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 The draft guidance published in the **Federal Register** on July 12, 2011 (76 FR 40921), and the comment period closed on October 11, 2011.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]

BILLING CODE 4160–01–P

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.

[FR Doc. 2011–32436 Filed 12–19–11; 8:45 am]

BILLING CODE 4160–01–P

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

tentative schedule of forthcoming meetings of its public advisory committees for 2012. During 1991, at the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of the IOM's recommendations was for the Agency to publish an annual tentative schedule of its meetings in the **Federal Register**. This publication implements the IOM's recommendation.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5290, Silver Spring, MD 20993, (301) 796–8220.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report in 1992, one of the IOM's recommendations was for FDA to adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the **Federal Register**; FDA has implemented this recommendation. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. Because the schedule is tentative, amendments to this notice will not be published in the **Federal Register**. However, changes to the schedule will be posted on the FDA advisory committees' Internet site located at *http://www.fda.gov/AdvisoryCommittees/default.htm.* FDA will continue to publish a **Federal Register** notice 15 days in advance of each upcoming advisory committee meeting, to announce the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for 2012.

TABLE 1

Committee name	Tentative date(s) of meeting(s)
OFFICE OF THE COMMISSIONER	
Pediatric Advisory Committee	January 30–31, May & December date(s), if needed, to be determined.
Risk Communication Advisory Committee	February 13–14, April 30, May 1, August 16–17, November 1–2.
Science Board to FDA	January 6, May 2, October 3.
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
Allergenic Products Advisory Committee	April 18, October 18.
Blood Products Advisory Committee	February 28–29, May 15–16, July 31–August 1, December 4–5.
Cellular, Tissue and Gene Therapies Advisory Committee	February 9–10, June 27–28, November 29–30.
Transmissible Spongiform Encephalopathies Advisory Committee	Date(s), if needed, to be determined.
Vaccines and Related Biological Products Advisory Committee	February 28–29, May 16–17, September 19–20, November 14–15.
CENTER FOR DRUG EVALUATION AND RESEARCH	
Anesthetic and Analgesic Drugs Advisory Committee (formerly the Anesthetic and Life Support Drugs Advisory Committee).	February 9.
Anti-Infective Drugs Advisory Committee	Date(s), if needed, to be determined.
Antiviral Drugs Advisory Committee	May 16–17.
Arthritis Advisory Committee	March 12.
Cardiovascular and Renal Drugs Advisory Committee	February 23.
Dermatologic and Ophthalmic Drugs Advisory Committee	February 27.
Drug Safety and Risk Management Advisory Committee	Date(s), if needed, to be determined.
Endocrinologic and Metabolic Drugs Advisory Committee	February 22, March 28–29.
Gastrointestinal Drugs Advisory Committee	March 13–14.
Medical Imaging Drugs Advisory Committee	Date(s), if needed, to be determined.
Nonprescription Drugs Advisory Committee	Date(s), if needed, to be determined.
Oncologic Drugs Advisory Committee	February 8–9, March 20–21, June 20–21, July 24–25, September 12–13, November 6–7, December 4–5.
Peripheral and Central Nervous System Drugs Advisory Committee	Date(s), if needed, to be determined.
Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.	March 14.
Psychopharmacologic Drugs Advisory Committee	Date(s), if needed, to be determined.
Pulmonary-Allergy Drugs Advisory Committee	February 23–24.
Advisory Committee for Reproductive Health Drugs	January 20, April 5.
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	
Medical Devices Advisory Committee (Comprised of 18 Panels)	
Device Good Manufacturing Practices Advisory Committee	Date(s), if needed, to be determined.
Anesthesiology and Respiratory Therapy Devices Panel	June 8, November 16.
Circulatory System Devices Panel	Date(s), if needed, to be determined.
Clinical Chemistry and Clinical Toxicology Devices Panel	April 20, July 18–19, September 20–21.
Dental Products Panel	Date(s), if needed, to be determined.
Ear, Nose, and Throat Devices Panel	Date(s), if needed, to be determined.
Gastroenterology-Urology Devices Panel	July 13.
General and Plastic Surgery Devices Panel	July 17.
General Hospital and Personal Use Devices Panel	August 16–17.
Hematology and Pathology Devices Panel	June 28.
Immunology Devices Panel	Date(s), if needed, to be determined.

TABLE 1—Continued

Committee name	Tentative date(s) of meeting(s)
Medical Devices Dispute Resolution Panel	Date(s), if needed, to be determined.
Microbiology Devices Panel	Date(s), if needed, to be determined.
Molecular and Clinical Genetics Panel	June 27.
Neurological Devices Panel	Date(s), if needed, to be determined.
Obstetrics and Gynecology Devices Panel	July 5–6.
Ophthalmic Devices Panel	November 8–9.
Orthopedic and Rehabilitation Devices Panel	September 13–14, November 16, December 6–7.
Radiological Devices Panel	November 2.
National Mammography Quality Assurance Advisory Committee	October 18.
Technical Electronic Product Radiation Safety Standards Committee	June 14.
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	
Food Advisory Committee	December 13–14.
CENTER FOR TOBACCO PRODUCTS	
Tobacco Products Scientific Advisory Committee	January 18–20, March 1–2.
CENTER FOR VETERINARY MEDICINE	
Veterinary Medicine Advisory Committee	Date(s), if needed, to be determined.
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)	
Science Advisory Board to NCTR	October 23–24.

Dated: December 14, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–32469 Filed 12–19–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Los Angeles District Office, in cosponsorship with the Society of Clinical Research Associates (SoCRA), is announcing a public workshop. The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of the FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, of IRB, and research sponsors.

Date and Time: The public workshop will be held on March 7 and 8, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Hyatt Regency Newport Beach, 1107 Jamboree Rd., Newport Beach, CA 92660, 1 (949) 729–1234.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $145.00 plus applicable taxes (available until February 14, 2012, or until the SoCRA room block is filled).

Contact: Linda Hartley, Office of Regulatory Affairs, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, (949) 608–4413, FAX: (949) 608–4417; or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 1 (800) 762–7292 or (215) 822–8644; FAX: (215) 822–8633, email *SoCRAmail@aol.com*, Web site: *www.socra.org.*

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the public workshop will receive confirmation. The cost of the registration is as follows:

COST OF REGISTRATION

SoCRA nonmember (includes membership)	650.00
Federal Government SoCRA member	450.00
Federal Government SoCRA nonmember	525.00
FDA Employee	[*]

* Fee Waived.

If you need special accommodations due to a disability, please contact SoCRA or Linda Hartley (see *Contact*) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) Credits for SoCRA CE and continuing nurse education (CNE). SOCRA designates this educational activity for a maximum of 13.3 American Medical Association Physician's Recognition Award *Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation. SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. SoCRA is an approved provider of CNE by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC).