8. It must be shown that the inflatable restraint will not impede rapid egress of the occupants 10 seconds after its deployment.

9. To comply with HIRF and lightning requirements, the inflatable restraint system is considered a critical system since its deployment could have a hazardous effect on the airplane.

10. It must be shown that the inflatable restraints will not release hazardous quantities of gas or particulate matter into the cabin.

11. The inflatable restraint system installation must be protected from the effects of fire such that no hazard to occupants will result.

12. There must be a means to verify the integrity of the inflatable restraint activation system before each flight or it must be demonstrated to reliably operate between inspection intervals.

13. A life limit must be established for appropriate system components.

14. Qualification testing of the internal firing mechanism must be performed at vibration levels appropriate for a general aviation airplane.

Issued in Kansas City, Missouri, on July 21, 2011.

Earl Lawrence,
Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Part 14
[Docket No. FDA–2010–N–0002]

Advisory Committee; Medical Imaging Drugs Advisory Committee; Re-establishment

AGENCY: Food and Drug Administration, HHS.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the re-establishment of the Medical Imaging Drugs Advisory Committee in FDA’s Center for Drug Evaluation and Research. This rule amends the current language for the Medical Imaging Drugs Advisory Committee in the Agency’s list of standing advisory committees in FDA’s regulations.

DATES: Effective date: This rule is effective August 5, 2011.

Applicability: Authority for the committee being established will end on May 18, 2013, unless the Commissioner of Food and Drugs (the Commissioner) formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, Division of Advisory Committee and Consultant Management, Bldg. 31, rm. 2417, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533 or e-mail: MIDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app.2)); section 1004 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394); and 21 CFR 14.40(b), FDA is announcing the establishment of the Medical Imaging Drugs Advisory Committee by the Commissioner. The Committee advises the Commissioner and designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner.

The Medical Imaging Drugs Advisory Committee will be composed of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of nuclear medicine, radiology, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Elsewhere in this issue of the Federal Register, FDA is publishing notices requesting nominations for membership of members as well as a consumer and industry representative on this committee.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely adds the name of the Medical Imaging Drugs Advisory Committee, already established by charter, to the list of standing advisory committees in 21 CFR 14.100.

Therefore the Agency is amending 21 CFR 14.100(a) as set forth below.

List of Subjects in 21 CFR Part 14
Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows: