

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 6, 2009

TO: The Secretary
Through: DS
COS ES

FROM: Acting Commissioner of Food and Drugs

SUBJECT: Annual Report on the Food and Drug Administration Advisory
Committee Vacancies and Public Disclosures

BACKGROUND

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures and transmittal letters to Congress for your signature. This is the second report the Food and Drug Administration (FDA) has submitted under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the Act). The report covers fiscal year (FY) 2008 and summarizes how the FDA has met each of the conditions specified in Section 712(e) of the Act, in response to this statutory requirement.

HIGHLIGHTS

The report describes, for FY 2008, the number of vacancies on each advisory committee, new vacancies, the number of nominees considered for each committee, and the number of such nominees willing to serve. The report also describes the number of disclosures made in FY 2008 and the percentage of individuals to whom disclosures did not apply in FY 2008.

RECOMMENDATION

I recommend that you review and approve the report and forward it to Congress.

/s/

Frank M. Torti, M.D., MPH

Attachments (2) Tab A -
Transmittal Letters Tab B -
Report to Congress

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 19 2009

The Honorable Joe Biden
President of the Senate
United States Senate
Washington, DC 20510

Dear Mr. President:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the second report the Food and Drug Administration (FDA) has submitted under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the Act). The report covers fiscal year 2008 and summarizes how the FDA has met each of the conditions specified in Section 712(e) of the Act, in response to this statutory requirement.

I hope you will find the report useful and informative.

Sincerely,

/S/

Kathleen Sebelius

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 19 2009

The Honorable Joe L. Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, DC 20510

Dear Mr. Barton

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the second report the Food and Drug Administration (FDA) has submitted under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the Act). The report covers fiscal year 2008 and summarizes how the FDA has met each of the conditions specified in Section 712(e) of the Act, in response to this statutory requirement.

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Sincerely,

/S/

Kathleen Sebelius

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 19 2009

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the second report the Food and Drug Administration (FDA) has submitted under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the Act). The report covers fiscal year 2008 and summarizes how the FDA has met each of the conditions specified in Section 712(e) of the Act, in response to this statutory requirement.

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Sincerely,

/S/

Kathleen Sebelius

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 19 2009

The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Senator Enzi:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the second report the Food and Drug Administration (FDA) has submitted under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the Act). The report covers fiscal year 2008 and summarizes how the FDA has met each of the conditions specified in Section 712(e) of the Act, in response to this statutory requirement.

I hope you will find the report useful and informative.

Sincerely,

/S/

Kathleen Sebelius

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 19 2009

The Honorable Henry A. Waxman
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, DC 20510

Dear Mr. Chairman:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the second report the Food and Drug Administration (FDA) has submitted under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the Act). The report covers fiscal year 2008 and summarizes how the FDA has met each of the conditions specified in Section 712(e) of the Act, in response to this statutory requirement.

I hope you will find the report useful and informative.

Sincerely,

/S/

Kathleen Sebelius

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 19 2009

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515

Dear Madam Speaker:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the second report the Food and Drug Administration (FDA) has submitted under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the Act). The report covers fiscal year 2008 and summarizes how the FDA has met each of the conditions specified in Section 712(e) of the Act, in response to this statutory requirement.

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Sincerely,

/S/

Kathleen Sebelius

Enclosure

Report to Congress

**FDA Amendments Act of 2007
Section 712 (e) of the Federal Food, Drug, and Cosmetic Act**

**Fiscal Year 2008 Annual Report on FDA Advisory Committee
Vacancies and Public Disclosures**

**Department of Health and Human Services
Food and Drug Administration
March 2009**

Submit to HHS for review and concurrence before final signature:

_____/s/_____
Frank M. Torti, M.D., MPH
Acting Commissioner of Food and Drugs

Date 3/6/09

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Background

Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the Act)¹ requires FDA to report annually on its advisory committee vacancies and public disclosures of information. Specifically, Section 712(e) requires a report that describes:

- (1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;*
- (2) with respect to such year, the aggregate number of disclosures required under subsection (c)(3) [Section 712(c)(3)] for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;*
- (3) with respect to such year, the number of times the disclosures required under subsection (c)(3) [Section 712(c)(3)] occurred under subparagraph (B) of such subsection; and*
- (4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.*

Reporting Period

This report covers the period from October 1, 2007, through September 30, 2008. Because Section 712(e) went into effect October 1, 2007,² and requires new collections of data, some responsive data was not available for the FY 2007 report. FDA has been tracking all responsive data since the effective date, and is submitting a complete report for FY 2008.

