

implementation for a risk control plan is recommended time to achieve long-term 90 days, which is the minimum behavior change.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR REGULATORS<sup>1</sup>

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Voluntary Food Safety Management System Evaluation (includes validation, verification, and completion of verification inspection checklist)	50,000	1	50,000	16	800,000
Total Annual Burden for Regulators					800,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

It is difficult to predict the number of State, local, and tribal regulatory jurisdictions that will use the Regulator's Manual. But FDA anticipates that retail and foodservice establishments which voluntarily develop and implement a food safety management system based on the Operator's Manual will request their regulatory authorities to conduct an evaluation of their system. The estimates in table 2 of this document for the annual burden to State, local, and tribal regulators that follow the recommendations in the Regulator's Manual were calculated based on the usual time needed for one person to evaluate a voluntarily-implemented food safety management system and record the findings. The number of times an inspector may be asked by an operator to evaluate a voluntarily-implemented system is not expected to exceed once per year.

Dated: December 8, 2005.

**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 2006**

**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 2006. 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 the 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 schedule advisory committee meeting for 2006. 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(s) of Meetings	Advisory Committee 10-Digit Information Line Code
OFFICE OF THE COMMISSIONER		
Pediatric Advisory Committee	March, June, and November day(s) to be announced.	8732310001
Science Board to the Food and Drug Administration	April and November day(s) to be announced.	3014512603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		
Allergenic Products Advisory Committee	March 31, September 13.	3014512388
Blood Products Advisory Committee	March 9-10, July 13-14, October 26-27.	3014519516
Cellular, Tissue and Gene Therapies Advisory Committee	February 9-10, July 13-14, November 2-3.	3014512389
Transmissible Spongiform Encephalopathies Advisory Committee	To be announced.	3014512392

Committee Name	Tentative Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Vaccines and Related Biological Products Advisory Committee	February 17, May 17–18, September 20–21, November 15–16.	3014512391
CENTER FOR DRUG EVALUATION AND RESEARCH		
Anesthetic and Life Support Drugs Advisory Committee	To be announced.	3014512529
Anti-Infective Drugs Advisory Committee	To be announced.	3014512530
Antiviral Drugs Advisory Committee	To be announced.	3014512531
Arthritis Advisory Committee	To be announced.	3014512532
Cardiovascular and Renal Drugs Advisory Committee	April 25–26, July 25–26, November 1–2.	3014512533
Dermatologic and Ophthalmic Drugs Advisory Committee	To be announced.	3014512534
Drug Safety and Risk Management Advisory Committee	February 9–10, May 4–5.	3014512535
Endocrinologic and Metabolic Drugs Advisory Committee	January 23, May 3–4, August 23–24, November 8–9.	3014512536
Gastrointestinal Drugs Advisory Committee	September and November day(s) to be announced.	3014512538
Nonprescription Drugs Advisory Committee	January 23–24.	3014512541
Oncologic Drugs Advisory Committee	March 14 (Pediatric Subcommittee), March 15, June 2, September 12–13, December 6–7.	3014512542
Peripheral and Central Nervous System Drugs Advisory Committee	March 7–8.	3014512543
Pharmaceutical Science, Advisory Committee for	April 13–14 (Clinical Pharmacology Subcommittee), October 18–19 (Clinical Pharmacology Subcommittee), April, May, and October day(s) to be announced.	3014512539
Psychopharmacologic Drugs Advisory Committee	To be announced.	3014512544
Pulmonary-Allergy Drugs Advisory Committee	January 24.	3014512545
Reproductive Health Drugs, Advisory Committee for	May and June day(s) to be announced.	3014512537
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		
Device Good Manufacturing Practice Advisory Committee	No tentative meeting scheduled.	3014512398
Medical Devices Advisory Committee (Comprised of 18 Panels)		
Anesthesiology and Respiratory Therapy Devices Panel	April 7, October 6.	3014512624
Circulatory System Devices Panel	February 16, April 21, June 16, August 18, October 20.	3014512625
Clinical Chemistry and Clinical Toxicology Devices Panel	February 22–23, May 24–25, September 7–8, December 6–7.	3014512514
Dental Products Panel	February 28, July 25, October 24.	3014512518
Ear, Nose, and Throat Devices Panel	February 1–2, April 3–4, June 15–16, August 10–11, October 11–12, December 4–5.	3014512522
Gastroenterology-Urology Devices Panel	March 3, May 5, July 21, October 20.	3014512523
General and Plastic Surgery Devices Panel	April 27–28, August 24–25, December 4–5.	3014512519
General Hospital and Personal Use Devices Panel	February 9–10, June 12–13, September 28–29.	3014512520
Hematology and Pathology Devices Panel	April 28, October 20.	3014512515

Committee Name	Tentative Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Immunology Devices Panel	July 14, November 8.	3014512516
Medical Devices Dispute Resolution Panel	Meeting scheduled as needed.	3014510232
Microbiology Devices Panel	February 23–24, September 21–22, October 26–27.	3014512517
Molecular and Clinical Genetics Panel	April 13–14, October 5–6.	3014510231
Neurological Devices Panel	March 2–4, August 3–4, June 5–6, August 28–29, November 13–14.	3014512513
Obstetrics-Gynecology Devices Panel	March 27–28, June 5–6, August 28–29, November 13–14.	3014512524
Ophthalmic Devices Panel	March 7–8, May 18, July 13–14, September 19–20, November 2–3.	3014512396
Orthopaedic and Rehabilitation Devices Panel	February 2–3, July 27–28, October 26–27, December 11–12.	3014512521
Radiological Devices Panel	February 7, May 23, September 12, November 7.	3014512526
National Mammography Quality Assurance Advisory Committee	August 28.	3014512397
Technical Electronic Product Radiation Safety Standards Committee	October 4.	3014512399
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		
Food Advisory Committee	March 1, May 3, July 12, September 13.	3014510564
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	March 15, October 16.	3014512548
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)		
Science Advisory Board to NCTR	April day(s) to be announced.	3014512559
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hands)	February day(s) to be announced.	3014512560

Dated: December 14, 2005.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004P–0329]

#### Hand-Held, Doppler Ultrasound Prenatal Listening Devices

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

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss scientific information bearing

on whether hand-held Doppler ultrasound prenatal listening devices should be made available for use over-the-counter (OTC). This 1-day workshop is intended to provide members of the academic, scientific, and clinical communities; industry; consumer, and patient advocacy groups; and others with a forum for presenting their perspectives about available scientific literature and clinical studies relating to hand-held Doppler ultrasound prenatal listening devices. Written comments submitted to the docket before the workshop and information gathered at the workshop will be used by FDA to further identify and evaluate the risks and benefits associated with possible OTC availability of hand-held prenatal Doppler ultrasound listening devices.

*Date and Time:* The public workshop will be held on Wednesday, March 29, 2006, from 9 a.m. to 3:30 p.m. The deadline for registration is Friday,

March 10, 2006. Requests to make presentations at the public workshop and written or electronic comments will be accepted until Friday, March 10, 2006.

*Addresses:* The public workshop will be held at the Hilton Washington DC North, 620 Perry Pkwy., Gaithersburg, MD, 20877. Additional information about and directions to the facility are available on the Internet at <http://www.hilton.com/en/hi/hotels/index.jhtml?ctyhocn=GAIGHHF>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.