Report to Congress

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

Fiscal Year 2016 Annual Report on FDA Advisory Committee Vacancies and Public Disclosures

Department of Health and Human Services

Food and Drug Administration

/s/ Date 1/11/17

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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) enacted in 2012, which amends section 712(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDASIA requires the Food and Drug Administration (FDA or the Agency) to provide information on its advisory committee vacancies and public disclosures of information for fiscal year (FY) 2016. The reporting 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 2016 include:

- FDA continues in its goal to decrease the vacancies on advisory committees and has a current vacancy percentage of 11 percent, which is unchanged from FY 2015 and considerably lower than FY 2008 when it was 35 percent;
- FDA granted 8 waivers (0.76 percent of total meeting participants in attendance at meetings) under 18 USC 208(b)(3), an increase from the value in FY 2015 of 0.11 percent. This rate has been 1 percent or less since FY 2009;
- FDA found that 5 percent of the total number of persons contacted to serve on an advisory committee did not participate because of the potential for conflicts of interest for such participation as determined by the Agency, a decrease from the FY 2015 value of 8 percent. (For FY 2016, 1770 total contacted; 91 not serving due to potential conflicts of interest);
- FDA received 507 applications from the Membership Nomination Portal launched in FY 2014. FDA identified 34 percent of the nominees received (173) as being qualified and willing to serve.

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Background

Section 712(e) of the FD&C Act[1] requires FDA 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—

> *(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 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 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, 2015, through September 30, 2016.

Scope of the FY 2016 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 such nominees willing to serve[4] in FY 2015, 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 authorized member positions as described in the committee charter, the total number of vacancies for each advisory committee at the end of FY 2015, the number of new vacancies during FY 2016, and the number of these vacancies filled during FY 2016, the number of nominees received to fill vacancies, and of those received, the number of nominees willing to serve that were reviewed during the reporting period.

FDA continues in its effort to decrease the number of vacancies on advisory committees and has a current vacancy percentage of 11 percent, which is unchanged from FY 2015 (see Table 1) and considerably lower than FY 2008 when it was 35 percent (see Figure 1).

To further increase the efficiency of FDA advisory committees, FDA terminated one committee and to expand committee expertise, added three Ex-Officio members to a second committee.

Table 1 - 712(e)(1)(A) Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing To Serve - FY 2016

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/15	Vacancies as of 9/30/15	New Vacancies during reporting period (10/01/15-9/30/16)	Vacancies Filled (10/01/15-9/30/16)	Authorized Membership as of 9/30/16	Vacancies as of 9/30/16	Nominees Received (10/01/15-9/30/16)	Nominees Willing to Serve (10/1/15-9/30/16)
Total All Offices/Centers	577	63 (11%)	161	161	564	63 (11%)	507	173 (34%)
Advisory Committee Name (by Office/Center)	**Authorized Membership as of 9/30/15**	**Vacancies as of 9/30/15**	**New Vacancies during reporting period (10/01/15-9/30/16)**	**Vacancies Filled (10/01/15-9/30/16)**	**Authorized Membership as of 9/30/16**	**Vacancies as of 9/30/16**	**Nominees Received (10/01/15-9/30/16)**	**Nominees Willing to Serve (10/01/15-9/30/16)**
OFFICE OF THE COMMISSIONER	**52**	**5 (9%)**	**15**	**14**	**52**	**6 (12%)**	**51**	**5 (10%)**
Science Board to the FDA	21	1	4	0	21	5	17	0
FDA Pediatric AC	16	4	5	8	16	1	10	2
Risk Communication Advisory Committee	15	0	6	6	15	0	24	3
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	**71**	**8*(11%)**	**19**	**17**	**58**	**10 (17%)**	**39**	**37 (95%)**
Allergenic Products	10	2	3	2	10	3	7	6
Blood Products	18	4	3	4	18	3	9	9
Cellular, Tissue, & Gene Therapies	14	1	5	3	14	3	8	8
*Transmissible Spongiform Encephalopathies	16	0*	0	0	0	0	0	0
Vaccines and Related Biological Products	13	1	8	8	16+	1	15	14

