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]

BILLING CODE 4160–01–S

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*, 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.

[FR Doc. 2010–3595 Filed 2–23–10; 8:45 am]

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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/