

Report to Congress

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

**Fiscal Year 2017 Annual Report on FDA Advisory Committee
Vacancies and Public Disclosures**

Department of Health and Human Services

Food and Drug Administration

Executive Summary

This report is required under section 1142 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 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 advisory committee member conflicts of interest information on an annual basis. The reporting of advisory committee information was first mandated by the Food and Drug Administration Amendments Act of 2007, which added section 712 to the FD&C Act, and which was subsequently modified by FDASIA.

As required in the statute, this report describes the following information for FY 2017:

- 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 2017 include:

- FDA maintained a vacancy percentage of 11 percent on its advisory committees in FY 2017, unchanged from the last 3 years;
- FDA increased the number of waivers granted under 18 USC 208(b)(3), from 8 waivers in FY2016 to 15 waivers for FY2017 (less than 2 percent of total meeting participants in attendance at meetings);
- FDA found that, unchanged from last fiscal year, 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;
- FDA received 506 applications from the Membership Nomination Portal. FDA identified 49 percent of the nominees received (246) as being qualified and willing to serve. This is an increase from FY2016, when 37 percent of the nominees were found qualified and willing to serve.

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Background

Section 712(e) of the FD&C Act¹ 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, 2016, through September 30, 2017.

Scope of the FY 2017 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 nominations received,³ and the number of such nominees willing to serve⁴ in FY 2017, 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, and was 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 nomination “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. Beginning in June 28, 2017, a signed consent form allowing disclosure of the CV if the nominee is selected is also required. See 82 FR 23583 (notice of FDA’s information collection covering the advisory committee nomination process).

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 2016, the number of new vacancies during FY 2017, and the number of these vacancies filled during FY 2017, 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 maintained a low annual vacancy percentage of 11 percent on its advisory committees in FY 2017, unchanged from the last 3 years (see Figure 1).

Table 1 - 712(e)(1)(A) Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing to Serve (FY 2017)

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/16	Vacancies as of 9/30/16	New Vacancies During Reporting Period (10/01/16-9/30/17)	Vacancies Filled (10/01/16-9/30/17)	Authorized Membership as of 9/30/17	Vacancies as of 9/30/17	Nominees Received (10/01/16-9/30/17)	Nominees Willing to Serve (10/1/16-9/30/17)
Total All Offices/Centers	564	63 (11%)	142	141	564	64 (11%)	506	246 (49%)
OFFICE OF THE COMMISSIONER	52	6 (12%)	12	11	52	7 (13%)	59	10 (17%)
Science Board to the FDA	21	5	2	3	21	4	30	0
FDA Pediatric AC	16	1	5	3	16	3	9	2
Risk Communication Advisory Committee	15	0	5	5	15	0	20	8
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	58	10 (17%)	12	18	58	4 (7%)	39	38 (17%)
Allergenic Products	10	3	3	4	10	2	5	5
Blood Products	18	3	4	7	18	0	10	10
Cellular, Tissue, & Gene Therapies	14	3	4	6	14	1	15	14
Vaccines and Related Biological Products	16	1	1	1	16	1	9	9

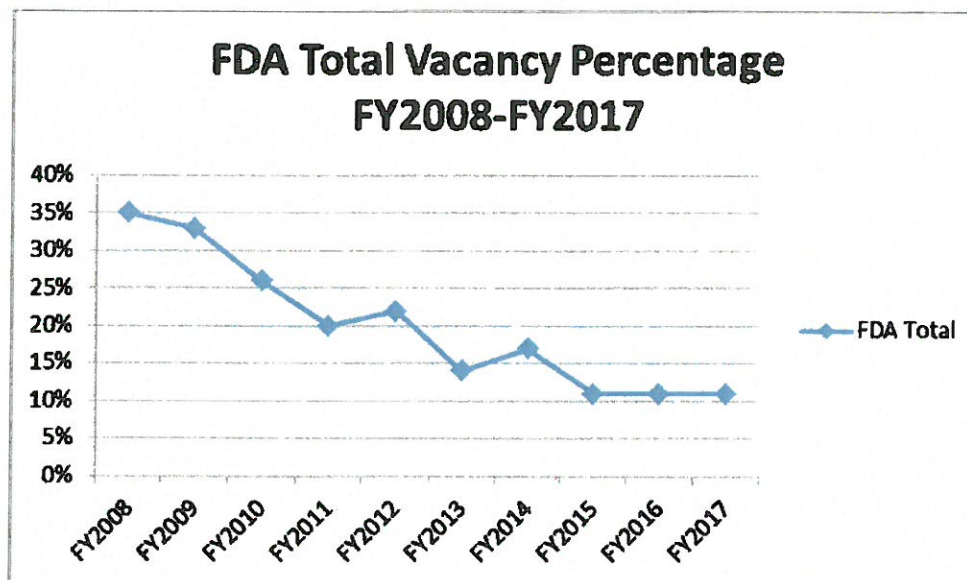
Advisory Committee Name (by	Authorized Membership	Vacancies as of	New Vacancies During	Vacancies Filled	Authorized Membership	Vacancies as of	Nominees Received	Nominees Willing to
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⁴ See section 712(c)(1)(B) of the FD&C Act. The nominees that FDA received 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.