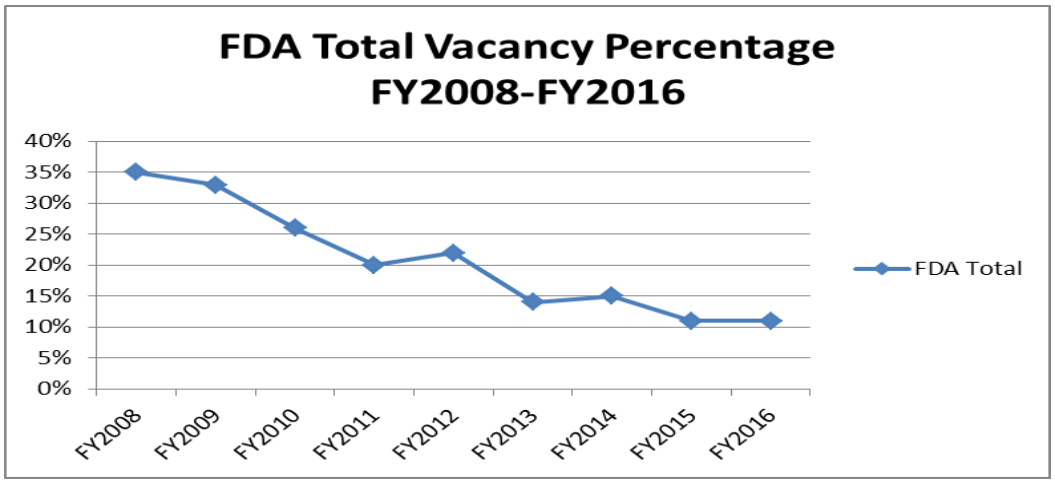
Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/15	Vacancies as of 9/30/15	New Vacancies during reporting period (10/01/15-9/30/16)	Vacancies Filled (10/01/15 9/30/16)	Authorized Membership as of 9/30/16	Vacancies as of 9/30/16	Nominees Received (10/01/15-9/30/16)	Nominees Willing to Serve (10/01/15-9/30/16)
CENTER FOR DRUG EVALUATION AND RESEARCH	**209**	**18 (9%)**	**71**	**80**	**209**	**9 (4%)**	**172**	**51 (30%)**
Advisory Committee of Pharmaceutical Science and Clinical Pharmacology	17	3	6	7	17	2	21	7
Anesthetic and Life Support Drugs	12	0	3	3	12	0	6	6
Antimicrobial Drugs formerly known as Anti-Infective Drugs	14	1	5	6	14	0	13	0
Antiviral Drugs	0	0	0	0	0	0	0	0
Arthritis	12	0	5	5	12	0	9	9
Bone, Reproductive and Urologic Drugs	12	1	3	4	12	0	3	0
Cardiovascular and Renal Drugs	12	2	4	5	12	1	13	5
Dermatologic and Ophthalmic Drugs	10	3	3	4	10	2	15	4
Drug Safety and Risk Management	12	0	4	3	12	1	28	0
Endocrinologic and Metabolic Drugs	12	1	5	6	12	0	12	4
Gastrointestinal Drugs	12	0	5	4	12	1	2	2
Medical Imaging Drugs	13	0	6	5	13	1	7	5
Nonprescription Drugs	11	0	6	6	11	0	15	6
Oncologic Drugs	14	1	5	6	14	0	7	0
Peripheral and Central Nervous System Drugs	10	0	3	3	10	0	3	3
Pharmacy Compounding	14	0	3	2	14	1	6	0
Psychopharmacologic Drugs	10	6	2	8	10	0	11	0
Pulmonary-Allergy Drugs	12	0	3	3	12	0	1	0
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	**207**	**30 (14%)**	**49**	**43**	**207**	**36 (17%)**	**182**	**70 (38%)**
Device Good Manufacturing Practice Advisory Committee	9	1	2	1	9	2	9	6
Medical Devices Advisory Committee (Comprised of 18 Panels)								
Anesthesiology and Respiratory Therapy Devices Panel	9	0	3	1	9	2	2	2
Circulatory System Devices Panel	9	1	2	3	9	0	5	5

