

Report to Congress

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

**Fiscal Year 2018 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 information about advisory committee conflict of interest information on an annual basis. The reporting information was first mandated by the Food and Drug Administration Amendments Act of 2007 (FDAAA), section 712, and subsequently modified by FDASIA.

As required in the statute, this report describes the following information for FY 2018:

- 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 2018 include:

- FDA attained a low vacancy percentage of 10 percent on its advisory committees, down from 11 percent over the previous 3 years;
- FDA decreased the number of waivers granted under 18 USC 208(b)(3), from 15 waivers in FY2017 to 12 waivers for FY2018 (less than 2 percent of total meeting participants in attendance at meetings);
- Of the total number of persons contacted to serve on an advisory committee, 5 percent did not participate because of the potential for conflicts of interest for such participation as determined by the Agency;
- FDA received 258 applications from the Membership Nomination Portal. FDA identified 44 percent of the nominees received (113) as being 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, 2017, through September 30, 2018.

Scope of the FY 2018 Annual Report

In response to the information to be reported under section 712(e)(1)(A), Table 1 presents, for each advisory committee, the data on the number of vacancies, the number of nominations

¹ 21 U.S.C. 379d-1(e). This annual report requirement was added by FDAAA, signed into law on September 27, 2007, and amended by 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.

received,³ and the number of such nominees willing to serve⁴ in FY 2018.

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 2017; the number of new vacancies during FY 2018; the number of new vacancies filled during FY 2018; the number of nominees received to fill vacancies; and, of the nominations received, the number of nominees willing to serve that were reviewed during the reporting period.

In FY 2018, FDA reduced the number of vacancies on advisory committees to 10 percent from 11 percent over the previous 3 years (see Figure 1).

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 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).

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.

Table 1 - 712(e)(1)(A) Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing to Serve - FY 2018

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/17	Vacancies as of 9/30/17	New Vacancies during Reporting Period (10/01/17- 9/30/18)	Vacancies Filled (10/01/17- 9/30/18)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	Nominees Received (10/01/17- 9/30/18)	Nominees Willing to Serve (10/1/17-9/30/18)
Total All Offices/Centers	564	59 (11%)	145	150	547	57 (10%)	258	113 (44%)
OFFICE OF THE COMMISSIONER	52	7 (13%)	16	16	52	7 (13%)	29	6 (2%)
Science Board to the FDA	21	4	9	8	21	5	11	0
FDA Pediatric Advisory Committee	16	3	7	8	16	2	14	6
Risk Communication Advisory Committee	15	0	0	0	15	0	4	0
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	58	4 (7%)	23	23	58	4 (7%)	31	24 (77%)
Allergenic Products	10	2	3	4	10	1	2	2
Blood Products	18	0	7	5	18	2	7	7
Cellular, Tissue, and Gene Therapies	14	1	5	6	14	0	10	7
Vaccines and Related Biological Products	16	1	8	8	16	1	12	8

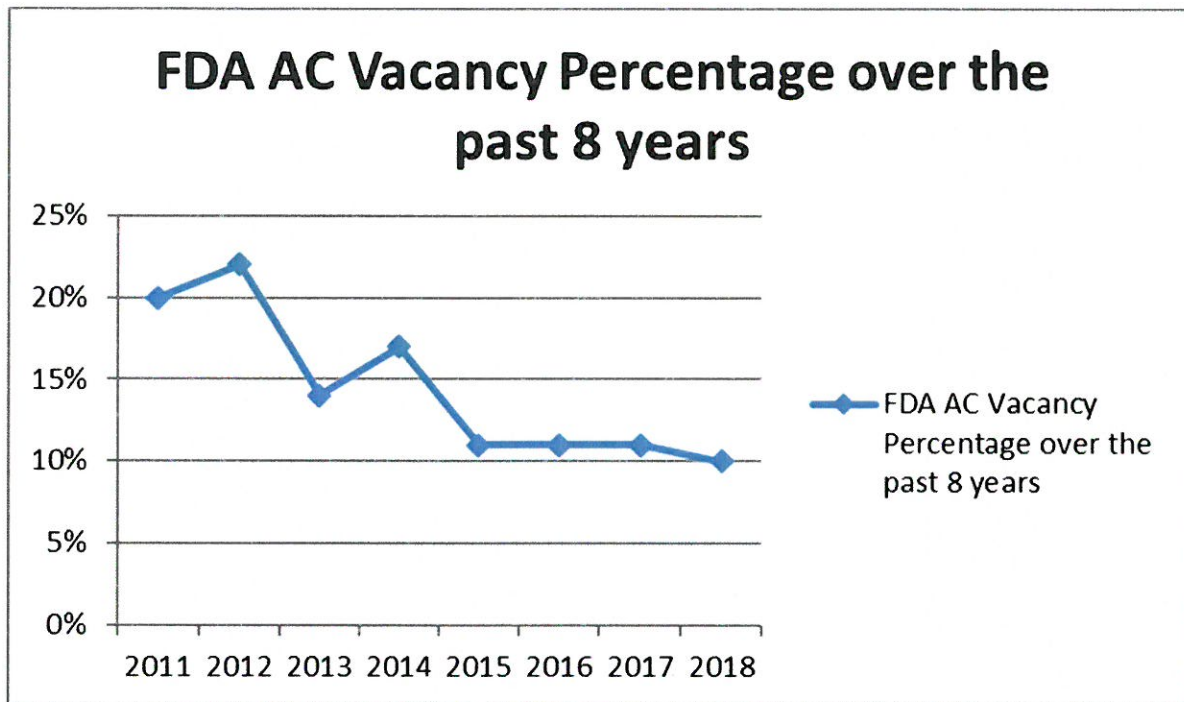
Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/17	Vacancies as of 9/30/17	New Vacancies during Reporting Period (10/01/17-9/30/18)	Vacancies Filled (10/01/17-9/30/18)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	Nominees Received (10/01/17-9/30/18)	Nominees Willing to Serve (10/1/17-9/30/18)
CENTER FOR DRUG EVALUATION AND RESEARCH	209	15 (7%)	51	54	209	15 (7%)	131	37 (28%)
Advisory Committee of Pharmaceutical Science and Clinical Pharmacology	17	2	3	5	17	2	9	3
Anesthetic and Life Support Drugs	12	0	4	1	12	3	13	4
Antimicrobial Drugs formerly known as Anti-Infective Drugs	14	0	2	1	14	1	14	6
Arthritis	12	0	3	3	12	0	1	1
Bone, Reproductive, and Urologic Drugs	12	1	4	3	12	2	0	0
Cardiovascular and Renal Drugs	12	2	3	3	12	2	9	3
Dermatologic and Ophthalmic Drugs	10	0	3	3	10	0	3	2
Drug Safety and Risk Management	12	0	3	3	12	0	14	1
Endocrinologic and Metabolic Drugs	12	1	4	5	12	0	1	0
Gastrointestinal Drugs	12	2	2	4	12	0	6	4
Medical Imaging Drugs	13	1	1	1	13	1	3	0

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/17	Vacancies as of 9/30/17	New Vacancies during Reporting Period (10/01/17- 9/30/18)	Vacancies Filled (10/01/17- 9/30/18)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	Nominees Received (10/01/17- 9/30/18)	Nominees Willing to Serve (10/1/17-9/30/18)
CENTER FOR DRUG EVALUATION AND RESEARCH (CONT...)	209	15 (7%)	51	54	209	15 (7%)	131	37 (28%)
Nonprescription Drugs	11	1	2	2	11	2	11	1
Oncologic Drugs	14	0	5	5	14	0	13	2
Peripheral and Central Nervous System Drugs	10	1	3	3	10	1	6	2
Pharmacy Compounding	14	1	4	5	14	0	19	3
Psychopharmacologic Drugs	10	0	1	0	10	1	3	0
Pulmonary-Allergy Drugs	12	3	4	7	12	0	6	6

