Report to Congress

Food and Drug Administration Safety and Innovation Act of 2012

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

Fiscal Year 2013 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 1/31/14

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

EXECUTIVE SUMMARY

This report is required under Section 1142 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. FDASIA requires the Food and Drug Administration (FDA) to provide information on its advisory committee vacancies and public disclosures of information for fiscal year 2013. The reporting of information was first mandated by the Food and Drug Administration Amendments Act of 2007, section 712, and subsequently modified by FDASIA.

As required in the statute, this report describes:

- the number of persons nominated for participation at meetings for each advisory committee;
- the number of persons so nominated and willing to serve;
- the number of vacancies on each advisory committee;
- the number of persons contacted for service as members on each advisory committee meeting for each advisory committee;
- the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for such participation to constitute a disqualifying financial interest under 18 U.S.C. 208;
- the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for such participation to constitute a disqualifying financial interest under 18 U.S.C. 208;
- the number of members attending meetings for each advisory committee; and
- the aggregate number of waiver disclosures and the percentage of individuals who served on a committee for each meeting to whom waiver disclosures did not apply.

Some highlights of FY 2013 include:

- FDA reduced the total number of vacancies across all advisory committees by approximately 33 percent (136 total vacancies to 90 total vacancies);
- FDA reduced the number of vacancies across all advisory committees in the Center for Drug Evaluation and Research by approximately 30 percent (92 total vacancies to 64 total vacancies); and
- FDA granted waivers under 18 U.S.C. 208(b)(3) for fewer than 0.6 percent of meeting participants (waivers granted to only 6 out of 1186 meeting participants).

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Background

Section 712(e) of the FD&C Act[1] requires the Food and Drug Administration (FDA or Agency) to report annually on its advisory committee vacancies and public disclosures of information. Specifically, section 712(e)[2] requires a report that describes:

> *(1) IN GENERAL.—Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives, a report that describes—*
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> *(A) with respect to the fiscal year that ended on September 30 of the previous year, the number of persons nominated for participation at meetings for each advisory committee, the number of persons so nominated and willing to serve, the number of vacancies on each advisory committee, and the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;*
>
> *(B) with respect to such year, the number of persons contacted for services as members for each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;*
>
> *(C) with respect to such year, the number of members attending meetings for each advisory committee; and*
>
> *(D) with respect to such year, the aggregate number of disclosures required under subsection (d) and the percentage of individuals to whom such disclosures did not apply who served on such committee.*

Reporting Period

This report covers the period from October 1, 2012, through September 30, 2013.

Scope of the FY 2013 Annual Report

In response to the information to be reported under section 712(e)(1)(A), Table 1 presents the data on the number of vacancies, the number of nominees received,[3] and the number of nominees willing to serve[4] in FY 2013 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, and amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), effective October 1, 2012. Title VII of FDAAA added new conflict of interest provisions applicable to FDA advisory committees, effective October 1, 2007.

[2] References to "sections" in this report are to sections of the FD&C Act unless otherwise specified.

[3] FDA considers a nominee 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.

[4] *See* section 712(c)(1)(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, Table 1 lists the total number of vacancies for each advisory committee at the start of FY 2013, the number of new vacancies during FY 2013, and the number of these vacancies filled during FY 2013.

Table 1 - 712(e)(1)(A) Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing To Serve FY 2013