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/15	Vacancies as of 9/30/15	New Vacancies during reporting period (10/01/15-9/30/16)	Vacancies Filled (10/01/15-9/30/16)	Authorized Membership as of 9/30/16	Vacancies as of 9/30/16	Nominees Received (10/01/15-9/30/16)	Nominees Willing to Serve (10/01/15-9/30/16)
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH Cont.								
Clinical Chemistry and Clinical Toxicology Devices Panel	9	0	1	0	9	1	1	1
Dental Products Panel	10	1	2	2	10	1	2	2
Ear, Nose, and Throat Devices Panel	9	0	0	0	9	0	2	2
Gastroenterology-Urology Devices Panel	9	0	2	2	9	0	4	4
General and Plastic Surgery Devices Panel	9	3	3	3	9	3	5	5
General Hospital and Personal Use Devices Panel	9	1	1	1	9	1	5	5
Hematology and Pathology Devices Panel	9	2	0	0	9	2	1	1
Immunology Devices Panel	9	2	4	3	9	3	2	2
Medical Devices Dispute Resolution Panel	5	0	0	0	5	0	9	9
Microbiology Devices Panel	9	0	2	0	9	2	0	0
Molecular and Clinical Genetics Panel	9	1	2	1	9	2	2	2
Neurological Devices Panel	9	1	4	3	9	2	2	2
Obstetrics-Gynecology Devices Panel	9	2	1	3	9	0	1	1
Ophthalmic Devices Panel	9	0	3	1	9	2	6	6
Orthopedic and Rehabilitation Devices Panel	9	2	3	3	9	2	5	5
Radiological Devices Panel	9	0	1	0	9	1	3	3
National Mammography Quality Assurance Advisory Committee	19	3	4	7	15	0	7	5
Patient Engagement Advisory Committee	0	9	0	0	9	9	106	0
Technical Electronic Product Radiation Safety Standards Committee	15	1	9	9	15	1	3	2
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	**17**	**1 (6%)**	**2**	**3**	**17**	**0 (0%)**	**13**	**0 (0%)**
Food Advisory Committee	17	1	2	3	17	0	13	0

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/15	Vacancies as of 9/30/15	New Vacancies during reporting period (10/01/15-9/30/16)	Vacancies Filled (10/01/15-9/30/16)	Authorized Membership as of 9/30/16	Vacancies as of 9/30/16	Nominees Received (10/01/15-9/30/16)	Nominees Willing to Serve (10/01/15-9/30/16)
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**9**	**1(11%)**	**2**	**2**	**9**	**1 (11%)**	**8**	**8 (100%)**
Science Advisory Board to the National Center for Toxicological Research	9	1	2	2	9	1	8	8
CENTER FOR TOBACCO PRODUCTS	**12**	**0 (0%)**	**3**	**2**	**12**	**1 (8%)**	**42**	**2 (5%)**
Tobacco Products Scientific Advisory Committee	12	0	3	2	12	1	42	2

*On June 9, 2016, the Transmissible Spongiform Encephalopathies Advisory Committee was terminated. The two vacancies remaining from FY 2015 were excluded from the table for computation and representation of the data for the Center for FY 2016.

[+]On December 16, 2015, the Vaccines and Related Biological Products Advisory Committee increased its voting membership from 12 to 15, by adding 3 Ex-Officio members.



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 conflicts of interest law[5] that applies 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

[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.

than potential conflicts of interest. Table 2 also presents the number of waiver disclosures made in FY 2016 and the percentage of individuals to whom disclosures did not apply in FY 2016.

Table 2 - 712(e)(1)(D) Number of Meetings, Persons Contacted, Persons Contacted Who Did Not Serve, Participants, and Waivers Granted FY 2016