Office/Center)	as of 9/30/16	9/30/16	Reporting Period (10/01/16-9/30/17)	(10/01/16-9/30/17)	as of 9/30/17	9/30/17	(10/01/16-9/30/17)	Serve (10/01/16-9/30/17)
CENTER FOR DRUG EVALUATION AND RESEARCH	205	9 (4%)	48	43	209	14 (7%)	182	43 (24%)
Advisory Committee of Pharmaceutical Science and Clinical Pharmacology	17	2	2	2	17	2	23	7
Anesthetic and Life Support Drugs	12	0	3	3	12	0	7	3
Antimicrobial Drugs (formerly known as Anti-Infective Drugs)	14	0	2	2	14	0	9	1
Arthritis	12	0	0	0	12	0	5	4
Bone, Reproductive, and Urologic Drugs	12	0	4	3	12	1	5	4
Cardiovascular and Renal Drugs	12	1	3	2	12	2	16	1
Dermatologic and Ophthalmic Drugs	10	2	2	4	10	0	3	2
Drug Safety and Risk Management	12	1	4	5	12	0	32	4
Endocrinologic and Metabolic Drugs	12	0	1	0	12	1	7	1
Gastrointestinal Drugs	12	1	3	2	12	2	9	3
Medical Imaging Drugs	13	1	3	3	13	1	4	1
Nonprescription Drugs	11	0	4	3	11	1	18	3
Oncologic Drugs	14	0	3	3	14	0	17	2
Peripheral and Central Nervous System Drugs	10	0	1	0	10	1	9	1
Pharmacy Compounding	14	1	4	5	14	0	10	2
Psychopharmacologic Drugs	10	0	2	2	10	0	5	2
Pulmonary-Allergy Drugs	12	0	7	4	12	3	3	2
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	207	36 (17%)	57	61	207	32 (15%)	171	125 (72%)
Device Good Manufacturing Practice Advisory Committee	9	2	4	0	9	6	12	5
Medical Devices Advisory Committee (Comprised of 18 Panels)								
Anesthesiology and Respiratory Therapy Devices Panel	9	2	0	0	9	2	5	3
Circulatory System Devices Panel	9	0	2	1	9	1	5	3
Advisory Committee Name (by Office/Center)	Authorized Membership as of	Vacancies as of 9/30/16	New Vacancies During Reporting	Vacancies Filled (10/01/16-	Authorized Membership as of	Vacancies as of 9/30/17	Nominees Received (10/01/16-	Nominees Willing to Serve

	9/30/16		Period (10/01/16- 9/30/17)	9/30/17)	9/30/17		9/30/17)	(10/01/16- 9/30/17)
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH Cont.								
Clinical Chemistry and Clinical Toxicology Devices Panel	9	1	3	2	9	2	3	3
Dental Products Panel	10	1	1	1	10	1	3	2
Ear, Nose, and Throat Devices Panel	9	0	3	2	9	1	3	1
Gastroenterology- Urology Devices Panel	9	0	6	4	9	2	2	1
General and Plastic Surgery Devices Panel	9	3	4	2	9	5	3	2
General Hospital and Personal Use Devices Panel	9	1	1	1	9	1	4	3
Hematology and Pathology Devices Panel	9	2	4	6	9	0	1	0
Immunology Devices Panel	9	3	1	2	9	2	4	4
Medical Devices Dispute Resolution Panel	5	0	2	0	5	2	12	4
Microbiology Devices Panel	9	2	4	6	9	0	5	4
Molecular and Clinical Genetics Panel	9	2	3	3	9	2	3	3
Neurological Devices Panel	9	2	4	3	9	3	10	6
Obstetrics-Gynecology Devices Panel	9	0	2	1	9	1	5	3
Ophthalmic Devices Panel	9	2	1	3	9	0	5	1
Orthopedic and Rehabilitation Devices Panel	9	2	2	4	9	0	2	1
Radiological Devices Panel	9	1	1	2	9	0	1	0
National Mammography Quality Assurance Advisory Committee	15	0	4	4	15	0	10	1
Patient Engagement Advisory Committee	9	9	0	9	9	0	71	71
Technical Electronic Product Radiation Safety Standards Committee	15	1	5	5	15	1	4	4
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	17	0 (0%)	6	0	17	6 (35%)	24	17 (75%)
Food Advisory Committee	17	0	6	0	17	6	24	17

