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

February 29, 2012

The Honorable Joseph R. Biden, Jr.
President
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 fifth 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 2011 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.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Enclosure

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

February 29, 2012

The Honorable Fred Upton
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Attached is the annual report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the fifth 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 2011 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.

Sincerely,

Kathleen Sebelius

Enclosure

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

February 29, 2012

The Honorable Tom Harkin
Chairman
Committee on Health, Education,
Labor and Pensions
United States Senate
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 fifth 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 2011 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.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Enclosure

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

February 29, 2012

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 fifth 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 2011 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.

Sincerely,

Kathleen Sebelius

Enclosure

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

February 29, 2012

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Waxman:

Attached is the annual report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the fifth 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 2011 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.

Sincerely,

Kathleen Sebelius

Enclosure

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

February 29, 2012

The Honorable John Boehner
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Attached is the annual report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. This is the fifth 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 2011 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.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Enclosure

Report to Congress

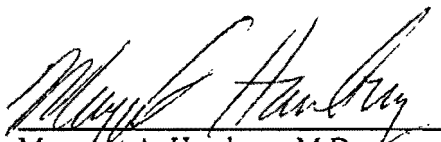
Food and Drug Administration Amendments Act of 2007
Section 712 (e) of the Federal Food, Drug, and Cosmetic Act

Fiscal Year 2011 Annual Report on FDA Advisory Committee Vacancies and Public Disclosures

Department of Health and Human Services

Food and Drug Administration

Submit to HHS for review and concurrence before final signature:



Date 2/2/12

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

EXECUTIVE SUMMARY

This report of the Food and Drug Administration Amendments Act of 2007, Section 712(e) of the Federal Food, Drug, and Cosmetic Act, provides the information required by the Food and Drug Administration (FDA) on its advisory committee vacancies and public disclosures of information for fiscal year 2011.

This report describes the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of nominees willing to serve; the aggregate number of waiver disclosures for each meeting of each advisory committee and the percentage of individuals who served on a committee for each meeting, to whom waiver disclosures did not apply; and how the Secretary plans to reduce the number of vacancies and mechanisms to encourage the nomination of individuals for service on an advisory committee.

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Background

Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)[1] requires the Food and Drug Administration (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, 2010, through September 30, 2011.

Scope of the FY 2011 Annual Report

In response to the information to be reported under section 712(e)(1), Table 1 (on page 2) presents the data on the number of vacancies, the number of nominees received[2] and the number of such nominees willing to serve[3] in FY 2011, for each advisory committee.

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[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, effective October 1, 2007.

[2] FDA considers a nomination as "received" when the submission includes all of the following information for the nominee: complete *curriculum vitae*, a current 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.

[3] *See* section 712(c)(3)(B) of the FD&C 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 lists the total number of vacancies for each advisory committee at the start of FY 2011, the number of new vacancies during FY 2011, and the number of these vacancies filled during FY 2011. *See* Table 1.

Table 1 - 712(e)(1) Pre-existing Vacancies, New Vacancies, Nominees Received and Nominees Willing To Serve FY 2011