Scope of the FY 2008 Annual Report

In response to the information to be reported under Section 712(e)(1), Table 1 presents the data on the number of vacancies, the number of nominees received³ and the number of such nominees willing to serve⁴ in FY 2008, for each advisory committee.

¹ 21 U.S.C. 379d-1(e). This annual report requirement was added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), signed into law on September 27, 2007. Title VII of FDAAA added new conflict of interest provisions applicable to FDA advisory committees. These provisions became effective on October 1, 2007.

² See footnote 1.

³ FDA considers a nomination as “received” when the submission includes all of the following information for the nominee: a complete *curriculum vitae*, a current business address and telephone number, the advisory committee(s) or advisory panel(s) for which the nominee is recommended, and a written confirmation that the nominee is aware of the nomination.

⁴ See Section 712(c)(3)(B) of the Act. The nominees that FDA received were counted as “willing to serve” if a review of the submission indicated that the nominee appeared to meet qualifications to serve and the nominee confirmed his/her willingness to serve after being contacted by FDA and informed of the committee requirements for service, including conflict of interest requirements.

The number of vacancies on an FDA advisory committee may vary within any given year depending on when openings are filled and when new vacancies occur. In order to provide a complete picture of this dynamic process, FDA listed the sum of the number of vacancies for each advisory committee existing at the start of FY 2007 and the number of vacancies that occurred during FY 2008. FDA also shows the number of these vacancies that were filled during FY 2008. *See* Table 1.

Table 1- 712(e)(1) Pre-existing Vacancies, New Vacancies, Nominees Received and Nominees Willing to Serve (FDAAA Report)

Advisory Committee Name (by Office/Center)	Reporting Period (10/1/2007-9/30/08)				Nominees Received (10/01/07-9/30/08)	Nominees Willing to Serve (10/1/07-9/30/08)
	Vacancies on 9/30/07	New Vacancies during reporting period (10/01/07- 9/30/08)	Vacancies Filled (10/01/07-9/30/08)	Vacancies as of 9/30/08		
OFFICE OF THE COMMISSIONER	19	19	25	13	59	48
Science Board to the FDA	2	13	5	10	18	18
Pediatric Advisory Committee	2	5	4	3	25	25
Risk Communication Advisory Committee	15	1	16	0	16	5
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	14	20	21	13	62	44
Allergenic Products	4	3	3	4	10	8
Blood Products	1	6	7	0	15	9
Cellular, Tissue, & Gene Therapies	1	3	0	4	13	8
Transmissible Spongiform Encephalopathies	4	3	6	1	9	8
Vaccines and Related Biological Products	4	5	5	4	15	11
CENTER FOR DRUG EVALUATION AND RESEARCH	57	82	48	91	240	51
Anesthetic and Life Support Drugs	8	4	9	3	14	9
Anti-Infective Drugs	4	3	1	6	4	1
Antiviral Drugs	0	4	4	0	5	4
Arthritis	2	4	3	3	5	3
Cardiovascular and Renal Drugs	3	5	4	4	42	4
Dermatologic and Ophthalmic Drugs	11	4	2	13	8	2
Drug Safety and Risk Management	6	2	2	6	7	2
Endocrinologic and Metabolic Drugs	4	3	5	2	7	5
Gastrointestinal Drugs	2	5	1	6	1	1
Nonprescription Drugs	5	6	1	10	11	1
Oncologic Drugs	3	5	4	4	108	4
Peripheral and Central Nervous System Drugs	0	3	1	2	5	4
Pharmaceutical Science and Clinical Pharmacology	2	21	5	18	11	5
Psychopharmacologic Drugs	3	5	4	4	10	4
Pulmonary-Allergy Drugs	1	6	1	6	1	1
Reproductive Health Drugs	3	2	1	4	1	1
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	6	4	0	10	38	20
Food Advisory Committee	6	4	0	10	38	20
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	63	42	34	71	113	53
Device Good Manufacturing Practice Advisory Committee	9	0	0	9	4	0