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/12	New Vacancies during reporting period (10/01/12- 9/30/13)	Vacancies Filled (10/01/12-9/30/13)	Vacancies as of 9/30/13	Nominees Received (10/01/12-9/30/13)	Nominees Willing to Serve (10/1/12-9/30/13)
Total All Offices/Centers	**136**	**137**	**169**	**90*** **	**622**	**313**
Advisory Committee Name (by Office/Center)	**Vacancies as of 9/30/12**	**New Vacancies during reporting period (10/01/12- 9/30/13)**	**Vacancies Filled (10/01/12- 9/30/13)**	**Vacancies as of 9/30/13**	**Nominees Received (10/01/12-9/30/13)**	**Nominees Willing to Serve (10/01/12-9/30/13)**
OFFICE OF THE COMMISSIONER	**11**	**8**	**12**	**7**	**100**	**29**
Science Board to the FDA	2	4	4	2	61	4
*Pediatric Advisory Committee	8	0	5	3	12	5
Risk Communication Advisory Committee	1	4	3	2	27	20
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	**3**	**10**	**13**	**0**	**47**	**35**
Allergenic Products	0	2	2	0	5	4
Blood Products	0	2	2	0	10	8
Cellular, Tissue, & Gene Therapies	0	3	3	0	5	4
Transmissible Spongiform Encephalopathies	3	2	5	0	9	8
Vaccines and Related Biological Products	0	1	1	0	18	11
CENTER FOR DRUG EVALUATION AND RESEARCH	**92**	**53**	**81**	**64**	**249**	**77**
Anesthetic and Life Support Drugs	2	5	6	1	16	8
Anti-Infective Drugs	1	4	4	1	26	5
Antiviral Drugs	0	1	1	0	4	4
Arthritis	2	4	0	6	6	0
Cardiovascular and Renal Drugs	4	2	4	2	35	6
Dermatologic and Ophthalmic Drugs	7	5	1	11	10	5
Drug Safety and Risk Management	3	4	7	0	17	4
Endocrinologic and Metabolic Drugs	3	2	4	1	9	3
Gastrointestinal Drugs	2	3	3	2	14	5
Medical Imaging Drugs	12	0	11	1	10	3
Nonprescription Drugs	8	4	12	0	37	12
Oncologic Drugs	6	2	8	0	9	8
Peripheral and Central Nervous System Drugs	5	2	6	1	7	0
Pharmaceutical Science and Clinical Pharmacology	11	8	1	18	14	5

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/12	New Vacancies during reporting period (10/01/12- 9/30/13)	Vacancies Filled (10/01/12- 9/30/13)	Vacancies as of 9/30/13	Nominees Received (10/01/12- 9/30/13)	Nominees Willing to Serve (10/01/12- 9/30/13)
**Pharmacy Compounding	13	0	0	13	2	0
Psychopharmacologic Drugs	4	1	2	3	14	1
Pulmonary-Allergy Drugs	4	5	5	4	15	8
Reproductive Health Drugs	5	1	6	0	4	0
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	**17**	**52**	**52**	**17**	**129**	**111**
Device Good Manufacturing Practice Advisory Committee	2	4	5	1	10	5
Medical Devices Advisory Committee (Comprised of 18 Panels)						
- Anesthesiology and Respiratory Therapy Devices Panel	0	0	0	0	5	3
- Circulatory System Devices Panel	2	3	3	2	12	5
- Clinical Chemistry and Clinical Toxicology Devices Panel	1	1	2	0	2	2
- Dental Products Panel	1	1	1	1	5	4
- Ear, Nose, and Throat Devices Panel	0	3	2	1	10	10
- Gastroenterology-Urology Devices Panel	0	4	4	0	13	13
- General and Plastic Surgery Devices Panel	2	2	4	0	4	4
- General Hospital and Personal Use Devices Panel	0	1	1	0	5	5
- Hematology and Pathology Devices Panel	0	4	4	0	4	4
- Immunology Devices Panel	0	2	1	1	0	1
- Medical Devices Dispute Resolution Panel	0	1	1	0	3	3
- Microbiology Devices Panel	2	3	3	2	7	4
- Molecular and Clinical Genetics Panel	2	2	2	2	4	5
- Neurological Devices Panel	0	2	2	0	7	5
- Obstetrics-Gynecology Devices Panel	0	3	3	0	3	3
- Ophthalmic Devices Panel	0	1	1	0	12	12
- Orthopedic and Rehabilitation Devices Panel	2	4	5	1	17	13
- Radiological Devices Panel	1	2	0	3	1	1
National Mammography Quality Assurance Advisory Committee	1	5	3	3	2	5
Technical Electronic Product Radiation Safety Standards Committee	1	4	5	0	3	4

