prescription of imaging exams? Should manufacturers incorporate special provisions for pediatric and female patients?

2. Should manufacturers incorporate access controls and audit capabilities into CT and fluoroscopic equipment in order to identify the user(s) of the device during any particular exam, and to identify those responsible for creating and changing imaging protocols and exposure settings? If so, why, and what access controls and audit capabilities should be incorporated? If not, why not?

3. Should manufacturers incorporate warnings, alerts, lockouts, or overrides into CT and fluoroscopic equipment that would inform users and require confirmation or possibly procedure modification during an imaging session in which the patient could be exposed to high levels of radiation? If so, why, and what warnings, alerts, lockouts, or overrides should be incorporated? If not, why not?

4. Should manufacturers set default imaging protocols for CT and fluoroscopic procedures so that they incorporate the ALARA concept (maintaining dose As Low As Reasonably Achievable) and utilize or provide for incorporation of diagnostic reference levels into CT and fluoroscopic devices? If so, why and how? If not, why not?

5. Should manufacturers incorporate exam referral criteria into CT and fluoroscopy equipment to allow users to check the appropriateness of an imaging exam before it is initiated or flag an exam after it is done? If so, why and how? If not, why not?

6. Should manufacturers incorporate into CT and fluoroscopic equipment features to ensure that exposure settings, imaging protocols, and metrics of body dose and peak skin dose are displayed to the operator(s) of the equipment and recorded for physician review? If so, why and how? If not, why not?

7. Should manufacturers incorporate features into CT and fluoroscopic equipment to facilitate transmission of technique parameters, imaging protocols, and dose metrics to a patient's imaging record, an electronic health record, or other database? If so, why and how? If not, why not?

8. Should manufacturers take steps to improve the labeling of CT and fluoroscopic devices, such as including more information about radiation exposure, including more information

about the clinical applications of the device that have been shown to be safe and effective, improving instructions for use for each distinct clinical application, and including a comprehensive quality control manual? If so, why and how? If not, why not?

9. Should manufacturers submit more data to FDA as part of their premarket submissions for approval or clearance of CT and fluoroscopic devices, related to the safety and effectiveness of these devices (e.g., data demonstrating the safety and effectiveness of the device specific to each distinct clinical indication, or clinical data demonstrating the benefit of relatively high-dose procedures, for example, those with peak skin doses exceeding 1 Gy)? If so, why, and what data should be submitted? If not, why not?

10. Should manufacturers submit technical data to FDA as part of their premarket submissions for approval or clearance of CT and fluoroscopic devices, demonstrating dose reduction and image quality claims? If so, why, and what data should be submitted? If not, why not?

11. In addition to the already-required indications for use statement, should manufacturers of CT and fluoroscopic devices submit to FDA as part of their premarket submissions a list of common clinical applications for which the device could be used (such as those requiring special software supported by the device) and the appropriate demographics of the likely patient populations for those exams? If so, why, and what level of information should be submitted? If not, why not?

12. What changes should manufacturers make to CT and fluoroscopic devices currently on the market in order to reduce unnecessary patient exposure to ionizing radiation?

#### B. User Training

1. Should manufacturers provide training to medical imaging equipment users to ensure adequate understanding of equipment capabilities, operating principles for the technology, general information about optimizing patient dose and image quality, and specific dose-reduction equipment features? If so, why, and what training should be provided? If not, why not?

2. If manufacturers provide such training, which personnel should receive it to ensure proper use of medical imaging equipment and dose reduction features? In your response, please consider radiologic technologists or technologists in other specialties as well as physicians in all medical specialties who operate fluoroscopic equipment.

3. If manufacturers provide such training, how, when, and how often should it be delivered so that it is easily and effectively implemented at imaging facilities? For example, for software upgrades that affect dose, should training be performed at each site as well as training at the time of equipment installation?

#### C. Quality Assurance Measures

1. Should manufacturers provide quality assurance (QA) instructions and standard operating procedures to medical imaging facilities and users of CT and fluoroscopic devices? If so, why, and what instructions should be provided? If not, why not?

2. Should manufacturers provide training on quality assurance practices? If so, why, what type of training should be provided, and to which personnel? If not, why not?

#### D. Evaluation

1. What tools and metrics should FDA, in collaboration with others in the Federal Government and the healthcare professional community, use to evaluate the impact of efforts to reduce unnecessary radiation exposure from medical imaging?

#### IV. 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, 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>.

Dated: February 18, 2010.

**Jeffrey Shuren,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. 2010-3674 Filed 2-23-10; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

##### Pulmonary-Allergy Drugs Advisory Committee; Amendment of Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Pulmonary-Allergy Drugs Advisory

Committee. This meeting was announced in the **Federal Register** of February 2, 2010 (75 FR 5334). The amendment is being made to reflect a change in the *Name of Committee* portion of the document. There are no other changes.

#### FOR FURTHER INFORMATION CONTACT:

Kristine T. Khuc, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail:

[Kristine.Khuc@fda.hhs.gov](mailto:Kristine.Khuc@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), code 3014512545. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 2, 2010, FDA announced that a meeting of the Pulmonary-Allergy Drugs Advisory Committee would be held on March 10 and 11, 2010. On page 5334, in the second column, the *Name of Committee* portion of the document is changed to read as follows:

*Name of Committees:* Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 18, 2010.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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#### DEPARTMENT OF HOMELAND SECURITY

##### Office of the Secretary

[Docket No. DHS-2010-0007]

##### Privacy Act of 1974; Department of Homeland Security Immigration and Customs Enforcement-007 Alien Criminal Response Information Management System of Records

**AGENCY:** Privacy Office, DHS.

**ACTION:** Notice of modification to existing Privacy Act system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974 the Department of Homeland Security U.S. Immigration and Customs Enforcement is updating an existing system of records titled, Department of Homeland Security/