



Report to Congress

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

Fiscal Year 2019 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) enacted in 2012, which amends section 712(e) of the Federal Food, Drug, and Cosmetic Act. FDASIA requires the Food and Drug Administration (FDA or the Agency) to provide, on an annual basis, (1) information on its advisory committee vacancies and (2) public disclosures of information about advisory committee conflicts of interest. The reporting information was first mandated by section 712 of the Food and Drug Administration Amendments Act of 2007 and subsequently modified by FDASIA.

As required in the statute, this report describes the following information for fiscal year (FY) 2019:

- 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 2019 include the following:

- FDA decreased the number of waivers granted under 18 U.S.C. 208(b)(3), from 12 waivers in FY 2018 to seven waivers in FY 2019 (which is less than one percent of the total meeting participants);
- less than four 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 333 applications for nominees from the Membership Nomination Portal. FDA identified 40 percent of these nominees (i.e., 134) as being qualified and willing to serve.

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Background

Section 712(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)¹ requires the Food and Drug Administration (FDA or the 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—*
- (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, 2018, through September 30, 2019.

Scope of the Fiscal Year 2019 Annual Report

In response to the information to be reported under section 712(e)(1)(A), Table 1 presents data on the number of vacancies on each committee, the number of nominations received³

¹ 712(e) FD&C Act (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, 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 the following information for the nominee: complete *curriculum vitae* (CV), 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 on June 28, 2017, a signed consent form allowing disclosure of the CV if the nominee is selected is also required. See the *Federal Register* notice of FDA’s information collection covering the advisory committee nomination process, available at 82 FR 23583 (May 23, 2017).

for each committee, and the number of such nominees willing to serve⁴ in fiscal year (FY) 2019 on each committee.

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. 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 2018, the number of new vacancies during FY 2019, the number of these vacancies filled during FY 2019, the number of nominees received to fill vacancies, and of those received, the number of nominees willing to serve who were reviewed during the reporting period.

In FY 2019, the number of vacancies on FDA advisory committees increased from 10 percent over the previous year to 12 percent currently (see Figure 1).

⁴ See section 712(e) of the FD&C Act (21 U.S.C. 379d-1(e)). 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 if the nominee confirmed his/her willingness to serve after being contacted by FDA and informed of the committee’s 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 2019

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	New Vacancies During Reporting Period (10/01/18 - 9/30/19)	Vacancies Filled (10/01/18 - 9/30/19)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	Nominees Received (10/01/18 - 9/30/19)	Nominees Willing to Serve (10/1/18 - 9/30/19)
Total All Offices/Centers	547	56 (10%)	131	122	547	65 (12%)	333	134 (40%)
OFFICE OF THE COMMISSIONER	52	7 (13%)	19	16	52	10 (19%)	37	16 (43%)
Pediatric Advisory Committee	16	2	7	5	16	4	8	5
Risk Communication Advisory Committee	15	0	4	2	15	2	7	2
Science Board to the Food and Drug Administration	21	5	8	9	21	4	22	9
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	58	4 (7%)	12	9	58	7 (12%)	22	9 (41%)
Allergenic Products Advisory Committee	10	1	3	1	10	3	2	1
Blood Products Advisory Committee	18	2	3	4	18	1	10	4
Cellular, Tissue, & Gene Therapies Advisory Committee	14	0	4	2	14	2	7	2
Vaccines and Related Biological Products Advisory Committee	16	1	2	2	16	1	3	2