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/12	New Vacancies during reporting period (10/01/12- 9/30/13)	Vacancies Filled (10/01/12-9/30/13)	Vacancies as of 9/30/13	Nominees Received (10/01/12-9/30/13)	Nominees Willing to Serve (10/1/12-9/30/13)
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	**3**	**5**	**7**	**1**	**65**	**55**
Food Advisory Committee	3	5	7	1	65	55
CENTER FOR VETERINARY MEDICINE	**10**	**4**	**0**	**0**	**4**	**0**
***Veterinary Medicine Advisory Committee	10	4	0	0	4	0
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**0**	**3**	**2**	**1**	**4**	**4**
Science Advisory Board to the National Center for Toxicological Research	0	3	2	1	4	4
CENTER FOR TOBACCO PRODUCTS	**0**	**2**	**2**	**0**	**24**	**2**
Tobacco Products Scientific Advisory Committee	0	2	2	0	24	2

* Pediatric Advisory Committee vacancies for 9/30/12 were reported incorrectly on FY 2012 Annual Report. The correct number was 8.

** On April 25, 2012, the charter for the Pharmacy Compounding Advisory Committee was filed, re-establishing the Committee. Announcement of the formation of the Committee and the solicitation of nominations for the 13 member vacancies was on hold pending discussions about the role of the Committee, which was described in a statutory provision under discussion in Congress for amendment. [Note: the legislation was enacted after the close of the reporting period for this report, and the agency amended the charter to reflect the new legislation and is soliciting nominations for the Committee.]

***On September 24, 2013, the charter for the Veterinary Medicine Advisory Committee was terminated.

Section 712(e)(1)(D) of the FD&C Act calls for an annual report of the aggregate number of waiver disclosures required under section 712(c) and the percentage of individuals to whom such disclosures did not apply who served on such committee. Under section 712(c), 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[5] that apply to all advisory committees, 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 individuals contacted who did not serve due to potential conflicts of interest and those who did not serve for reasons other than potential conflicts of interest. Table 2 also presents the number of waiver disclosures made in FY 2013 and the percentage of individuals to whom disclosures did not apply in FY 2013.

[5] 18 U.S.C. 208

[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 21 USC 379d-1(c)(1)(B), the reasons for a waiver determination must be disclosed, including, as appropriate, a statement concerning the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.

Table 2 - 712(e)(1)(D) Number of Meetings, Persons Contacted, Persons Contacted Who Did Not Serve, Participants, and Waivers Granted FY 2013

	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
TOTAL	78	2037	110	741	1186	6	1180	99.49%

Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants Not Issued Waivers
OFFICE OF THE COMMISSIONER		11	253	8	65	180	1	179	99.44%
Science Board to the FDA	10/3/12	1	19	0	0	19	0	19	100.00%
Science Board to the FDA	2/27/13	1	18	0	3	15	0	15	100.00%
Science Board to the FDA	6/24/13	1	18	0	3	15	0	15	100.00%
Pediatric	3/14/13	1	40	1	21	18	1	17	94.44%
Pediatric	9/19/13-9/20/13	1	37	4	16	17	0	17	100.00%
Pediatric- Neonatology Subcommittee	3/15/13	1	20	0	8	12	0	12	100.00%
Pediatric- Ethics Subcommittee	9/9/13-9/10/13	1	28	0	6	22	0	22	100.00%
Risk Communication	2/12/13	1	18	0	3	15	0	15	100.00%
Risk Communication	4/29/13-4/30/13	1	18	0	1	17	0	17	100.00%
Risk Communication (joint with TPSAC)	8/15/13	1	26	3	3	20	0	20	100.00%
Risk Communication	8/16/13	1	11	0	1	10	0	10	100.00%
CENTER FOR BIOLOGICS EVALUATION & RESEARCH		10	165	5	21	139	0	139	100.00%
Allergenic Products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Blood Products	12/4/12-12/5/12	1	25	1	6	18	0	18	100.00%
Blood Products	2/12/13	1	19	1	3	15	0	15	100.00%
Blood Products	8/2/13	1	16	0	1	15	0	15	100.00%
Cellular Tissue & Gene Therapies	11/29/12	1	13	0	0	13	0	13	100.00%
Cellular Tissue & Gene Therapies	1/15/13	1	13	0	0	13	0	13	100.00%
Cellular Tissue & Gene Therapies	4/17/13	1	14	0	4	10	0	10	100.00%
Transmissible Spongiform Encephalopathies	3/14/13	1	15	1	0	14	0	14	100.00%
Vaccines and Related Biologics	11/14/12 - 11/15/12	1	20	1	4	15	0	15	100.00%
Vaccines and Related Biologics	2/27/13	1	19	1	0	18	0	18	100.00%
Vaccines and Related Biologics	5/8/13	1	11	0	3	8	0	8	100.00%

Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants Not Issued Waivers
CENTER FOR DRUG EVALUATION AND RESEARCH		**36**	**1092**	**50**	**462**	**580**	**3**	**577**	**99.48%**
Anesthetic and Life Support Drugs	12/7/12	1	27	2	10	15	0	**15**	**100.00%**
Anti-Infective Drugs	11/2/12	1	38	1	19	18	0	**18**	**100.00%**
Anti-Infective Drugs	11/28/12	1	26	2	6	18	0	**18**	**100.00%**
Anti-Infective Drugs	11/29/12	1	29	2	12	15	0	**15**	**100.00%**
Antiviral Drugs	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**	**N/A**
Arthritis	12/20/12	1	26	0	12	14	0	**14**	**100.00%**
Arthritis	7/22/13	1	31	1	15	15	0	**15**	**100.00%**
Arthritis	7/23/13	1	31	1	16	14	0	**14**	**100.00%**
Cardiovascular and Renal Drugs	8/5/13	1	35	3	17	15	0	**15**	**100.00%**
Cardiovascular and Renal Drugs	8/6/13	1	23	2	10	11	0	**11**	**100.00%**
Dermatologic and Ophthalmic Drugs	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**	**N/A**
Drug Safety and Risk Management	12/12/12 - 12/13/12	1	48	0	23	25	0	**25**	**100.00%**
Drug Safety and Risk Management	1/24/13- 1/25/13	1	54	0	23	31	0	**31**	**100.00%**
Drug Safety and Risk Management	7/10/13	1	45	2	25	18	0	**18**	**100.00%**
Endocrinologic and Metabolic Drugs	10/17/12	1	29	2	12	15	0	**15**	**100.00%**
Endocrinologic and Metabolic Drugs	10/18/12	1	27	2	10	15	0	**15**	**100.00%**
Endocrinologic and Metabolic Drugs	11/7/12	1	18	2	6	10	0	**10**	**100.00%**
Endocrinologic and Metabolic Drugs	11/8/12	1	26	3	11	12	1	**11**	**91.67%**
Endocrinologic and Metabolic Drugs	1/10/13	1	29	2	12	15	0	**15**	**100.00%**
Endocrinologic and Metabolic Drugs (joint with DSaRM)	6/5/13- 6/6/13	1	54	1	27	26	0	**26**	**100.00%**
Gastrointestinal Drugs	10/16/12	1	30	0	18	12	0	**12**	**100.00%**
Medical Imaging Drugs	2/14/13	1	20	0	3	17	0	**17**	**100.00%**
Medical Imaging Drugs (joint w/ ODAC)	5/3/2013	1	45	2	25	18	0	**18**	**100.00%**
Nonprescription Drugs	11/9/12	1	18	0	7	11	0	**11**	**100.00%**
Nonprescription Drugs	7/31/13	1	39	1	20	18	0	**18**	**100.00%**
Oncologic Drugs (Pediatric Oncology Subcommittee)	12/4/12	1	20	4	5	11	0	**11**	**100.00%**
Oncologic Drugs	5/2/13	1	33	7	7	19	2	**17**	**89.47%**
Oncologic Drugs	9/12/13	1	26	2	10	14	0	**14**	**100.00%**
Peripheral and Central Nervous System Drugs	5/22/13	1	22	3	2	17	0	**17**	**100.00%**
Pharmacy Compounding Drugs	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**	**N/A**

Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants Not Issued Waivers
Pharmaceutical Science and Clinical Pharmacology	9/25/13	1	25	1	9	15	0	**15**	**100.00%**
Psychopharmacologic Drugs	3/21/13	1	29	1	13	15	0	**15**	**100.00%**
Pulmonary-Allergy Drugs	1/29/13	1	33	0	16	17	0	**17**	**100.00%**
Pulmonary-Allergy Drugs	1/30/13	1	24	0	9	15	0	**15**	**100.00%**
Pulmonary-Allergy Drugs	4/17/13	1	22	0	9	13	0	**13**	**100.00%**
Pulmonary-Allergy Drugs	9/10/13	1	22	0	9	13	0	**13**	**100.00%**
Reproductive Health Drugs	3/4/13	1	17	1	2	14	0	**14**	**100.00%**
Reproductive Health Drugs (Joint w/ DSaRM)	3/5/13	1	35	0	14	21	0	**21**	**100.00%**
Reproductive Health Drugs (Joint w/ DSaRM)	4/18/13	1	36	0	18	18	0	**18**	**100.00%**
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		**1**	**16**	**0**	**6**	**10**	**0**	**10**	**100.00%**
Food Advisory Committee	9/23/13-9/24/13	1	16	0	6	10	0	**10**	**100.00%**
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		**17**	**471**	**47**	**181**	**243**	**2**	**241**	**99.18%**
Device Good Manufacturing Practice Advisory Committee	4/11/13	1	8	0	2	6	0	**6**	**100.00%**
Medical Devices Advisory Committee (Comprised of 18 Panels)									
- Anesthesiology and Respiratory Therapy Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**	**N/A**
- Circulatory System Devices Panel	12/5/12-12/6/12	1	21	0	4	17	0	**17**	**100.00%**
- Circulatory System Devices Panel	3/20/13	1	36	19	5	12	2	**10**	**83.33%**
- Circulatory System Devices Panel	9/11/13-9/12/13	1	26	1	6	19	0	**19**	**100.00%**
- Clinical Chemistry and Clinical Toxicology Devices Panel	4/25/13	1	17	0	5	12	0	**12**	**100.00%**
- Dental Products Panel	7/18/13	1	31	0	21	10	0	**10**	**100.00%**
- Ear, Nose, and Throat Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**	**N/A**
- Gastroenterology-Urology Devices Panel	6/27/13	1	30	0	13	17	0	**17**	**100.00%**
- Gastroenterology-Urology Devices Panel	9/9/13	1	40	0	17	23	0	**23**	**100.00%**
- General and Plastic Surgery Devices Panel	5/2/13	1	23	2	11	10	0	**10**	**100.00%**
- General and Plastic Surgery Devices Panel	6/26/13	1	16	0	6	10	0	**10**	**100.00%**
- General Hospital and Personal Use Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**	**N/A**
- Hematology and Pathology Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**	**N/A**

Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total meeting Participants with no waivers	% of Meeting Participants Not Issued Waivers
- Immunology Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Medical Devices Dispute Resolution Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Microbiology Devices Panel	6/13/13	1	25	0	9	16	0	16	100.00%
- Molecular and Clinical Genetics Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Neurological Devices Panel	12/10/12	1	31	9	9	13	0	13	100.00%
- Neurological Devices Panel	2/22/13	1	33	7	10	16	0	16	100.00%
- Obstetrics-Gynecology Devices	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Ophthalmic Devices Panel	4/8/13	1	29	1	13	15	0	15	100.00%
- Ophthalmic Devices Panel	9/19/13	1	35	2	19	14	0	14	100.00%
- Orthopedic and Rehabilitation Devices Panel	5/21/13-5/22/13	1	37	0	17	20	0	20	100.00%
- Radiological Devices Panel	10/24/12	1	33	6	14	13	0	13	100.00%
National Mammography Quality Assurance Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Technical Electronic Product Radiation Safety Standards Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CENTER FOR VETERINARY MEDICINE		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Veterinary Medicine Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		1	9	0	0	9	0	9	100.00%
Science Advisory Board to the National Center for Toxicological Research	10/23/12 - 10/24/12	1	9	0	0	9	0	9	100.00%
CENTER FOR TOBACCO PRODUCTS		2	31	0	6	25	0	25	100.00%
Tobacco Products Scientific Advisory Committee	4/30/13	1	13	0	0	13	0	13	100.00%
Tobacco Products Scientific Advisory Committee	8/16/13	1	18	0	6	12	0	12	100.00%
TOTAL		**78**	**2037**	**110**	**741**	**1186**	**6**	**1180**	**99.49%**