		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 to 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
FDA TOTAL		**64**	**1770**	**91(5%)**	**638 (36%)**	**1049**	**8 (0.76%)**	**1041**	**99.24%**
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		**5**	**111**	**2 (2%)**	**28 (25%)**	**82**	**0 (0%)**	**82**	**100.00%**
Science Board to the Food and Drug Administration	11/18/ 2015	1	20	0	7	13	0	13	**100.00%**
Science Board to the Food and Drug Administration	3/1/2016	1	24	1	3	20	0	20	**100.00%**
Pediatric Advisory Committee	4/12/ 2016	1	22	0	3	19	0	19	**100.00%**
Pediatric Advisory Committee	9/14/ 2016	1	29	1	11	18	0	18	**100.00%**
Risk Communication Advisory Committee(RCAC)	2/16-17/2016	1	16	0	4	12	0	12	**100.00%**
CENTER FOR BIOLOGICS EVALUATION & RESEARCH		**9**	**175**	**8 (4%)**	**38 (22%)**	**129**	**1 (0.78%)**	**128**	**99.22%**
Allergenic Products	1/21/ 2016	1	12	1	1	10	0	10	**100.00%**
Blood Products	6/20/ 2016	0	14	0	4	10	0	10	**100.00%**
Cellular, Tissue and Gene Therapies//Joint Meeting with Oncologic Drugs	11/18/ 2015	1	50	2	21	27	0	27	**100.00%**
Cellular, Tissue and Gene Therapies	2/16/ 2016	1	13	0	1	12	0	12	**100.00%**
Cellular Tissue and Gene Therapy Advisory Committee	7/26/ 2016	1	11	0	2	9	0	9	**100.00%**
Cellular Tissue and Gene Therapy Advisory Committee	9/7/2016	1	11	0	1	10	0	10	**100.00%**
Vaccines and Related Biological Products	11/13/ 2015	1	20	4	3	13	1	12	**92.31%**