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/10	New Vacancies during reporting period (10/01/10-9/30/11)	Vacancies Filled (10/01/10-9/30/11)	Vacancies as of 9/30/11	Nominees Received (10/01/10-9/30/11)	Nominees Willing to Serve (10/1/10-9/30/11)
Total All Centers	**160**	**125**	**169**	**116**	**638**	**301**
Advisory Committee Name (by Office/Center)	**Vacancies as of 9/30/10**	**New Vacancies during reporting period (10/01/10-9/30/11)**	**Vacancies Filled (10/01/10-9/30/11)**	**Vacancies as of 9/30/11**	**Nominees Received (10/01/10-9/30/11)**	**Nominees Willing to Serve (10/01/10-9/30/11)**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Science Board to the FDA	5	4	6	3	67	7
FDA Pediatric AC	4	3	2	5	11	5
Risk Communication Advisory Committee	0	4	4	0	15	1
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Allergenic Products	1	1	1	1	7	2
Blood Products	6	4	6	4	26	12
Cellular, Tissue, & Gene Therapies	1	3	2	2	26	3
Transmissible Spongiform Encephalopathies	10	0	8	2	18	9
Vaccines and Related Biological Products	1	3	3	1	24	4
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Anesthetic and Life Support Drugs	3	4	0	7	11	3
Anti-Infective Drugs	2	3	3	2	7	4
Antiviral Drugs	0	4	4	0	34	5
Arthritis	2	3	0	5	9	2
Cardiovascular and Renal Drugs	3	2	0	5	16	9
Dermatologic and Ophthalmic Drugs	4	3	4	3	15	15
Drug Safety and Risk Management	9	3	12	0	13	0
Endocrinologic and Metabolic Drugs	5	3	6	2	11	11
Gastrointestinal Drugs	4	1	2	3	6	2
*Medical Imaging Drugs	0	12	0	12	4	0
Nonprescription Drugs	6	2	0	8	6	8
Oncologic Drugs	4	4	5	3	31	27
Peripheral and Central Nervous System Drugs	1	3	0	4	10	9
Pharmaceutical Science and Clinical Pharmacology	7	5	4	8	9	3

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/10	New Vacancies during reporting period (10/01/10-9/30/11)	Vacancies Filled (10/01/10-9/30/11)	Vacancies as of 9/30/11	Nominees Received (10/01/10-9/30/11)	Nominees Willing to Serve (10/01/10-9/30/11)
Psychopharmacologic Drugs	3	3	5	1	7	7
Pulmonary-Allergy Drugs	4	5	9	0	5	3
Reproductive Health Drugs	5	1	1	5	6	5
[redacted]						
Device Good Manufacturing Practice Advisory Committee	7	0	7	0	0	0
Medical Devices Advisory Committee (Comprised of 18 Panels)						
- Anesthesiology and Respiratory Therapy Devices Panel	0	3	2	1	5	2
- Circulatory System Devices Panel	1	3	4	0	11	7
- Clinical Chemistry and Clinical Toxicology Devices Panel	2	3	5	0	5	5
- Dental Products Panel	2	1	3	0	3	1
- Ear, Nose, and Throat Devices Panel	4	2	6	0	4	3
- Gastroenterology-Urology Devices Panel	0	0	0	0	12	5
- General and Plastic Surgery Devices Panel	1	2	2	1	33	13
- General Hospital and Personal Use Devices Panel	0	5	4	1	4	3
- Hematology and Pathology Devices Panel	0	1	1	0	12	9
- Immunology Devices Panel	1**	3	2	2	2	1
- Medical Devices Dispute Resolution Panel	3	0	3	0	0	0
- Microbiology Devices Panel	2	0	2	0	18	13
- Molecular and Clinical Genetics Panel	3	2	4	1	2	2
- Neurological Devices Panel	8	0	7	1	3	3
- Obstetrics-Gynecology Devices	1	1	2	0	12	11
- Ophthalmic Devices Panel	7	1	6	2	3	3
- Orthopedic and Rehabilitation Devices Panel	0	0	0	0	7	4
- Radiological Devices Panel	2	3	5	0	14	9
National Mammography Quality Assurance Advisory Committee	5	2	7	0	1	1
Technical Electronic Product Radiation Safety Standards Committee	15	0	2	13	40	25

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/09	New Vacancies during reporting period (10/01/09-9/30/10)	Vacancies Filled (10/01/09-9/30/10)	Vacancies as of 9/30/10	Nominees Received (10/01/09-9/30/10)	Nominees Willing to Serve (10/1/09-9/30/10)
Food Advisory Committee	1	3	4	0	11	8
Veterinary Medicine Advisory Committee	2	4	0	6	26	1
Science Advisory Board to the National Center for Toxicological Research	3	0	3	0	7	7
Tobacco Products Scientific Advisory Committee	0	3	1	2	9	9

*In March FDA announced the re-establishment of the Medical Imaging Drugs Advisory Committee. Nominations are still being received and considered to fill vacancies on this committee.
**Number of "vacancies for 9/30/10" for this committee was reported incorrectly for FY 2010. The correct number was 1.