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/17	Vacancies as of 9/30/17	New Vacancies during Reporting Period (10/01/17- 9/30/18)	Vacancies Filled (10/01/17- 9/30/18)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	Nominees Received (10/01/17- 9/30/18)	Nominees Willing to Serve (10/1/17-9/30/18)
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	207	32 (15%)	48	49	207	31 (15%)	56	42 (75%)
Device Good Manufacturing Practice Advisory Committee	9	6	1	4	9	3	4	4
National Mammography Quality Assurance Advisory Committee	15	0	1	0	15	1	0	0
Patient Engagement Advisory Committee	9	0	0	0	9	0	0	0
Technical Electronic Product Radiation Safety Standards Committee	15	1	3	4	15	0	3	0
Medical Devices Advisory Committee (Composed of 18 Panels)								
Anesthesiology and Respiratory Therapy Devices Panel	9	2	3	4	9	1	3	3
Circulatory System Devices Panel	9	1	2	2	9	1	3	3
Clinical Chemistry and Clinical Toxicology Devices Panel	9	2	4	4	9	2	0	0
Dental Products Panel	10	1	3	3	10	1	3	3

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/17	Vacancies as of 9/30/17	New Vacancies during Reporting Period (10/01/17- 9/30/18)	Vacancies Filled (10/01/17- 9/30/18)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	Nominees Received (10/01/17- 9/30/18)	Nominees Willing to Serve (10/1/17-9/30/18)
Medical Devices Advisory Committee, Continued... (Composed of 18 Panels)								
Ear, Nose, and Throat Devices Panel	9	1	3	3	9	1	2	2
Gastroenterology-Urology Devices Panel	9	2	2	2	9	2	0	0
General and Plastic Surgery Devices Panel	9	5	1	4	9	2	1	1
General Hospital and Personal Use Devices Panel	9	1	3	4	9	0	1	1
Hematology and Pathology Devices Panel	9	0	3	2	9	1	0	0
Immunology Devices Panel	9	2	1	0	9	3	3	3
Medical Devices Dispute Resolution Panel	5	2	1	3	5	0	3	3
Microbiology Devices Panel	9	0	3	0	9	3	5	3
Molecular and Clinical Genetics Panel	9	2	2	1	9	3	1	1

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/17	Vacancies as of 9/30/17	New Vacancies during Reporting Period (10/01/17-9/30/18)	Vacancies Filled (10/01/17- 9/30/18)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	Nominees Received (10/01/17- 9/30/18)	Nominees Willing to Serve (10/1/17-9/30/18)
Medical Devices Advisory Committee, Continued... (Composed of 18 Panels)								
Neurological Devices Panel	9	3	2	4	9	1	5	3
Obstetrics-Gynecology Devices Panel	9	1	3	4	9	0	1	1
Ophthalmic Devices Panel	9	0	3	0	9	3	1	1
Orthopedic and Rehabilitation Devices Panel	9	0	3	2	9	1	4	2
Radiological Devices Panel	9	0	4	3	9	1	4	2
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION								
Food Advisory Committee								
This Committee was terminated during Fiscal Year 2018								
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	9	1 (11%)	3	4	9	0 (0%)	3	0 (0%)
Science Advisory Board to the National Center for Toxicological Research	9	1	3	4	9	0	3	0
CENTER FOR TOBACCO PRODUCTS	12	0 (0%)	4	4	12	0 (0%)	7	4 (57%)
Tobacco Products Scientific Advisory Committee	12	0	4	4	12	0	7	4



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 who served on committees to whom such disclosures did not apply. 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 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 2018 and the percentage of individuals to whom disclosures did not apply in FY 2018.