*** Not including Industry Representatives, FDA Employees, or Guest Speakers**

Reducing the Number of Vacancies on Advisory Committees

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.

Under section 712(b)(1)(A), FDA is to 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 directed to seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. FDA is also expected to take into account the levels of activity (including the numbers of annual meetings) and the number of vacancies of the advisory committees. The statute lists a number of suggested recruitment activities. With these suggested strategies in mind, the Agency is currently employing the following outreach practices:

- FDASIA Sec. 712(b)(1)(c) recommends that at least every 180 days, FDA request referrals for potential members of advisory committees from a variety of stakeholders, including (i) product developers, patient groups, and disease advocacy organizations; and (ii) relevant (I) professional societies; (II) medical societies; (III) academic organizations; and (IV) governmental organizations. 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 2013, FDA issued nine such notices. FDA also uses its Advisory Committee website at http://www.fda.gov/AdvisoryCommittees/default.htm to display such vacancies.

- FDA's 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 on Agency outreach activities.

- 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.

- Individuals may submit their *curriculum vitae* and nomination information directly to FDA's ACOMS e-mailbox and receive prompt acknowledgement of their application. During FY 2013, FDA received more than 500 submissions to this e-mailbox.

- 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.

- 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. Second Annual Health Professionals' Organizations Conference hosted by the Office of Special Health Issues, FDA, Silver Spring, MD.
    2. Transcatheter Therapeutics Conference, Miami Beach, FL.
    3. Gene Therapy Symposium for Heart, Lung, and Blood Diseases, Sonoma, CA.
    4. Drug Information Association (DIA)'s Pharmacovigilance and Risk Management Strategies 2013 Conference, Washington, DC.
    5. Institute of Medicine Workshop on Genome-Based Therapeutics & Companion Diagnostic Tests, Washington, DC.
    6. FDA Center for Biologics Evaluation and Research (CBER) Workshop, "Statistical Process Controls for Blood Establishments," Silver Spring, MD.
    7. FDA CBER Workshop, "Burkholderia: Exploring Current Issues and Identifying Regulatory Science Gaps," Silver Spring, MD.
    8. The 16th U.S.-Japan Cellular and Gene Therapy Conference, Rockville, MD.
    9. International Society for Cardiovascular Translational Research: 6th Annual Symposium, San Francisco, CA.
    10. California Institute for Regenerative Medicine (CIRM) workshop, "Regulatory Pathway/Preclinical Considerations for Cell Therapy to Treat Parkinson's Disease," Berkeley, CA.
    11. Pharmaceutical- Education and Research Institute Workshop, Arlington, VA.
    12. The 2nd Annual MCMi Regulatory Science Symposium, "FDA's Medical Countermeasures Initiative," Silver Spring, MD.
    13. National Coalition for the Oversight of Assisted Reproductive Technologies meeting, "FDA Update," Arlington, VA.
    14. Eye Bank Association of America (EBAA) Annual Meeting, "FDA, Legal, and EBAA Medical Standards Panel," Chicago, IL.
    15. The Plasma Protein Therapeutics Association (PPTA) 2013 Plasma Protein Forum, Reston, VA.
    16. American Association of Family and Consumer Sciences, Houston, TX.
    17. National Hispanic Medical Association, Washington, DC.