Section 712(e)(2) of the FD&C Act calls for an annual report of the aggregate number of waiver disclosures required under section 712(c)(3) for each advisory committee meeting and the percent of advisory committee members to whom such disclosures did not apply who served on such committee for each such meeting. Under section 712(c)(3), FDA is required to publicly disclose on its website the type, nature, and magnitude of the financial interests of each advisory committee member who receives a waiver under the Federal conflict of interests laws[4] that apply to all advisory committees or under FDAAA,[5] and the reasons for granting the waiver.[6] This information is posted on FDA's website prior to each meeting. Table 2 presents the number of waiver disclosures made in FY 2011 and the percentage of individuals to whom disclosures did not apply in FY 2011.

Table 2 - 712(e)(2) Number of Meetings, Participants and Waivers Granted FY 2011

Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	Section 208(b)(1) and (b)(3) Waivers Granted	712(c)(2)(B) Waivers granted	Total meeting Participants with no Waivers	% of Meeting Participants Not Issued Waivers
TOTAL		86	1337	11	7	1326	99.17%

* Not including Industry Representatives, FDA Employees or Guest Speakers

[4] 18 U.S.C. 208
[5] 712(c)(2)(B), 21 USC 379d-1(c)(2)(B)
[6] A waiver under 18 USC 208(b)(1) may be granted for an employee if the financial interest is not so substantial as to be deemed likely to affect the integrity of the employee's services. A waiver under 18 USC 208(b)(3) may be granted for a special governmental employee serving on a federal advisory committee if the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. Under FDAAA, 21 USC 379d-1(c)(2) a waiver may be granted if necessary to afford the advisory committee essential expertise.

Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	Section 208(b)(1) and (b)(3) Waivers Granted	712(c)(2)(B) Waivers granted	Total meeting Participants with no Waivers	% of Meeting Participants Not Issued Waivers
[illegible]							
Science Board to the FDA	11/15/2010	1	14	0	0	14	100.00%
Science Board to the FDA	5/20/2011	1	13	0	0	13	100.00%
Science Board to the FDA	8/19/2011	1	15	0	0	15	100.00%
Pediatric	12/6-7/10	1	16	0	0	16	100.00%
Pediatric	5/11/11	1	13	0	0	13	100.00%
Pediatric	5/16/11	1	18	0	0	18	100.00%
Pediatric	9/22-23/11	1	19	0	0	19	100.00%
Risk Communication	11/8-9/10	1	12	1	1	11	91.67%
Risk Communication	5/5/11	1	14	0	0	14	100.00%
Risk Communication	8/15-16/11	1	15	1	1	14	93.33%
[illegible]							
Allergenic Products	5/12/11	1	11	0	0	11	100.00%
Blood Products	12/14-15/10	1	15	0	0	15	100.00%
Blood Products	4/28-29/11	1	14	0	0	14	100.00%
Blood Products	8/2-3/11	1	14	0	0	14	100.00%
Cellular Tissue & Gene Therapies	11/19/10	1	13	0	0	13	100.00%
Cellular Tissue & Gene Therapies	12/14/10	1	9	0	0	9	100.00%
Cellular Tissue & Gene Therapies	5/31/11	1	12	0	0	12	100.00%
Cellular Tissue & Gene Therapies	6/29/11	1	19	1	1	18	94.74%
Cellular Tissue & Gene Therapies	9/22-23/11	1	25	0	0	25	100.00%
Transmissible Spongiform Encephalopathies	10/28-29/10	1	15	0	0	15	100.00%
Transmissible Spongiform Encephalopathies	8/1/11	1	16	0	0	16	100.00%
Vaccines and Related Biologics	11/16-17/10	1	19	0	0	19	100.00%
Vaccines and Related Biologics	2/25/11	1	17	0	0	17	100.00%
Vaccines and Related Biologics	4/6-7/11	1	13	0	0	13	100.00%
Vaccines and Related Biologics	9/20/11	1	12	0	0	12	100.00%
[illegible]							
Anesthetic and Life Support Drugs	10/21-22/10	1	18	0	0	18	100.00%
Anesthetic and Life Support Drugs	3/10/11	1	26	0	0	26	100.00%
Anti-Infective Drugs	4/5/11	1	13	0	0	13	100.00%
Antiviral Drugs	4/27/11	1	18	0	0	18	100.00%
Antiviral Drugs	4/28/11	1	18	0	0	18	100.00%
Arthritis	11/16/10	1	15	0	0	15	100.00%
Arthritis	6/21/11	1	12	0	0	12	100.00%
Cardiovascular and Renal Drugs	10/18/10	1	17	0	0	17	100.00%
Cardiovascular and Renal Drugs	12/8/10	1	12	0	0	12	100.00%
Cardiovascular and Renal Drugs	5/2/11	1	23	0	0	23	100.00%
Cardiovascular and Renal Drugs	9/8/11	1	12	0	0	12	100.00%
Dermatologic and Ophthalmic Drugs	6/17/11	1	10	0	0	10	100.00%

Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	Section 208(b)(1) and (b)(3) Waivers Granted	712(c)(2)(B) Waivers granted	Total meeting Participants with no Waivers	% of Meeting Participants Not Issued Waivers
Drug Safety and Risk Management	N/A	0	0	0	0	0	N/A
Endocrinologic and Metabolic Drugs	12/7/10	1	20	0	0	20	100.00%
Endocrinologic and Metabolic Drugs	5/19/11	1	13	0	0	13	100.00%
Endocrinologic and Metabolic Drugs	7/19/11	1	15	1	0	14	93.33%
Gastrointestinal Drugs	11/4/10	1	15	0	0	15	100.00%
Gastrointestinal Drugs	11/5/10	1	22	1	1	21	95.45%
Gastrointestinal Drugs	1/12/11	1	12	0	0	12	100.00%
Gastrointestinal Drugs	7/20/11	1	18	0	0	18	100.00%
Gastrointestinal Drugs	7/21/11	1	15	2	2	13	86.67%
Medical Imaging Drugs	N/A	0	0	0	0	0	N/A
Nonprescription Drugs	5/17-18/11	1	23	0	0	23	100.00%
Oncologic Drugs	11/30/10	1	16	0	0	16	100.00%
Oncologic Drugs	12/1/10	1	19	0	0	19	100.00%
Oncologic Drugs	12/2/10	1	10	0	0	10	100.00%
Oncologic Drugs	2/8/11	1	15	0	0	15	100.00%
Oncologic Drugs	4/12/11	1	10	0	0	10	100.00%
Oncologic Drugs	7/14/11	1	11	0	0	11	100.00%
Oncologic Drugs	9/14/11	1	20	0	0	20	100.00%
Peripheral and Central Nervous System Drugs	11/3/10	1	30	0	0	30	100.00%
Peripheral and Central Nervous System Drugs	1/20-21/11	1	23	0	0	23	100.00%
Peripheral and Central Nervous System Drugs	3/10/11	1	14	2	0	12	85.71%
Pharmaceutical Science and Clinical Pharmacology	3/2/11	1	14	0	0	14	100.00%
Pharmaceutical Science and Clinical Pharmacology	7/26/11	1	13	0	0	13	100.00%
Pharmaceutical Science and Clinical Pharmacology	7/27/11	1	12	0	0	12	100.00%
Psychopharmacologic Drugs	N/A			0	0	0	N/A
Pulmonary-Allergy Drugs	3/8/11	1	17	0	0	17	100.00%
Pulmonary-Allergy Drugs	6/23/11	1	13	0	0	13	100.00%
Reproductive Health Drugs	9/9/11	1	23	0	0	23	100.00%
[redacted]							
Device Good Manufacturing Practice Advisory Committee	N/A	0	0	0	0	0	N/A
Medical Devices Advisory Committee (Comprised of 18 Panels)							
- Anesthesiology and Respiratory Therapy Devices Panel	N/A	0	0	0	0	0	N/A
- Circulatory System Devices Panel	1/25-26/11	1	22	0	0	22	100.00%
- Circulatory System Devices Panel	7/20-21/11	1	24	1	0	23	95.83%
- Clinical Chemistry and Clinical Toxicology Devices Panel	N/A	0	0	0	0	0	N/A
- Dental Products Panel	12/14-15/10	1	20	0	0	20	100.00%
- Ear, Nose, and Throat Devices Panel	N/A						N/A

Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	Section 208(b)(1) and (b)(3) Waivers Granted	712(c)(2)(B) Waivers granted	Total meeting Participants with no Waivers	% of Meeting Participants Not Issued Waivers
- Gastroenterology-Urology Devices Panel	12/2-3/10	1	15	1	1	14	93.33%
- General and Plastic Surgery Devices Panel	11/18/10	1	19	0	0	19	100.00%
- General and Plastic Surgery Devices Panel	4/27/11	1	10	0	0	10	100.00%
- General and Plastic Surgery Devices Panel	8/30-31/11	1	16	0	0	16	100.00%
- General Hospital and Personal Use Devices Panel	N/A	0	0	0	0	0	N/A
- Hematology and Pathology Devices Panel	N/A	0	0	0	0	0	N/A
- Immunology Devices Panel	N/A	0	0	0	0	0	N/A
- Medical Devices Dispute Resolution Panel	N/A	0	0	0	0	0	N/A
- Microbiology Devices Panel	6/29/11	1	16	0	0	16	100.00%
- Molecular and Clinical Genetics Panel	3/8-9/11	1	20	0	0	20	100.00%
- Neurological Devices Panel	10/8/10	1	18	0	0	18	100.00%
Neurological Devices Panel	1/27-28/11	1	17	0	0	17	100.00%
Neurological Devices Panel	3/17-18/11	1	18	0	0	18	100.00%
- Obstetrics-Gynecology Devices	9/8-9/11	1	17	0	0	17	100.00%
- Ophthalmic Devices Panel	N/A	0	0	0	0	0	N/A
- Orthopedic and Rehabilitation Devices Panel	5/12/11	1	21	0	0	21	100.00%
- Radiological Devices Panel	N/A	0	0	0	0	0	N/A
National Mammography Quality Assurance Advisory Committee	N/A	0	0	0	0	0	N/A
Technical Electronic Product Radiation Safety Standards Committee	N/A	0	0	0	0	0	N/A
[redacted]							
Food Advisory Committee	3/30-31/11	1	14	0	0	14	100.00%
[redacted]							
Veterinary Medicine Advisory Committee	N/A	0	0	0	0	0	N/A
[redacted]							
Science Advisory Board to the National Center for Toxicological Research	10/19-20/10	1	7	0	0	7	100.00%
[redacted]							
Tobacco Products Scientific Advisory Committee	10/7/10	1	10	0	0	10	100.00%
Tobacco Products Scientific Advisory Committee	11/18/10	1	11	0	0	11	100.00%
Tobacco Products Scientific Advisory Committee	1/10-11/11	1	12	0	0	12	100.00%
Tobacco Products Scientific Advisory Committee	2/10/11	1	11	0	0	11	100.00%
Tobacco Products Constituents Subcommittee	2/11/11	1	7	0	0	7	100.00%
Tobacco Products Constituents Subcommittee	3/2/11	1	11	0	0	11	100.00%
Tobacco Products Menthol Report Subcommittee	3/17-18/11	1	9	0	0	9	100.00%
Tobacco Products Menthol Report Subcommittee	7/21-22/11	1	12	0	0	12	100.00%
*Not Including Industry Representatives, FDA Employees or Guest Speakers							

Under section 712(e)(3) of the FD&C 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 website less than 15 days prior to a meeting.[7] There were no waiver disclosures posted less than 15 days prior to a meeting for FY 2011.

As required by section 712(e)(4) of the FD&C Act, the following is a description of FDA strategies to reduce the number of vacancies on advisory committees to encourage the nomination of individuals for service on an advisory committee.

