

address at <http://www.cms.hhs.gov/regulations/pral/>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Reduction Act Reports Clearance Officer designated at the address below:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Melissa Musotto, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 8, 2004.

**John P. Burke, III,**

*CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs Regulations Development Group.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Advisory Committees; Tentative Schedule of Meetings for 2005**

**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 2005. 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 2005. You may also obtain up-to-date meeting information by calling the Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area).

Committee Name	Tentative Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
<b>OFFICE OF THE COMMISSIONER</b>		
Pediatric Advisory Committee	February 14-15, June-day to be announced, November-day to be announced	8732310001
Science Board to the Food and Drug Administration	April 15, November-day to be announced	3014512603
<b>CENTER FOR BIOLOGICS EVALUATION AND RESEARCH</b>		
Allergenic Products Advisory Committee	April 7	3014512388
Cellular, Tissue and Gene Therapies Advisory Committee (formerly Biological Response Modifiers Advisory Committee)	March 3-4, July 28-29, November 9-10	3014512389
Blood Products Advisory Committee	March 17-18, July 21-22, December 1-2	3014519516
Transmissible Spongiform Encephalopathies Advisory Committee	February 8-9, June 28-29, October 27-28	3014512392
Vaccines and Related Biological Products Advisory Committee	February 16-17, March 15-16, May 4-5, September 20-21, November 16-17	3014512391
<b>CENTER FOR DRUG EVALUATION AND RESEARCH</b>		
Anesthetic and Life Support Drugs Advisory Committee	May 24-25, July 20-21, November 9-10	3014512529
Anti-Infective Drugs Advisory Committee	To Be Announced	3014512530
Antiviral Drugs Advisory Committee	March 10-11, August 3-4	3014512531
Arthritis Advisory Committee	February 16-17, May 12-13, September 15-16	3014512532

Committee Name	Tentative Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Cardiovascular and Renal Drugs Advisory Committee	February 24, April 5–6, June 15–16, August 17–18, November 16–17	3014512533
Dermatologic and Ophthalmic Drugs Advisory Committee	March 24–25—Joint Meeting with Nonprescription Drugs Advisory Committee, June 2–3, October 20–21, November 3–4	3014512534
Drug Safety and Risk Management Advisory Committee	March 8–9—Joint Meeting with Gastrointestinal Drugs Advisory Committee, June 2–3, October 20–21, November 3–4	3014512535
Endocrinologic & Metabolic Drugs Advisory Committee	January 13–14—Joint Meeting with Nonprescription Drugs Advisory Committee, May 5–6, September 22–23, December 13–14	3014512536
Gastrointestinal Drugs Advisory Committee	March 9—Joint Meeting with Drug Safety and Risk Management Advisory Committee, March 10, October—day to be announced	3014512538
Nonprescription Drugs Advisory Committee	January 13–14—Joint Meeting with Endocrinologic and Metabolic Drugs Advisory Committee March 23–25—Joint Meeting with Dermatologic and Ophthalmic Drugs Advisory Committee	3014512541
Oncologic Drugs Advisory Committee	March 2–3, May 11–12, September 13–14, December 7–8	3014512542
Peripheral and Central Nervous System Drugs	May 4	3014512543
Pharmaceutical Science, Advisory Committee for (Parent Committee)	April, October—Parent Committee—days to be announced April, November—Clinical Pharmacology Subcommittee—days to be announced March, June, September—Manufacturing Subcommittee—days to be announced	3014512539
Psychopharmacologic Drugs Advisory Committee	To be announced	3014512544
Pulmonary-Allergy Drugs Advisory Committee	April 27–28, August 30–31, December 12–13	3014512545
Reproductive Health Drugs, Advisory Committee for	To be announced	3014512537
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		
Device Good Manufacturing Practice Advisory Committee	December—day to be announced	3014512398
Medical Devices Advisory Committee (Comprised of 18 Panels)		
Anesthesiology and Respiratory Therapy Devices Panel	April 25–26, November 3–4	3014512624
Circulatory System Devices Panel	January 13, March 17, May 19, July 21, September 22, November 17	3014512625
Clinical Chemistry and Clinical Toxicology Devices Panel	March 21–22, April 21–22, May 23–24, July 11–12, September 8–9, December 5–6	3014512514
Dental Products Panel	April 11–12, July 18–19	3014512518
Ear, Nose, and Throat Devices Panel	February 24–25, April 28–29, June 20–21, August 1–2, October 6–7, December 1–2	3014512522
Gastroenterology-Urology Devices Panel	March 4, May 3, July 22, October 21	3014512523
General and Plastic Surgery Devices Panel	February 7–8, June 9–10, August 25–26, November 7–8	3014512519
General Hospital and Personal Use Devices Panel	February 10–11, May 9–10, August 8–9, December 5–6	3014512520
Hematology and Pathology Devices Panel	April 29, October 21	3014512515
Immunology Devices Panel	May 19, November 10	3014512516

Committee Name	Tentative Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Medical Devices Dispute Resolution Panel	Meeting(s) scheduled as needed	3014510232
Microbiology Devices Panel	March 31–April 1, June 16–17, September 19–20, December 8–9	3014512517
Molecular and Clinical Genetics Panel	April 18–19, October 17–18	3014510231
Neurological Devices Panel	April 28–29, June 20–21, September 22–23, December 1–2	3014512513
Obstetrics and Gynecology Devices Panel	March 10–11, May 16–17, August 15–16, November 14–15	3014512524
Ophthalmic Devices Panel	March 17–18, May 12–13, July 28–29, September 29–30, November 17–18	3014512396
Orthopaedic and Rehabilitation Devices Panel	January 31–February 1, April 7–8, July 25–26, November 3–4	3014512521
Radiological Devices Panel	February 1, May 10, August 2, November 1	3014512526
National Mammography Quality Assurance Advisory Committee	April 18	3014512397
Technical Electronic Product Radiation Safety Standards Committee	May 18	3014512399
<b>CENTER FOR FOOD SAFETY AND APPLIED NUTRITION</b>		
Food Advisory Committee—Parent	July-day to be announced	3014510564
Additives and Ingredients Subcommittee	June-day to be announced	Do.
Biotechnology Subcommittee	July-day to be announced	Do.
Contaminants and Natural Toxicants Subcommittee	November-day to be announced	Do.
Dietary Supplements Subcommittee	To be announced	Do.
Infant Formula Subcommittee	August-day to be announced	Do.
Nutrition Subcommittee	To be announced	Do.
<b>CENTER FOR VETERINARY MEDICINE</b>		
Veterinary Medicine Advisory Committee	January 31, May 19, October 20	3014512548
<b>NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)</b>		
Science Advisory Board to NCTR	March 30–31	3014512559
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	May, September, November-days to be announced	3014512560

Dated: December 8, 2004.

**Sheila Dearybury Walcott,**

*Associate Commissioner for External Relations.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004D–0524]

**Draft Guidance for Industry on ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information.” The draft guidance is intended to assist applicants with the submission of abbreviated new drug applications (ANDAs) when a drug substance exists in polymorphic forms.

**DATES:** Submit written or electronic comments on the draft guidance by March 21, 2005. General comments on