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.

Table 2 - 712(e)(1)(D) Number of Meetings, Persons Contacted, Persons Contacted, Persons Contacted Who Did Not Serve, Participants, and Waivers Granted - FY 2018

Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants (Voting and Nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants Not Issued Waivers
FDA TOTALS	-----	55	1422	61 (5%)	490 (32%)	872	12 (1.9%)	860	98.62%
OFFICE OF THE COMMISSIONER		4	101	0	31	70	0	70	100.00%
Science Board to the Food and Drug Administration	4/23/2018	1	16	0	1	15	0	15	100.00%
Pediatric Advisory Committee (Joint meeting with Endocrinologic and Metabolic Drugs Advisory Committee)	5/11/2018	1	31	0	11	20	0	20	100.00%
Pediatric Advisory Committee	9/20/2018	1	22	0	8	14	0	14	100.00%
Risk Communication Advisory Committee	3/5-6/2018	1	32	0	11	21	0	21	100.00%
CENTER FOR BIOLOGICS EVALUATION & RESEARCH		9	197	6	58	133	0	133	100.00%
Allergenic Products Advisory Committee	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Blood Products Advisory Committee	3/21-22/2018	1	33	4	13	16	0	16	100.00%
Blood Products Advisory Committee	6/22/2018	1	15	0	4	11	0	11	100.00%

Blood Products Advisory Committee	7/18-19/2018	1	29	2	9	18	0	18	100.00%
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Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants (Voting and Nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR BIOLOGICS EVALUATION & RESEARCH, CONTINUED...									
Blood Products Advisory Committee	11/30-12/1/2017	1	26	0	5	21	0	21	100.00%
Cellular, Tissue, and Gene Therapies Advisory Committee	10/12/2017	1	17	0	0	17	0	17	100.00%
Vaccines and Related Biological Products Advisory Committee	10/4/2017	1	17	0	0	17	0	17	100.00%
Vaccines and Related Biological Products Advisory Committee	10/4/2017	1	14	0	4	10	0	10	100.00%
Vaccines and Related Biological Products Advisory Committee	5/17/2018	1	16	0	4	12	0	12	100.00%
Vaccines and Related Biological Products Advisory Committee	3/1/2018	1	15	0	1	14	0	14	100.00%
CENTER FOR DRUG EVALUATION & RESEARCH		33	891	31	318	538	8	530	98.51%
Anesthetic and Analgesic Drug Products Advisory Committee	2/14-15/2018	1	16	1	5	10	0	10	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee	2/14/2018	1	36	1	14	21	0	21	100.00%

Anesthetic and Analgesic Drug Products Advisory Committee	5/22/2018	1	28	0	9	19	0	19	100.00%
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Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants (Voting and Nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants Not Issued Waivers
CENTER FOR DRUG EVALUATION & RESEARCH, CONTINUED...									
Anesthetic and Analgesic Drug Products Advisory Committee	6/26/2018	1	33	0	16	17	0	17	100.00%
Antimicrobial Drugs Advisory Committee	5/2/2018	1	33	1	16	16	0	16	100.00%
Antimicrobial Drugs Advisory Committee	11/16/17	1	18	0	3	15	0	15	100.00%
Antimicrobial Drugs Advisory Committee	1/11/2018	1	17	0	1	16	0	16	100.00%
Antimicrobial Drugs Advisory Committee	5/1/2018	1	24	1	6	17	0	17	100.00%
Antimicrobial Drugs Advisory Committee	7/26/2018	1	22	1	8	13	0	13	100.00%
Antimicrobial Drugs Advisory Committee	8/7/2018	1	40	0	22	14	0	14	100.00%
Antimicrobial Drugs Advisory Committee	8/8/2018	1	31	0	13	18	0	18	100.00%

Antimicrobial Drugs Advisory Committee	7/12/2018	1	19	2	4	13	0	13	100.00%
Arthritis Advisory Committee	4/23/2018	1	15	0	0	15	0	15	100.00%

Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants (Voting and Nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DRUG EVALUATION & RESEARCH, CONTINUED...									
Arthritis Advisory Committee	4/24-25/2018	1	26	2	3	21	2	19	90.48%
Bone, Reproductive, and Urologic Drugs Advisory Committee	1/10/2018	1	64	2	43	19	1	19	94.74%
Bone, Reproductive, and Urologic Drugs Advisory Committee	1/9/2018	1	64	2	43	19	1	19	94.74%
Bone, Reproductive, and Urologic Drugs Advisory Committee	12/7/2017	1	19	4	0	15	0	15	100.00%
Cardiovascular and Renal Drugs Advisory Committee	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Dermatologic and Ophthalmic Drugs Advisory Committee	10/13/17	1	12	0	2	10	0	10	0	10	100.00%
Drug Safety and Risk Management Advisory Committee	8/3/2018	1	41	3	19	19	0	19	0	19	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	10/18/2017	1	24	1	6	17	0	17	0	17	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	5/10/2018	1	25	2	3	20	0	20	0	20	100.00%

Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants (Voting and Nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants Not Issued Waivers
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CENTER FOR DRUG EVALUATION & RESEARCH, CONTINUED...

Gastrointestinal Drugs Advisory Committee	5/3/2018	1	37	1	12	24	0	24	100.00%
Gastrointestinal Drugs Advisory Committee	3/8/2018	1	31	5	10	16	3	13	81.25%
Medical Imaging Drugs Advisory Committee	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Nonprescription Drugs Advisory Committee	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Oncologic Drugs Advisory Committee	3/7/2018	1	23	0	11	12	0	12	100.00%

Pediatric Sub-Committee/Oncologic Drugs Advisory Committee	6/20/2018	1	20	0	3	17	0	17	0	17	100.00%
Peripheral and Central Nervous System Drugs Advisory Committee	4/19/2018	1	23	2	8	13	0	13	0	13	100.00%
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	9/20/2018	1	14	0	3	11	0	11	0	11	100.00%
Pharmacy Compounding Advisory Committee	11/20-21/2017	1	16	0	0	16	0	16	0	16	100.00%
Pharmacy Compounding Advisory Committee	9/12/2018	1	16	0	0	16	1	16	1	16	93.75%

Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants (Voting and Nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants Not Issued Waivers
CENTER FOR DRUG EVALUATION & RESEARCH, CONTINUED...									
Psychopharmacologic Drugs Advisory Committee	10/31/2017	1	33	0	14	19	0	19	100.00%
Psychopharmacologic Drugs Advisory Committee	11/1/2017	1	33	0	33	21	0	21	100.00%
Psychopharmacologic Drugs Advisory Committee	3/27/2018	1	20	0	8	12	0	12	100.00%
Pulmonary-Allergy Drugs Advisory Committee	7/25/2018	1	18	0	1	17	0	17	100.00%
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		0	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Food Advisory Committee	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		7	213	24	78	111	4	107	96.40%				
Device Good Manufacturing Practice Advisory Committee	N/A	0	N/A	N/A	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	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
National Mammography Quality Assurance Advisory Committee	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants (Voting and Nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants <u>Not</u> Issued Waivers
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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, CONTINUED...

Medical Devices Advisory Committee (Composed of 18 Panels)

Anesthesiology and Respiratory Therapy Devices Panel	6/14/2018	1	31	2	14	15	2	13	86.67%
Circulatory System Devices Panel	6/12/2018	1	39	7	14	18	1	17	94.44%
Clinical Chemistry and Clinical Toxicology Devices Panel	3/29-30/2018	1	29	1	10	18	0	18	100.00%
Dental Products Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Ear, Nose, and Throat Devices Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Gastroenterology and Urology Devices Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
General and Plastic Surgery Devices Panel	N/A	0	N/A	N/A	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	0	N/A	N/A	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	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants (Voting and Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants <u>Not</u> Issued Waivers
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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, CONTINUED...

