promptly-reported post-donation information, we will continue to monitor and assess our biological product deviation reporting program and make adjustments accordingly.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
600.14	3,486	115	4.1	476	2	952
606.171[2]	3,486	207	130.4	27,000	2	54,000
606.171[3]	3,486	6,021	1.1	6,446	2	12,892
Total						67,844

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Licensed manufacturers of human blood and blood components, including Source Plasma.
[3] Unlicensed registered blood establishments and transfusion services (2,800 + 3,221 = 6,021).

Dated: December 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–32160 Filed 12–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Tentative Schedule of Meetings for 2004

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 2004. During 1991, at the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of IOM's recommendations was for the agency to publish an annual tentative schedule of its meetings in the **Federal Register**. This publication implements 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: 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 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 FDA's 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 2004. 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	Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
OFFICE OF THE COMMISSIONER		
Science Board to the Food and Drug Administration	April 22, November 4	3014512603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		
Allergenic Products Advisory Committee	April 2	3014512388
Biological Response Modifiers Advisory Committee	March 18–19, July 15–16, November 18–19	3014512389
Blood Products Advisory Committee	March 18–19, July 12–13, October 21–22	3014519516
Transmissible Spongiform Encephalopathies Advisory Committee	February 12–13, June 29–30, October 14–15	3014512392

Committee Name	Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Vaccines and Related Biological Products Advisory Committee	February 18–19, May 6–7, September 22–23, November 17–18	3014512391
CENTER FOR DRUG EVALUATION AND RESEARCH		
Anesthetic and Life Support Drugs Advisory Committee	March 24–25, June 9–10, August 10–11, November 17–18	3014512529
Anti-Infective Drugs Advisory Committee	February 2—Joint Meeting with Pediatric Subcommittee and Psychopharmacologic Drugs Advisory Committee, February 3–4—Pediatric Subcommittee	3014512530
Antiviral Drugs Advisory Committee	April 27–28, October 27–28	3014512531
Arthritis Advisory Committee	May 12–13, July 14–15, October 21–22	3014512532
Cardiovascular and Drugs Health Advisory Committee	May 6–7, July 16, August 5–6	3014512533
Dermatologic and Ophthalmic Drugs Advisory Committee	February 26–27—Joint Meeting with Drug Safety and Risk Management Advisory Committee, April 1–2, May 6–7, June 24–25, August 26–27, September 9–10	3014512534
Drug Safety and Risk Management Advisory Committee	February 26–27—Joint Meeting with Dermatologic and Ophthalmic Drugs Advisory Committee, April 22–23, June 3–4, September 9–10, November 4–5	3014512535
Endocrinologic and Metabolic Drugs Advisory Committee	February 26–27, April 22–23, June 22–23, September 23	3014512536
Gastrointestinal Drugs Advisory Committee	To Be Announced	3014512538
Nonprescription Drugs Advisory Committee	March–Day To Be Announced June–Day To Be Announced December 16—Joint Meeting with Advisory Committee for Reproductive Health Drugs	3014512541
Oncologic Drugs Advisory Committee	March 16–17, June 15–16	3014512542
Peripheral and Central Nervous System Drugs	To Be Announced	3014512543
Pharmaceutical Science, Advisory Committee for	April 13–14	3014512539
Psychopharmacologic Drugs Advisory Committee	February 2—Joint Meeting with Anti-Infective Drugs Advisory Committee and Pediatric Subcommittee	3014512544
Pulmonary-Allergy Drugs Advisory Committee	June 29–30, November 4–5	3014512545
Reproductive Health Drugs, Advisory Committee for	October—Day To Be Announced, December—Day To Be Announced	3014512537
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		
Device Good Manufacturing Practice Advisory Committee	September 9–10	3014512398