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/16	Vacancies as of 9/30/16	New Vacancies During Reporting Period (10/01/16-9/30/17)	Vacancies Filled (10/01/16-9/30/17)	Authorized Membership as of 9/30/17	Vacancies as of 9/30/17	Nominees Received (10/01/17-9/30/17)	Nominees Willing to Serve (10/01/16-9/30/17)
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	9	1 (11%)	3	3	9	1 (11%)	8	100 (0%)
Science Advisory Board to the National Center for Toxicological Research	9	1	3	3	9	1	8	8
CENTER FOR TOBACCO PRODUCTS	12	1 (8%)	4	5	12	0 (0%)	21	5 (29%)
Tobacco Products Scientific Advisory Committee	12	1	4	5	12	0	21	5



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 law⁵ 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

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.

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 2017 and the percentage of individuals to whom disclosures did not apply in FY 2017.

Table 2 - 712(e)(1)(D) Number of Meetings, Persons Contacted, Persons Contacted Who Did Not Serve, Participants, and Waivers Granted (FY 2017)

		Number of Meetings	Number of Persons Contacted (Attending and Not Attending) *	Number of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	Number 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	Percent of Meeting Participants Not Issued Waivers
FDA TOTAL		50	1268	67 (5%)	406 (32%)	795	15 (1.9%)	780	98.11%
Committee Name	Meeting Date	Number of Meetings	Number of Persons Contacted (Attending and Not Attending) *	Number of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	Number 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	Percent of Meeting Participants Not Issued Waivers
OFFICE OF THE COMMISSIONER									
		8	195	2 (1%)	65 (28%)	138	1 (0.7%)	137	99.28%
Science Board to the Food and Drug Administration	11/15/2016	1	16	0	1	15	0	15	100.00%
Science Board to the Food and Drug Administration	5/9/2017	1	15	0	0	15	0	15	100.00%
Science Board to the Food and Drug Administration	6/26/2017	1	16	0	0	16	0	16	100.00%
Pediatric Advisory Committee	3/6-7/2017	1	26	0	10	16	1	15	93.75%
Pediatric Advisory Committee	5/18/2017	1	33	2	16	15	0	15	100.00%
Pediatric Advisory Committee	9/11/2017	1	38	0	12	26	0	26	100.00%
Pediatric Advisory Committee	9/12/2017	1	28	0	12	16	0	16	100.00%
Risk Communication Advisory Committee	11/7/2016	1	23	0	4	19	0	19	100.00%
CENTER FOR BIOLOGICS EVALUATION & RESEARCH									
		8	156	8 (5.1%)	39 (25%)	100	8 (8%)	100	100.00%
Allergenic Products	10/27/2016	1	7	0	1	6	0	6	100.00%
Blood Products	11/17-18/2016	1	22	1	4	17	0	17	100.00%
Blood Products	4/4-5/2017	1	36	5	11	20	0	20	100.00%
Cellular, Tissue, and Gene Therapies	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Vaccines and Related Biological	10/13/2016	1	18	0	2	16	0	16	100.00%