Advisory Committee Name (by Office/Center)	Vacancies on 9/30/07	New Vacancies during reporting period 10/01/07- 9/30/08)	Vacancies Filled (10/01/07-9/30/08)	Vacancies as of 9/30/08	Nominees Received (10/01/07-9/30/08)	Nominees Willing to Serve (10/1/07-9/30/08)
Medical Devices Advisory Committee (Comprised of 18 Panels)						
- Anesthesiology and Respiratory Therapy Devices Panel	5	3	8	0	0	0
- Circulatory System Devices Panel	4	4	4	4	7	5
- Clinical Chemistry and Clinical Toxicology Devices Panel	0	2	2	0	3	2
- Dental Products Panel	2	3	2	3	5	5
- Ear, Nose, and Throat Devices Panel	0	1	0	1	9	0
- Gastroenterology-Urology Devices Panel	3	0	3	0	0	0
- General and Plastic Surgery Devices Panel	5	1	0	6	9	4
- General Hospital and Personal Use Devices Panel	0	0	0	0	0	0
- Hematology and Pathology Devices Panel	3	3	3	3	0	2
- Immunology Devices Panel	2	4	2	4	6	6
- Medical Devices Dispute Resolution Panel	1	2	0	3	1	0
- Microbiology Devices Panel	4	0	0	4	2	2
- Molecular and Clinical Genetics Panel	5	3	4	4	13	9
- Neurological Devices Panel	0	2	0	2	0	0
- Obstetrics-Gynecology Devices	3	2	2	3	18	0
- Ophthalmic Devices Panel	0	1	1	0	1	0
- Orthopedic and Rehabilitation Devices Panel	2	2	0	4	18	12
- Radiological Devices Panel	0	3	3	0	6	0
National Mammography Quality Assurance Advisory Committee	0	6	0	6	11	6
Technical Electronic Product Radiation Safety Standards Committee	15	0	0	15	0	0
CENTER FOR VETERINARY MEDICINE	6	5	0	11	113	105
Veterinary Medicine Advisory Committee	6	5	0	11	113	105
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	3	2	4	1	4	4
Science Advisory Board to the National Center for Toxicological Research	3	2	4	1	4	4
Total for all FDA Advisory Committees	168	174	132	210	629	325

Section 712(e)(2) of the Act calls for the aggregate number of disclosures required under subsection 712(c)(3) of the Act for each FDA advisory committee meeting, and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting. Under subsection 712(c)(3), FDA is required to publicly disclose on its Web site the type, nature, and magnitude of the financial interests of each advisory committee member who receives a waiver under 18 U.S.C. 208 or Section 712(c)(2)(B), and the reasons for granting the waiver. This information is posted on FDA's Web site prior to each meeting. Table 2 presents the number of such disclosures made in FY 2008 and the percentage of individuals to whom disclosures did not apply in FY 2008.

Table 2- 712(e)(2) Number of Meetings, Participants and Waivers Granted (FDA Report)

