6. Part F.II(a)., Section 2692(a) of the PHS Act—AIDS Education and Training Centers (AETC);

7. Part F.II.(b)., Section 2692(b) of the PHS Act—Dental Schools Reimbursement Program.

This delegation supersedes the delegation memorandum from the Assistant Secretary for Health to the HRSA Administrator, dated May 24, 1991.

This delegation is effective upon date of signature. In addition, I hereby affirm and ratify any actions taken by the HRSA Administrator or any subordinates which, in effect, involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

Dated: January 20, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–2040 Filed 1–27–98; 8:45 am]

BILLING CODE 4160–15–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee on Immunization Practices (ACIP).

Times and Dates: 8:30 a.m.–5:15 p.m., February 11, 1998; 8:30 a.m.–1:15 p.m., February 12, 1998.

Place: CDC, Auditorium B, Building 2, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters To Be Discussed: Agenda items will include updates from the National Center for Infectious Diseases; the National Immunization Program; the Vaccine Injury Compensation Program; the National Vaccine Program; update on influenza A(H5N1): epidemiologic and virologic surveillance and present status of vaccine development; update on influenza surveillance—U.S. and worldwide; influenza vaccination and Guillain Barre syndrome: update and proposed changes to ACIP recommendations; proposed changes to the 1998–1999 ACIP recommendations for prevention and control of influenza; immunization of bone marrow transplant recipients recommendations on the use of Rotashield® (rotavirus vaccine) as part of the routine childhood immunization schedule; report of work group on computerization of ACIP recommendations; ACIP combination vaccines recommendation; comprehensive resolutions for the Vaccines for Children (VFC) Program; vaccine identification standards initiative; and alopecia associated with hepatitis B vaccination. Other matters of relevance among the committee's objectives may be discussed.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Gloria A. Kovach, Committee Management Specialist, CDC, 1600 Clifton Road, NE, M/S D–50, Atlanta, Georgia 30333, telephone 404/639–7250.

Dated: January 21, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–1998 Filed 1–27–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

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 1998. 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. The IOM recommended that the agency publish an annual tentative schedule of its meetings in the **Federal Register**. In response to that recommendation, FDA is publishing its annual tentative schedule of meetings for 1998.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4820.

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, the IOM recommended that FDA 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. A tentative schedule of forthcoming meetings will be published annually in the **Federal Register**. 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. The schedule is tentative and amendments to this notice will not be published in the **Federal Register**. FDA will publish a **Federal Register** notice at least 15 days in advance of each upcoming advisory committee meeting, announcing the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for 1998:

Committee Name	Dates of Meetings	Information-Line Code
OFFICE OF THE COMMISSIONER		
Science Board to the Food and Drug Administration	May 19 September 15	12603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		
Allergenic Products Advisory Committee	March 23–24 September 14–15	12388
Biological Response Modifiers Advisory Committee	March 23–24	12389

Committee Name	Dates of Meetings	Information-Line Code
	July 30–31	
	November 12–13	
Blood Products Advisory Committee	March 12–13	19516
	June 18–19	
	September 17–18	
	December 10–11	
Transmissible Spongiform Encephalopathies Advisory Committee	April 15–16	12392
	July 9–10	
	October 22–23	
Vaccines and Related Biological Products Advisory Committee	January 30	12391
	March 23–24	
	May 26–27	
	July 20–21	
	September 1–2	
	November 19–20	
CENTER FOR DRUG EVALUATION AND RESEARCH		
Advisory Committee for Pharmaceutical Science	April 7–8	12539
	June 23–24	
	October 22–23	
Advisory Committee for Reproductive Health Drugs	March 19–20	12537
	June 11–12	
	September 17–18	
Anesthetic and Life Support Drugs Advisory Committee	February 5–6	12529
	June 1–2	
	September 10–11	
Anti-Infective Drugs Advisory Committee	February 19–20	12530
	April 1–3	
	July 15–17	
	November 4–6	
Antiviral Drugs Advisory Committee	January 14	12531
	May 4–6	
	July 13–15	
	September 9–11	
Arthritis Advisory Committee	February 20	12532
	March 24–25	
	June 2–3	
	September 15–16	
	October 30	
	December 1–2	
Cardiovascular and Renal Drugs Advisory Committee	January 27–28	12533
	April 9	
	July 9–10	
	October 22–23	
Dermatologic and Ophthalmic Drugs Advisory Committee	March 19–20	12534
	June 4–5	
	July 23–24	
	August 20–21	
	September 10–11	
	October 1–2	
	November 5–6	
	December 2–4	
Drug Abuse Advisory Committee	February 19–20	12535
	June 25–26	
	October 22–23	
Endocrinologic and Metabolic Drugs Advisory Committee	March 12–13	12536
	April 9–10	
	May 14–15	
	July 30–31	
	September 17–18	
	October 15–16	
	December 10–11	
Gastrointestinal Drugs Advisory Committee	May 28–29	12538
Medical Imaging Drugs Advisory Committee	February 9	12540
	June 25–26	
	October 15–16	
Nonprescription Drugs Advisory Committee	March 11–13	12541