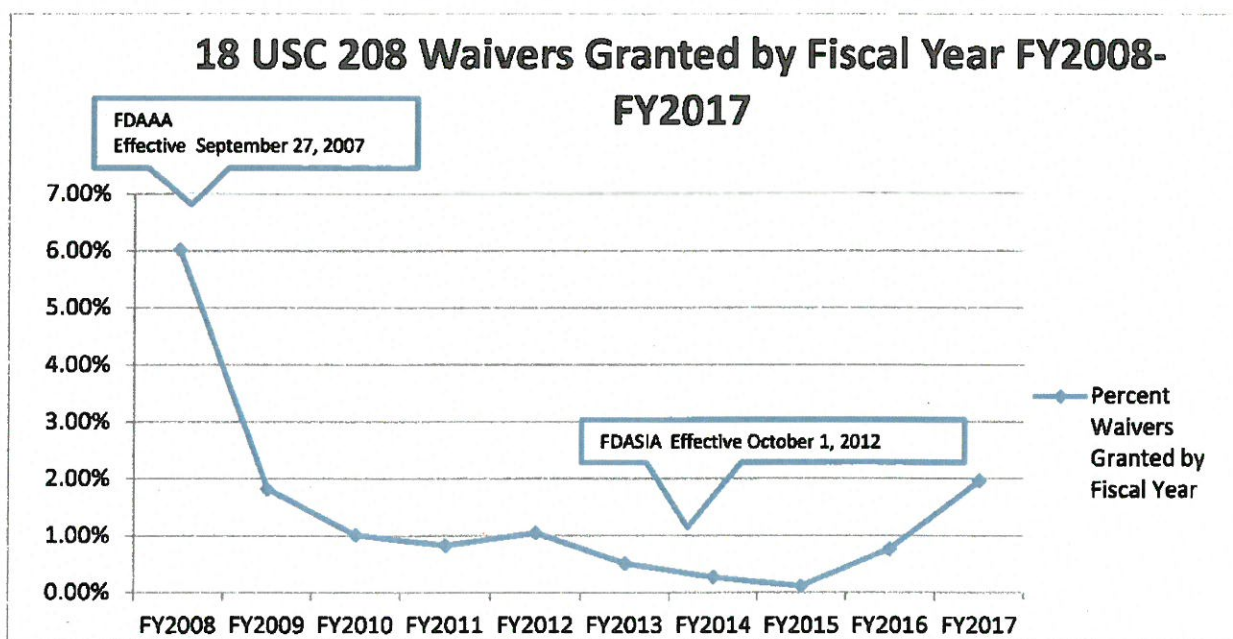
Products									
Committee Name	Meeting Date	Number of Meetings	Number of Persons Contacted (Attending and Not Attending) *	Number of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	Number of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of 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	Percent of Meeting Participants Not Issued Waivers
CENTER FOR BIOLOGICS EVALUATION & RESEARCH (CBER)									
Vaccines and Related Biological Products	3/9/2017	1	23	1	7	15	0	15	100.00%
Vaccines and Related Biological Products	5/17/2017	1	14	0	5	9	0	9	100.00%
Vaccines and Related Biological Products	9/13/2017	1	16	0	4	12	0	12	100.00%
Vaccines and Related Biological Products	7/28/2017	1	20	1	5	14	0	14	100.00%
CENTER FOR DRUG EVALUATION AND RESEARCH									
		27	745	48 (6%)	260 (35%)	437	10 (2.3%)	437	97.71%
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting with DSARM	10/5/16	1	41	0	13	28	0	28	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting with DSARM	3/13-14/2017	1	50	3	20	27	0	27	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting with DSARM	7/26/17	1	34	0	11	23	0	23	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee	4/5/17	1	30	1	9	20	0	20	100.00%
Antimicrobial Drugs Advisory Committee	11/4/16	1	23	0	10	13	0	13	100.00%
Antimicrobial Drugs Advisory Committee	4/13/17	1	26	0	6	20	0	20	100.00%
Arthritis Advisory Committee	8/2/2017	1	30	8	9	13	0	13	100.00%
Arthritis Advisory Committee	8/3/2017	1	28	0	17	11	0	11	100.00%
Bone, Reproductive, and Urologic Drugs Advisory Committee	10/19/2016	1	28	0	9	19	0	19	100.00%
Bone, Reproductive, and Urologic Drugs Advisory Committee	12/6/2016	1	26	1	4	21	0	21	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
Dermatologic and Ophthalmic Drugs Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Drug Safety and Risk Management Advisory Committee Joint Meeting with AADPAC	9/14/17	1	37	2	16	19	0	19	100.00%