Committee Name	Reporting Period -10/1/2007 to 9/30/08				Total meeting Participants with no waivers	% of Meeting Participants <u>Not</u> Issued Waivers
	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	Section 208(b)(1) and (b)(3) Waivers Granted *		
OFFICE OF THE COMMISSIONER		7	111	0	111	100.00%
Science Board to the FDA	12/3/2007	1	11	0	11	100.00%
	5/30/2008	1	9	0	9	100.00%
Pediatric Advisory Committee	11/27-29/07	1	22	0	22	100.00%
	3/25/2008	1	18	0	18	100.00%
Risk Communication Advisory Committee	2/28-29/08	1	18	0	18	100.00%
	5/15-16/08	1	19	0	19	100.00%
	8/14-15/08	1	14	0	14	100.00%
CENTER FOR BIOLOGICS EVALUATION & RESEARCH		7	107	5	102	95.33%
Allergenic Products						
Blood Products	5/1-2/08	1	21	1	20	95.24%
	9/10-11/08	1	20	0	20	100.00%
Cellular, Tissue, & Gene Therapies	2/5/2008	1	10	0	10	100.00%
	4/10-11/08	1	18	0	18	100.00%
Transmissible Spongiform Encephalopathies						
Vaccines and Related Biological Products	11/14/2007	1	8	0	8	100.00%
	2/20-21/08	1	17	2	15	88.24%
	9/25/2008	1	13	2	11	84.62%
CENTER FOR DRUG EVALUATION AND RESEARCH		28	397	26	371	93.45%
Anesthetic and Life Support Drugs	3/11/2008	1	11	1	10	90.91%
joint with DSaRM	5/5-6/2008	1	25	1	24	96.00%
	5/7/2008	1	11	0	11	100.00%
Anti-Infective Drugs	4/1-2/2008	1	13	0	13	100.00%
	7/16/2008	1	13	0	13	100.00%
Antiviral Drugs						
Arthritis	7/29/2008	1	11	0	11	100.00%
Cardiovascular and Renal Drugs	10/16/2007	1	14	1	13	92.86%
	12/11-12/2007	1	8	1	7	87.50%
	6/24/2008	1	18	0	18	100.00%

*In 37 cases, a waiver under section 712(c)(2)(B) was also issued.

Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	Section 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants <u>Not</u> Issued Waivers
	6/25/2008	1	11	0	11	100.00%
Dermatologic and Ophthalmic Drugs	5/29/2008	1	4	0	4	100.00%
	6/17-18/2008	1	13	0	13	100.00%
Drug Safety and Risk Management	2/1/2008	1	17	2	15	88.24%
Endocrinologic and Metabolic Drugs	7/1-2/2008	1	19	3	16	84.21%
Gastrointestinal Drugs	1/23/2008	1	15	3	12	80.00%
Nonprescription Drugs	10/18-19/2007 joint with PAC	1	22	1	21	95.45%
joint with EMDAC	12/13/2007	1	13	1	12	92.31%
	12/14/2007	1	12	1	11	91.67%
Oncologic Drugs	12/5/2007	1	9	4	5	55.56%
	3/12-13/2008	1	18	0	18	100.00%
*ped-subcommittee-Mtg. designated as General Matters thus no COI screening performed						
	4/16/2008	1	17	0	17	100.00%
	5/30/2008	1	16	2	14	87.50%
Peripheral and Central Nervous System Drugs	12/6/2007	1	13	0	13	100.00%
Pharmaceutical Science and Clinical Pharmacology	3/18-19/2008	1	16	1	15	93.75%
	7/22-23/2008	1	12	1	11	91.67%
Psychopharmacologic Drugs	2/6/2008	1	11	3	8	72.73%
	7/10/2008	1	21	0	21	100.00%
Pulmonary-Allergy Drugs						
Reproductive Health Drugs	9/8/2008	1	14	0	14	100.00%
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		0	0	0	0	0.00%
Food Advisory Committee		0	0	0	0	0.00%
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		11	158	16	142	89.87%
Device Good Manufacturing Practice Advisory Committee					0	
Medical Devices Advisory Committee (Comprised of 18 Panels)					0	
- Anesthesiology and Respiratory Therapy Devices Panel	6/12/2008	1	16	0	16	100.00%
- Circulatory System Devices Panel	10/10-11/2007	1	23	6	17	73.91%
	11/29-30/2007	1	19	3	16	84.21%
- Clinical Chemistry and Clinical Toxicology Devices Panel						
- Dental Products Panel						
- Ear, Nose, and Throat Devices Panel						
- Gastroenterology-Urology Devices Panel	6/25/2008	1	10	0	10	100.00%
- General and Plastic Surgery Devices Panel						
- General Hospital and Personal Use Devices Panel						

Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	Section 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants <u>Not</u> Issued Waivers
- Hematology and Pathology Devices Panel	7/18/2008	1	11	1	10	90.91%
- Immunology Devices Panel						
- Medical Devices Dispute Resolution Panel						
- Microbiology Devices Panel						
- Molecular and Clinical Genetics Panel						
- Neurological Devices Panel						
- Obstetrics-Gynecology Devices	12/13-14/2007	1	15	0	15	100.00%
- Ophthalmic Devices Panel	4/25/2008	1	10	1	9	90.00%
	6/10/2008	1	11	3	8	72.73%
- Orthopedic and Rehabilitation Devices Panel	7/15/2008	1	10	0	10	100.00%
- Radiological Devices Panel	3/4-5/2008	1	21	1	20	95.24%
National Mammography Quality Assurance Advisory Committee	11/5/2007	1	12	1	11	91.67%
Technical Electronic Product Radiation Safety Standards Committee						
CENTER FOR VETERINARY MEDICINE		0	0	0	0	0.00%
Veterinary Medicine Advisory Committee		0	0	0	0	0.00%
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		1	8	0	8	100.00%
Science Advisory Board to the National Center for Toxicological Research	8/12-13/08	1	8	0	8	100.00%
Total for all FDA Advisory Committees		54	781	47	734	93.98%
* Not including Industry Representatives, FDA Employees, or Guest Speakers						

Under Section 712(e)(3) of the Act, FDA is to provide the number of times a financial interest triggering the public disclosure requirement became known to FDA less than 30 days prior to an advisory committee meeting and the applicable disclosure was posted to FDA's Web site less than 15 days prior to the meeting.⁵ There were no disclosures posted less than 15 days prior to the meeting for FY 2008.

⁵ See Section 712(c)(3)(B) of the Act.

Pursuant to Section 712(e)(4) of the Act, FDA describes below its plans to reduce the number of vacancies on advisory committees and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by FDA as academicians or practitioners.

FDA takes a variety of actions to help find as broad a selection of advisory committee candidates as possible and include qualified experts with the fewest potential conflicts of interest. FDAAA added new requirements for recruiting potential members and evaluating their expertise and potential for financial conflicts of interest. FDA requests nominees under consideration for appointment to FDA advisory committees to complete confidential disclosure reports (using either FDA Form 3410 or OGE - 450) so that FDA may evaluate the individual's potential for financial conflicts of interest as well as their expertise prior to the final selection for appointment.

Under Section 712(b)(1)(A), FDA is to take into account the advisory committees with the greatest number of vacancies, and develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups. FDA is also directed to seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. The statute lists a number of suggested recruitment activities.

With these strategies in mind, the agency is currently employing the following outreach practices:

- FDA regularly notifies the public about vacancies on advisory committees through *Federal Register* Notices approximately four times annually. Many professional societies use these notices to share news of potential vacancies among interested professionals. In FY 2008, FDA issued six such notices.
- A staff member in FDA's Advisory Committee Oversight and Management Staff (ACOMS), Office of the Commissioner, has been given the responsibility to serve as the liaison and point of contact for information regarding the agency's advisory committee recruitment activities, vacancies, and nominations. The liaison contacts local, state, and federal authorities, organizations, and universities to discuss strategies for effective outreach and recruitment within those settings.
- In February 2007, FDA launched on its Web site a link to advisory committee information and available vacancies for individuals interested in advisory committee membership. The Web site is updated monthly. Individuals may submit their *curriculum vitae* and nomination information directly to FDA's ACOMS e-mail box and receive prompt acknowledgement of their application. During FY 2008, more than 516 individuals submitted their professional information to the Web site and indicated interest in serving on FDA advisory committees.

- Current and retiring committee members, familiar with conflict of interest rules and regulations, are communicating with fellow colleagues to recruit new members.
- FDA utilizes new member advisory committee training and updates to encourage current members to recruit and nominate potential candidates.
- FDA utilizes professional and FDA List Serves to inform interested parties of vacancies on its committees.
- FDA is continuing to distribute brochures containing advisory committee information and criteria for membership at advisory committee meetings, training sessions, and professional scientific meetings. During this reporting period, FDA Centers attended the American Society of Clinical Oncology and the American Association of Orthopedic Surgeons professional meetings.
- FDA advisory committee staff also contacted numerous professional organizations to seek individuals with pertinent expertise; including the American Registry of Radiologic Technologists, the American College of Radiology, and the American Association of Physicists in Medicine.
- FDA Centers and advisory committee staff participate in both FDA and organization-sponsored scientific training sessions and request nominations for potential candidates.