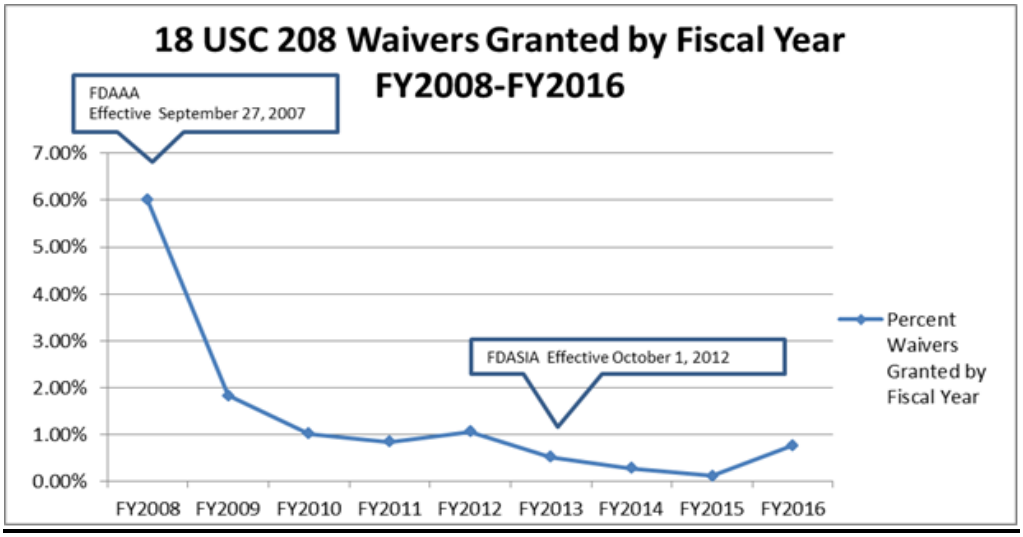
Committee Name	Meeting Date	Number of Meetings	# of persons contacted (attending and not attending)*	# of persons contacted and not serving due to potential conflicts of interest	# of persons contacted and not serving due reasons other than potential conflicts of interest	Total Number of Meeting Participants 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 BIOLOGICS EVALUATION & RESEARCH Cont.									
Vaccines and Related Biological Products	1/14/2016	1	12	0	1	11	0	11	**100.00%**
Vaccines and Related Biological Products	3/4/2016	1	22	1	4	17	0	17	**100.00%**
Vaccines and Related Biological Products	5/11/2016	1	10	0	0	10	0	10	**100.00%**
CENTER FOR DRUG EVALUATION AND RESEARCH		**36**	**1143**	**56 (5%)**	**453 (40%)**	**633**	**6 (0.95%)**	**627**	**99.05%**
Anesthetic and Analgesic Drug Products Advisory Committee	11/6/15	1	26	0	12	14	0	14	**100.00%**
Anesthetic and Analgesic Drug Products Advisory Committee	5/5/2016	1	33	3	10	20	0	20	**100.00%**
Anesthetic and Analgesic Drug Products Advisory Committee	6/7/2016	1	35	1	17	17	0	17	**100.00%**
Anesthetic and Analgesic Drug Products Advisory Committee	6/8/2016	1	33	0	18	15	0	15	**100.00%**
Anesthetic and Analgesic Drug Products Advisory Committee	8/4/2016	1	42	0	23	19	0	19	**100.00%**
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting with DSARM, and Pediatrics	9/15-16/2016	1	59	3	22	34	0	34	**100.00%**
Anti-Infective Drugs Advisory Committee (Antimicrobial Drugs)	11/5/2015	1	46	2	23	21	0	21	**100.00%**
Anti-Infective Drugs Advisory Committee (Antimicrobial Drugs)	6/9/2016	1	22	1	5	16	0	16	**100.00%**
Antiviral Drugs Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Arthritis Advisory Committee (joint w/ DSaRM)	10/23/2015	1	20	2	4	14	0	14	**100.00%**
Arthritis Advisory Committee	2/9/2016	1	39	4	9	26	0	26	**100.00%**
Arthritis Advisory Committee	7/12/2016	1	47	3	18	26	0	26	**100.00%**
Arthritis Advisory Committee	7/13/2016	1	41	5	16	20	0	20	**100.00%**
Cardiovascular and Renal Drugs Advisory Committee	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
CENTER FOR DRUG EVALUATION AND RESEARCH Cont.									
Dermatologic and Ophthalmic Drugs Advisory Committee	7/19/2016	1	50	2	30	18	0	18	**100.00%**
Drug Safety and Risk Management Advisory Committee	5/3-4/2016	1	55	2	22	30	0	30	**100.00%**
Endocrinologic and Metabolic Drugs Advisory Committee	12/14/2015	1	21	2	4	15	0	15	**100.00%**
Endocrinologic and Metabolic Drugs Advisory Committee	5/24/2016	1	34	0	17	17	0	17	**100.00%**
Endocrinologic and Metabolic Drugs Advisory Committee	5/25/2016	1	33	0	16	17	0	17	**100.00%**
Endocrinologic and Metabolic Drugs Advisory Committee	6/28/2016	1	40	2	15	23	1	22	**95.65%**
Gastrointestinal Drugs Advisory Committee (joint w/ Drug Safety and Risk Management Advisory Committee)	4/7/2016	1	32	1	14	17	0	17	**100.00%**
Nonprescription Drugs Advisory Committee	4/15/2016	1	38	1	21	16	0	16	**100.00%**
Oncologic Drugs Advisory Committee Pediatric Oncology Subcommittee	11/19/2015	1	21	4	7	10	0	10	**100.00%**
Oncologic Drugs Advisory Committee	9/14/2016	1	19	1	4	14	0	14	**100.00%**
Oncologic Drugs Advisory Committee	4/12/2016	1	20	2	4	14	0	14	**100.00%**
Pediatric Sub-Committee/ODAC	6/28-29/2016	1	25	0	9	16	4	12	**75.00%**
Peripheral and Central Nervous System Drugs Advisory Committee	11/24/2015	1	32	0	15	17	0	17	**100.00%**
Peripheral and Central Nervous System Drugs Advisory Committee	4/25/2016	1	17	1	3	13	0	13	**100.00%**
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pharmacy Compounding Advisory Committee	10/27-28/2015	1	24	0	10	14	0	14	**100.00%**
Pharmacy Compounding Advisory Committee	3/8-9/2016	1	18	0	6	12	0	12	**100.00%**
Pharmacy Compounding Advisory Committee	6/23/2016	1	17	1	4	12	0	**12**	**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 Cont.									
Psychopharmacologic Drugs Advisory Committee	12/1/2015	1	22	2	7	13	0	13	**100.00%**
Psychopharmacologic Drugs Advisory Committee	1/12/2016	1	29	1	11	17	0	17	**100.00%**
Psychopharmacologic Drugs Advisory Committee	2/3/2016	1	15	1	4	10	0	10	**100.00%**
Psychopharmacologic Drugs Advisory Committee	3/29/2016	1	27	1	12	14	0	14	**100.00%**
Psychopharmacologic Drugs Advisory Committee	9/14/2016	1	33	1	13	19	0	19	**100.00%**