Medical Devices Advisory Committee (Composed of 18 Panels)

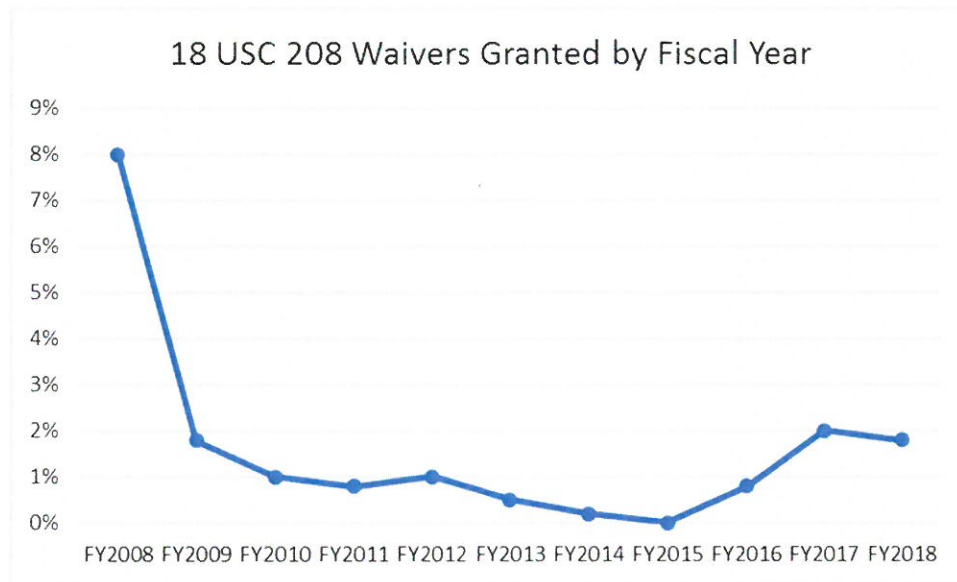
Immunology Devices Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Medical Devices Dispute Resolution Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Microbiology Devices Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Molecular and Clinical Genetics Devices Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Neurological Devices Panel	9/27/2018	1	37	10	9	18	1	17	94.44%
Neurological Devices Panel	3/1/2018	1	33	4	14	15	0	15	100.00%
Obstetrics and Gynecology Devices Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ophthalmic Devices Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Orthopedic and Rehabilitation Devices Panel	12/12/2017	1	35	0	17	18	0	18	100.00%
Committee Name	Meeting Date	No. of Meetings	No. of Persons Contacted (Attending and Not Attending)*	No. of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	No. of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total No. of Meeting Participants Attending (Voting and Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total No. of Meeting Participants with No Waivers	Percent of Meeting Participants Not Issued Waivers

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, CONTINUED...

Medical Devices Advisory Committee (Composed of 18 Panels)									
Radiologic Devices Panel	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		1	5	0	0	5	0	5	100.00%
Science Advisory Board to the National Center for Toxicological Research	11/6-7/2017	1	5	0	0	5	0	5	100.00%
CENTER FOR TOBACCO PRODUCTS		2	31	1	5	31	0	31	100.00%

Tobacco Products Scientific Advisory Committee	9/13-14/2018	1	16	1	5	16	0	16	100.00%
Tobacco Products Scientific Advisory Committee	1/24-25/2018	1	15	0	5	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:

- FDASIA section 712(b)(1)(c) 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 2018, FDA issued seven 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 who are 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 FY2018.
- FDA meets with relevant organizations to explain the advisory committee program and participation in nominating candidates. FDA participated in at least four such activities in FY 2018.
- 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 the following professional meetings:
 - American Public Health Association, Atlanta, GA.
 - National Black Nurses Association, St. Louis Mo.