Committee Name	Meeting Date	Number of Meetings	Number of Persons Contacted (Attending and Not Attending) *	Number of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	Number 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 206(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	Percent of Meeting Participants Not Issued Waivers
CENTER FOR DRUG EVALUATION AND RESEARCH Conf.									
Endocrinologic and Metabolic Drugs Advisory Committee	6/20/2017	1	31	1	11	19	1	18	94.74%
Gastrointestinal Drugs Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Medical Imaging Drugs Advisory Committee	9/8/2017	1	30	5	10	15	0	15	100.00%
Medical Imaging Drugs Advisory Committee	5/10/2017	1	27	0	14	13	0	13	100.00%
Nonprescription Drugs Advisory Committee Joint with DSARM	4/4/17	1	32	0	12	20	0	20	100.00%
Oncologic Drugs Advisory Committee	3/29/2017	1	18	3	5	10	0	10	100.00%
Oncologic Drugs Advisory Committee	5/24/2017	1	26	1	6	19	0	19	100.00%
Oncologic Drugs Advisory Committee	5/25/2017	1	33	0	17	16	0	16	100.00%
Oncologic Drugs Advisory Committee	7/11/2017	1	23	0	11	12	0	12	100.00%
Oncologic Drugs Advisory Committee	7/12/2017	1	34	12	11	11	0	11	100.00%
Oncologic Drugs Advisory Committee	7/13/2017	1	20	0	1	19	5	14	73.68%
Oncologic Drugs Advisory Committee	9/19/2017	1	28	7	9	12	0	12	100.00%
Pediatric Sub-Committee/ODAC	6/21-22/2017	1	20	0	7	13	4	9	69.23%
Peripheral and Central Nervous System Drugs Advisory Committee	9/28/17	1	12	0	1	11	0	11	100.00%
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	3/15/17	1	30	4	13	13	0	13	100.00%
Pharmacy Compounding Advisory Committee	11/3/16	1	11	0	2	9	0	9	100.00%
Pharmacy Compounding Advisory Committee	5/8-9/2017	1	17	0	6	11	0	11	100.00%
Psychopharmacologic Drugs Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pulmonary-Allergy 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	Number of Persons Contacted (Attending and Not Attending) *	Number of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	Number 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	Percent of Meeting Participants Not Issued Waivers
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Food Advisory Committee	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		5	148	0 (0%)	51 (34%)	85	4 (5%)	84	95.45%
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	2/23/2017	1	31	4	10	17	0	17	100.00%
Clinical Chemistry and Clinical Toxicology Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Dental Products Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
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	5/17/2017	1	39	5	18	16	1	15	93.75%
General and Plastic Surgery Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
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	11/9-10/2016	1	38	0	13	25	3	22	88.00%
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	3/17/2017	1	27	0	8	19	0	19	100.00%

Committee Name	Meeting Date	Number of Meetings	Number of Persons Contacted (Attending and Not Attending) *	Number of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	Number 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	Percent of Meeting Participants Not Issued Waivers
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH									
Orthopedic and Rehabilitation Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
TEPRSSC	10/25-26/2016	1	13	0	2	11	0	11	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
Radiologic Devices Panel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH									
Science Advisory Board to the National Center for Toxicological Research	11/1-2/2016	1	8	0	0	8	0	8	100.00%
CENTER FOR TOBACCO PRODUCTS									
Tobacco Products Scientific Advisory Committee	4/6/2017	1	16	0	1	15	0	15	100.00%

* 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:

- Section 712(b)(1)(C) of the FD&C Act requires 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 2017, FDA issued 10 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 participates in speaking opportunities at universities, conferences, workshops, and training sessions on the FDA advisory committee process. FDA participated in five such speaking opportunities in FY 2017.
- FDA meets with relevant organizations to explain the advisory committee program and the process for nominating candidates. FDA participated in at least five such activities in FY 2017.
- 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 many professional meetings, including the following:
 1. National Hispanic Medical Association, Washington, DC
 2. National Medical Association, Philadelphia, PA
 3. Gay and Lesbian Medical Association, Philadelphia, PA
 4. Medical Sociology & Community Health, Atlanta, GA
 5. Nurse Practitioner Association, Savannah GA; Arlington, VA; and Boston, MA
 6. 20th Global Summit & Expo on Vaccines, Immunization, & B2B, Houston, TX
 7. 2nd International Conference on Pediatric Oncology and Pediatric Medicine, Las Vegas, NV