Pulmonary-Allergy Drugs Advisory Committee	12/9/2015	1	22	5	3	14	0	14	**100.00%**
Pulmonary-Allergy Drugs Advisory Committee	12/10/2015	1	56	2	25	29	1	28	**96.55%**
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		**1**	**18**	**0 (0%)**	**6 (33%)**	**12**	**0 (0%)**	**12**	**100.00%**
Food Advisory Committee	12/7-8/2015	1	18	0	6	12	0	12	**100.00%**
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		**12**	**323**	**25 (7%)**	**113 (35%)**	**185**	**1 (0.54%)**	**184**	**99.46%**
Device Good Manufacturing Practice Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**
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	2/18/2016	1	22	1	7	14	0	14	**100.00%**
Circulatory System Devices Panel	3/15-16/2016	1	29	5	5	19	0	19	**100.00%**
Circulatory System Devices Panel	5/24/2016	1	34	14	1	19	1	18	**94.74%**
Circulatory System Devices Panel	6/2-3/2016	1	28	0	12	16	0	16	**100.00%**
Clinical Chemistry and Clinical Toxicology Devices Panel	7/21-22/2016	1	34	1	16	17	0	17	**100.00%**
Clinical Chemistry and Clinical Toxicology Devices Panel	8/10/2016	1	29	1	15	13	0	13	**100.00%**
Dental Products 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
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH Cont.									
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 and Urology Devices Panel	2/25-26/2016	1	25	1	10	14	0	14	**100.00%**
General and Plastic Surgery Devices Panel	9/20-21/2016	1	31	0	15	16	0	16	**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**
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	8/16/2016	1	27	1	9	17	0	17	**100.00%**
Molecular and Clinical Genetics Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**
Neurological Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**
Obstetrics and Gynecology Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**
Ophthalmic Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**
Orthopedic and Rehabilitation Devices Panel	2/19/2016	1	29	1	14	14	0	14	**100.00%**
Orthopedic and Rehabilitation Devices Panel	4/20/2016	1	22	0	7	15	0	15	**100.00%**
Radiologic Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**
Technical Electronic Safety Standards Advisory Committee Product Radiation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**
National Mammography Quality Assurance Advisory Committee	9/15/2016	1	13	0	2	11	0	11	**100.00%**
Patient Engagement 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**	**0**	**0 (0%)**	**0**	**8**	**0 (0%)**	8	**100.00%**
Science Advisory Board to the National Center for Toxicological Research	11/1-2/2015	1	0	0	0	8	0	8	**100.00%**
CENTER FOR TOBACCO PRODUCTS		**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
Tobacco Products Scientific Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	**N/A**

*** Not including Industry Representatives, Regular FDA Employees, and 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 numbers of vacancies on 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 section 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 several times annually. Many professional societies use these notices to share news of potential vacancies among interested professionals. In FY 2016, FDA issued 11 of these 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.
- 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 presented and/or distributed recruitment brochures at professional meetings, including the following:

    1. American Association of Tissue Banks Annual Meeting, New Orleans, Louisiana.
    2. American Academy of Pediatrics National Conference, Washington, DC.
    3. American Public Health Association Meeting, Chicago, Illinois.
    4. American Academy of Orthopaedic Surgeons, Orlando, Florida.
    5. American Academy of Physicians Assistants, San Antonio, Texas.
    6. Applied Pharmaceutical Toxicology Conference, Cambridge, Massachusetts.
    7. Gay and Lesbian Medical Association, St. Louis, Missouri.
    8. National Hemophilia Foundation 68th Annual Meeting, Orlando, Florida.
    9. National Hispanic Medical Association, Washington, DC.
    10. National Organization of Rare Diseases, Alexandria, Virginia.
    11. The 19th US-Japan Cellular and Gene Therapy Conference, Silver Spring, Maryland.