

CFR part 803)). The draft guidance published in the **Federal Register** on July 12, 2011 (76 FR 40921), and the comment period closed on October 11, 2011. There were 5 comments received.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to (301) 847-8149 to receive a hard copy. Please use the document number 1752 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in part 807, subparts B and C have been approved under OMB control number 0910-0387; the collections of information in part 820 have been approved under OMB control number 0910-0073; the collections of information in part 801 and § 809.10 have been approved under OMB control number 0910-0485; and the collections of information in part 803 have been approved under OMB control number 0910-0437.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-32437 Filed 12-19-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0885]

Food and Drug Administration Rare Disease Patient Advocacy Day; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following meeting: FDA Rare Disease Patient Advocacy Day. This meeting is intended to enhance the awareness of the rare disease community as to FDA's roles and responsibilities in the development of products (drugs, biological products, and devices) intended for the diagnosis, prevention, and/or treatment of rare diseases or conditions. The goal of this meeting is to engage and educate the rare disease community on the FDA regulatory processes.

This educational meeting will consist of a live and interactive simultaneous Web cast of presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. The interactive meeting will include two general panel discussion sessions, as well as afternoon breakout sessions for more indepth information on the roles of FDA. In addition, onsite attendees will have an opportunity during lunch to engage with FDA and outside experts in a small group setting.

Date and Time: The meeting will be held on March 1, 2012, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. For participants who cannot attend the live meeting, a live interactive Web cast will be made available. Participants may access this live Web cast by visiting the following site: <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/OOPDNewsArchive/ucm277194.htm>.

Contact: Soumya Patel, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5279, Silver Spring, MD 20993-0002, (301) 796-8660, FAX: (301) 847-8621, email: FDAadvocacy@fda.hhs.gov.

Registration: Interested participants may register for this meeting at the following Web site: https://www.teamshare.net/FDA_Rare_Disease_Patient_Advocacy_Day_Registration.

If you need sign language interpretation during this meeting, please contact Megan McNamee at mmcnamee@icfi.com by February 15, 2012.

The FDA Rare Disease Patient Advocacy Day is supported by FDA, the National Institutes of Health (NIH), the National Organization for Rare Disorders, and the Genetic Alliance.

FDA encourages all attendees to also plan on attending the NIH Rare Disease Day day-long celebration on February 29, 2011. Please refer to the following Web site for more information regarding the NIH Rare Disease Day event: <http://rarediseases.info.nih.gov/RareDiseaseDay.aspx>. (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Dated: December 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Advisory Committees; Tentative Schedule of Meetings for 2012

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a