Committee Name	Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Medical Devices Advisory Committee (Comprised of 18 Panels)		
Anesthesiology and Respiratory Therapy Devices Panel	March 25–26, June 17–18, September 9–10, November 15–16	3014512624
Circulatory Systems Panel	March 17–18, May 19–20, July 21–22, September 22–23, November 17–18	3014512625
Clinical Chemistry and Clinical Toxicology Devices Panel	March 30–31, June 24–25, September 16–17, December 6–7	3014512514
Dental Products Panel	April 14–15	3014512518
Ear, Nose, and Throat Devices Panel	April 21–22, June 15–16, August 30–31, October 6–7, December 1–2	3014512522
Gastroenterology-Urology Devices Panel	April 30, July 16, October 22	3014512523
General and Plastic Surgery Devices Panel	March 11–12, May 26–27, August 9–10, October 18–19	3014512519
General Hospital and Personal Use Devices Panel	April 6–7, July 12–13, October 18–19	3014512520
Hematology and Pathology Devices Panel	April 23, October 22	3014512515
Immunology Devices Panel	February 26, April 23, October 22	3014512516
Medical Devices Dispute Resolution Panel	To Be Announced as Needed	3014510232
Microbiology Devices Panel	April 8–9, July 29–30, November 9–10	3014512517
Molecular and Clinical Genetics Panel	April 28–29, July 19–20, October 20–21	3014510231
Neurological Devices Panel	February 23, April 1–2, August 5–6, October 28–29	3014512513
Obstetrics and Gynecology Devices Panel	April 26–27, July 26–27, October 25–26	3014512524
Ophthalmic Devices Panel	February 5–6, March 4–5, May 13–14, July 8–9, September 22–23, November 4–5	3014512396
Orthopaedic and Rehabilitation Devices Panel	March 22–23, June 3–4, August 12–13, December 2–3	3014512521
Radiological Devices Panel	February 3, May 18, August 10, November 16	3014512526
National Mammography Quality Assurance Advisory Committee	April 5	3014512397
Technical Electronic Product Radiation Safety Standards Committee	None	3014512399
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		
Food Advisory Committee—Full Committee and Subcommittee	August 16–17	3014510564
Additives and Ingredients Subcommittee	May 26–27	3014510564
Biotechnology Subcommittee	July 21–22	3014510564
Contaminants and Natural Toxicants Subcommittee	November 16–17	3014510564

Committee Name	Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Dietary Supplements Subcommittee	September 14–15	3014510564
Infant Formula	June 22–23	3014510564
Nutrition Subcommittee	March 30–31	3014510564
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	September 23–24	3014512548
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		
Science Advisory Board to National Center for Toxicological Research	August 11	3014512559
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Herbicides and Contaminants	January 21, April 12, August 3, October 26	3014512560

Dated: December 23, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–32103 Filed 12–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 18, 2004, from approximately 8:30 a.m. and 5 p.m.; and on March 19, 2004, from approximately 8:30 a.m. to 3 p.m.

Location: Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Gail Dapolito or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3014, e-mail *dapolito@cber.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 18 and 19, 2004, the committee will discuss issues related to the design of early phase clinical trials of cellular therapies for the treatment of cardiac diseases.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 11, 2004. Oral presentations from the public will be scheduled on March 18, 2004, between approximately 4:30 p.m. and 5 p.m.; and on March 19, 2004, between approximately 9:50 a.m. and 10:20 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 11, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 22, 2003.

Peter J. Pitts,

Assoicate Commissioner for External Relations.

[FR Doc. 03–32242 Filed 12–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8004]

Memorandum of Understanding Between the Food and Drug Administration, Department of Health and Human Services of the United States of America and Swissmedic of the Swiss Confederation Regarding Exchange of Information About Pharmaceutical Products for Human and Animal Use and Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration, Department of Health and Human Services of the United States of America and Swissmedic of the Swiss Confederation. The purpose of this MOU is to further enhance and strengthen communication and existing public health promotion and protection cooperative activities related to the regulation of human or animal pharmaceutical products and human medical devices in Switzerland and the United States of America.

DATES: The agreement became effective September 22, 2003.

FOR FURTHER INFORMATION CONTACT: Naomi Kawin, Office of International