

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: January 7, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8-571 Filed 1-14-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0240]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301-827-4816.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 11, 2007 (72 FR 57950), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0233. The approval expires on January 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: January 9, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Tentative Schedule of Meetings for 2008

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 2008. 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:

Theresa L. Green, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

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/oc/advisory/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 2008. You may also obtain up-to-date information by calling the Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area).

Committee Name	Tentative Date of Meeting(s)	Advisory Committee 10-Digit Information Line Code
OFFICE OF THE COMMISSIONER		
Pediatric Advisory Committee	March and November days to be announced	8732310001
Risk Communication Advisory Committee	February 28-29, May 15-16, August 21-22, November 17-18	8732112560
Science Board to FDA	May and October days to be announced	3014512603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		
Allergenic Products Advisory Committee	April 29, October 17	3014512388
Blood Products Advisory Committee	May 1-2, August 14-15, December 11-12	3014519516
Cellular, Tissue and Gene Therapies Advisory Committee	April 10-11, November 13-14	3014512389

Committee Name	Tentative Date of Meeting(s)	Advisory Committee 10-Digit Information Line Code
Transmissible Spongiform Encephalopathies Advisory Committee	To be announced	3014512392
Vaccines and Related Biological Products Advisory Committee	February 20–21, May 21–22, September 24–25, November 19–20	3014512391
CENTER FOR DRUG EVALUATION AND RESEARCH		
Anesthetic and Life Support Drugs Advisory Committee	March 11, May days to be announced	3014512529
Anti-Infective Drugs Advisory Committee	February 27–28, April 1–3	3014512530
Antiviral Drugs Advisory Committee	To be announced	3014512531
Arthritis Advisory Committee	July, September, and November days to be announced	3014512532
Cardiovascular and Renal Drugs Advisory Committee	June 24–25, August 19–20, December 9–10	3014512533
Dermatologic and Ophthalmic Drugs Advisory Committee	April days to be announced	3014512534
Drug Safety and Risk Management Advisory Committee	February 1, May days to be announced	3014512535
Endocrinologic and Metabolic Drugs Advisory Committee	April 16–17, July 1–2, October 29–30, November 19–20	3014512536
Gastrointestinal Drugs Advisory Committee	January 23, May days to be announced	3014512538
Nonprescription Drugs Advisory Committee	To be announced	3014512541
Oncologic Drugs Advisory Committee	March 13, April days to be announced, May 30, September 10–11, December 15–16	3014512542
Peripheral and Central Nervous System Drugs Advisory Committee	May days to be announced	3014512543
Pharmaceutical Science and Clinical Pharmacology, Advisory Committee for	March 18–19	3014512539
Psychopharmacologic Drugs Advisory Committee	February 6	3014512544
Pulmonary-Allergy Drugs Advisory Committee	February 20	3014512545
Reproductive Health Drugs, Advisory Committee for	To be announced	3014512537
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		
Device Good Manufacturing Practice Advisory Committee	August 12, October 20–21	3014512398
Medical Devices Advisory Committee (Comprised of 18 Panels)		
Anesthesiology and Respiratory Therapy Devices Panel	January 23, March 26, September 17	3014512624
Circulatory System Devices Panel	August 26–27, November 14–15	3014512625
Clinical Chemistry and Clinical Toxicology Devices Panel	April 9–10, August 13–14, December 4–5	3014512514
Dental Products Panel	June 11, September 10, November 19	3014512518
Ear, Nose, and Throat Devices Panel	April 16–17, June 25–26, August 28–29, October 28–29, December 10–11	3014512522
Gastroenterology-Urology Devices Panel	October 17	3014512523
General and Plastic Surgery Devices Panel	June 10–11, October 21–22	3014512519
General Hospital and Personal Use Devices Panel	May 6–7, September 16–17	3014512520
Hematology and Pathology Devices Panel	April 25, October 17	3014512515
Immunology Devices Panel	November 6–7	3014512516
Medical Devices Dispute Resolution Panel	To be announced as needed	3014510232
Microbiology Devices Panel	April 24–25, June 19–20, October 23–24	3014512517

Committee Name	Tentative Date of Meeting(s)	Advisory Committee 10-Digit Information Line Code
Molecular and Clinical Genetics Panel	May 6–7, November 11–12	3014510231
Neurological Devices Panel	March 25–26, June 3–4, September 23–24, November 6–7	3014512513
Obstetrics and Gynecology Devices Panel	April 17–18, June 19–20, August 14–15, October 16–17, December 11–12	3014512524
Ophthalmic Devices Panel	February 21–22, May 15–16, September 18–19, November 20–21	3014512396
Orthopedic and Rehabilitation Devices Panel	April 21–22, June 16–17, August 18–19, October 20–21, December 8–9	3014512521
Radiological Devices Panel	April 15–16, August 12, November 4	3014512526
National Mammography Quality Assurance Advisory Committee	October 13–14	3014512397
Technical Electronic Product Radiation Safety Standards Committee	October 8	3014512399
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		
Food Advisory Committee	July 22, December 2	3014510564
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	March day to be announced	3014512548
National Center for Toxicological Research (NCTR)		
Science Advisory Board to NCTR	August 12–13	3014512559

Dated: January 7, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–567 Filed 1–14–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the **Federal Register** of December 11, 2007 (72 FR 70336). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Teresa A. Watkins, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: Teresa.Watkins@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512535. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 11, 2007, FDA announced that a meeting of the Drug Safety and Risk Management Advisory Committee would be held on February 1, 2008. On page 70336, in the second column, the first paragraph of the *Agenda* portion of document is amended to read as follows:

Agenda: The committee will discuss the efficacy and safety of new drug application (NDA) 22–054, INJECTAFER (ferric carboxymaltose injection), Luitpold Pharmaceuticals Inc., used for the treatment of iron deficiency anemia in postpartum patients or iron deficiency anemia in patients with heavy uterine bleeding.

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: January 7, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–490 Filed 1–14–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notification of Exception to Competition

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notification of Exception to Competition.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing a non-competitive program expansion supplement to the National Health Care for the Homeless Council (NHCHC) to provide expanded training and technical assistance to HRSA-funded grantees serving individuals who are homeless.

Authority: This activity is under the authority of the Public Health Service Act, section 330(l).