FDA uses many strategies to help identify 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 Form FDA 3410 or Form OGE[8] 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 consider 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 suggested strategies in mind, the Agency is currently employing the following outreach practices:

- FDA Advisory Committee staff participates in FDA TRACK, an agency wide performance plan that provides monthly reporting on measurable objectives on its public website. As part of that effort, the advisory committee program reports on the monthly vacancy rates by committee, as well as outreach activities. In FY 2011, FDA saw a continued reduction in the number of advisory committee membership vacancies.

- 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 2011, FDA issued eleven such notices. FDA also uses its Advisory Committee website http://www.fda.gov/AdvisoryCommittees/default.htm to display such vacancies.

- A staff member in FDA's Advisory Committee Oversight and Management Staff (ACOMS), Office of the Commissioner, serves 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.

[7] See Section 712(c)(3)(B) of the FD&C Act.
[8] Office of Government Ethics (OGE)

- An individual may submit their *curriculum vitae* and nomination information directly to FDA's ACOMS e-mailbox and receive prompt acknowledgement of their application. During FY 2011, there were more than 600 submissions to this e-mailbox.

- In FY2011, FDA's Office of Minority Health began recruitment activities targeting groups based on committee needs with a goal to enhance participation from underrepresented groups.

- Current and retiring committee members, familiar with conflict of interest rules and regulations, are encouraged to communicate with colleagues and recruit new members.

- FDA utilizes new member advisory committee training and updates to encourage current members to recruit and nominate potential candidates.

- FDA actively seeks nominees for consumer representative membership by meeting quarterly with a group of consumer-oriented organizations.

- Agency representatives met with the following organizations to solicit nominations for FDA advisory committees and to establish an effective recruitment strategy:

    1. National Medical Association
    2. National Organization for Rare Diseases
    3. National Council of Asian & Pacific Islander Physicians
    4. National Hispanic Medical Association
    5. North American Veterinary Conference
    6. International Feed Expo, Aquaculture America
    7. National Science Teacher Association
    8. Association of Minority Health Professionals
    9. Agency for Healthcare Quality Assurance.

- FDA Centers participated in over 175 outreach activities, targeting recruitment to geographical locations and committees where vacancy rates were the highest.

- FDA distributes brochures containing advisory committee information and criteria for membership at training sessions, public advisory committee meetings, and professional scientific meetings. During this reporting period, FDA representatives distributed recruitment brochures at the following professional meetings:

    1. PhARMA Blood Paradigm,San Antonio, TX
    2. Local Steering Committee of the 2011 Lesbian Gay Bisexual Transvestite (LGBT) Health Summit, Bloomington, IN
    3. American Public Health Association, Denver, CO
    4. HHS Office of Minority Health Disparities Research, Crystal City, VA
    5. Consumer Healthcare Products Association, Bethesda, MD
    6. National Hemophilia Foundation Annual Meeting, New Orleans, LA
    7. 14th US-Japan Cellular and Gene Therapy Conference, National Institutes of Health (NIH), Bethesda, MD
    8. Drug Information Association, Washington, DC
    9. National Hispanic Medical Association, Washington, D.C.
    10. National Medical Association, Washington, D.C.

- FDA publishes articles to support recruitment and outreach efforts. In FY 2011, articles appeared in the following organizations' newsletters/journals:
    1. Science in Society (July 2011)
    2. American College of Physicians (January & March 2011)
    3. American Association Allergy & Immunology (February 2011)
    4. NATURE (February 2011).

- FDA Centers and advisory committee staff participate in both FDA and other government/organization-sponsored scientific training sessions, where FDA requests nominations for potential candidates.

- FDA has an ongoing relationship with the National Institutes of Health to discuss recruitment strategies and identify experts in specialized areas of research.

- FDA has an ongoing relationship with the Victory Fund, a national Lesbian Gay Bisexual Transvestite (LGBT) coalition working with the White House's Presidential Appointees Project, to nominate more qualified LGBT individuals to the Vaccine and Related Biological Products and the Blood Products Advisory Committees.