Committee Name	Dates of Meetings	Information-Line Code
	May 20–22 May 27–28 July 27–29 September 9–11 October 7–8 October 29–30 December 2–3 December 9–11	
Oncologic Drugs Advisory Committee	March 19–20 June 1–2	12542
Peripheral and Central Nervous System Drugs Advisory Committee	April 16–17 September 17–18	12543
Psychopharmacologic Drugs Advisory Committee	March 30–31	12544
Pulmonary-Allergy Drugs Advisory Committee	April 13–14 September 18	12545
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		
Food Advisory Committee	February 11–13 April 8–10 June 17–19 August 19–21 November 4–6	10564
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		
Device Good Manufacturing Practice Advisory Committee	May 2	12398
Medical Devices Advisory Committee		
Anesthesiology and Respiratory Therapy Devices Panel	May 22 August 28 November 6	12624
Circulatory System Devices Panel	March 16 May 7–8 August 20–21 October 26–27	12625
Clinical Chemistry and Clinical Toxicology Devices Panel	March 5–6 June 1–2 September 14 December 7	12514
Dental Products Panel	January 12–13 March 10–11 May 12–14 August 4–6 November 3–5	12518
Ear, Nose, and Throat Devices Panel	April 29 July 8 September 30	12522
Gastroenterology and Urology Devices Panel	February 12–13 April 30 and May 1 July 30–31 October 29–30	12523
General and Plastic Surgery Devices Panel	January 29–30 April 22–23 July 27–28 September 24–25 November 16–17	12519
General Hospital and Personal Use Devices Panel	March 2–3 June 8–9 September 14–15 November 16	12520
Hematology and Pathology Devices Panel	January 28 April 29–30 September 17–18 December 10–11	12515
Immunology Devices Panel	February 2 April 10 July 17 October 16	12516
Microbiology Devices Panel	February 11–13 April 16–17 June 4–5 August 13–14 October 8–9	12517
Neurological Devices Panel	March 12–13	12513

Committee Name	Dates of Meetings	Information-Line Code
Obstetrics and Gynecology Devices Panel	June 11–12 September 10–11 December 7–8 January 27–28 April 6–7 July 20–21 October 19–20	12524
Ophthalmic Devices Panel	February 12–13 April 23–24 July 23–24 October 22–23	12396
Orthopaedic and Rehabilitation Devices Panel	January 12–13 April 27–28 July 9–10 October 8–9	12521
Radiological Devices Panel	February 23 May 11 August 17 November 16	12525
National Mammography Quality Assurance Advisory Committee	May 13	12397
Technical Electronic Product Radiation Safety Standards Committee	September 22	12399
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	No meetings planned	12546
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	April 10–11	12560
Science Board to the National Center for Toxicological Research	March 24–25	12559

Dated: January 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2025 Filed 1–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0021]

Draft Guidance for Industry; Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Industry: Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products.'' The draft guidance is intended to provide recommendations and offer alternative methods for sterility testing to confirm the integrity of container and closure systems for sterile biological products, human and veterinary drugs, and medical devices. The draft guidance applies only to the replacement of the sterility test with an appropriate container and closure integrity test in the stability protocol, and it is not offered as a replacement for sterility testing for product release.

DATES: Written comments may be provided at any time, however, to ensure comments are considered for the next revision they should be submitted by March 30, 1998.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products.'' The draft guidance provides general information on procedures and practices that should be considered when a manufacturer selects alternative methods to confirm sterility during stability studies of sterile biological products, human and veterinary drugs, and medical devices.

All sterile products are required to have adequate container and closure integrity and to remain free from contamination throughout the product's entire dating period. As a consequence