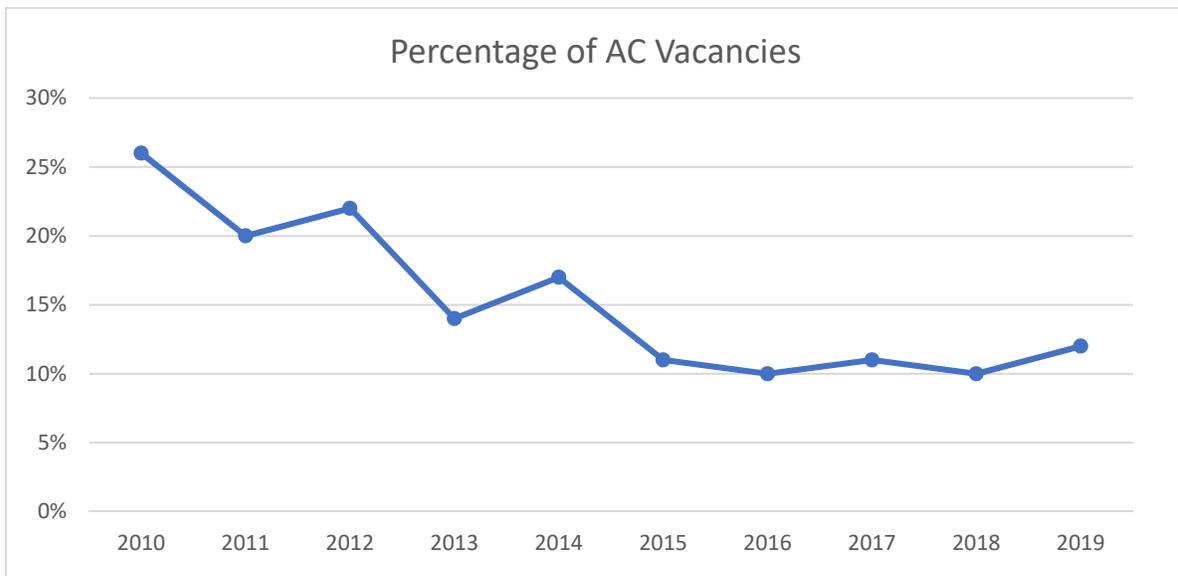
Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	New Vacancies During Reporting Period (10/01/18 - 9/30/19)	Vacancies Filled (10/01/18 - 9/30/19)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	Nominees Received (10/01/18 - 9/30/19)	Nominees Willing to Serve (10/1/18 - 9/30/19)
CENTER FOR DRUG EVALUATION AND RESEARCH	209	16 (8%)	49	57	209	8 (4%)	120	26 (22%)
Anesthetic and Analgesic Drug Products Advisory Committee	12	3	3	6	12	0	8	2
Antimicrobial Drugs Advisory Committee	14	1	5	6	14	0	9	2
Arthritis Advisory Committee	12	0	2	1	12	1	3	2
Bone, Reproductive and Urologic Drugs Advisory Committee	12	3	2	3	12	2	5	2
Cardiovascular and Renal Drugs Advisory Committee	12	2	3	5	12	0	5	1
Dermatologic and Ophthalmic Drugs Advisory Committee	10	0	1	1	10	0	2	1
Drug Safety and Risk Management Advisory Committee	12	0	1	1	12	0	14	0
Endocrinologic and Metabolic Drugs Advisory Committee	12	0	3	3	12	0	4	3
Gastrointestinal Drugs Advisory Committee	12	0	4	4	12	0	6	3
Medical Imaging Drugs Advisory Committee	13	1	5	6	13	0	2	0

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	New Vacancies During Reporting Period (10/01/18 - 9/30/19)	Vacancies Filled (10/01/18 - 9/30/19)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	Nominees Received (10/01/18 - 9/30/19)	Nominees Willing to Serve (10/1/18 - 9/30/19)
CENTER FOR DRUG EVALUATION AND RESEARCH (CONT...)	209	16	48	56	209	8	120	26
Nonprescription Drugs Advisory Committee	11	2	3	4	11	1	8	0
Oncologic Drugs Advisory Committee	14	0	6	5	14	1	12	4
Peripheral and Central Nervous System Drugs Advisory Committee	10	1	2	3	10	0	9	0
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	17	2	1	3	17	0	16	2
Pharmacy Compounding Advisory Committee	14	0	3	0	14	3	5	0
Psychopharmacologic Drugs Advisory Committee	10	1	3	4	10	0	9	2
Pulmonary-Allergy Drugs Advisory Committee	12	0	2	2	12	0	3	2

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	New Vacancies During Reporting Period (10/01/18 - 9/30/19)	Vacancies Filled (10/01/18 - 9/30/19)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	Nominees Received (10/01/18 - 9/30/19)	Nominees Willing to Serve (10/1/18 - 9/30/19)
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	207	29 (14%)	47	37	207	39 (19%)	127	56 (44%)
Device Good Manufacturing Practice Advisory Committee	9	3	2	0	9	5	15	7
National Mammography Quality Assurance Advisory Committee	15	1	5	4	15	2	3	2
Patient Engagement Advisory Committee	9	0	2	1	9	1	24	12
Technical Electronic Product Radiation Safety Standards Committee	15	1	3	0	15	4	0	0
Medical Devices Advisory Committee (Composed of 18 Panels)								
Anesthesiology and Respiratory Therapy Devices Panel	9	1	3	3	9	1	9	4
Circulatory System Devices Panel	9	1	3	2	9	2	3	2
Clinical Chemistry and Clinical Toxicology Devices Panel	9	2	1	1	9	2	0	0
Dental Products Panel	10	1	4	2	10	3	13	3

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	New Vacancies During Reporting Period (10/01/18 - 9/30/19)	Vacancies Filled (10/01/18 - 9/30/19)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	Nominees Received (10/01/18 - 9/30/19)	Nominees Willing to Serve (10/1/18 - 9/30/19)
Medical Devices Advisory Committee, Continued (Composed of 18 Panels)								
Ear, Nose, and Throat Devices Panel	9	1	3	4	9	0	6	4
Gastroenterology-Urology Devices Panel	9	2	0	1	9	1	2	1
General and Plastic Surgery Devices Panel	9	2	2	3	9	1	3	3
General Hospital and Personal Use Devices Panel	9	0	3	3	9	0	2	2
Hematology and Pathology Devices Panel	9	0	1	1	9	0	1	1
Immunology Devices Panel	9	3	2	0	9	5	1	0
Medical Devices Dispute Resolution Panel	5	0	1	1	5	0	10	1
Microbiology Devices Panel	9	3	0	2	9	1	1	1
Molecular and Clinical Genetics Panel	9	3	2	5	9	0	1	1

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/18	Vacancies as of 9/30/18	New Vacancies During Reporting Period (10/01/18 - 9/30/19)	Vacancies Filled (10/01/18 - 9/30/19)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	Nominees Received (10/01/18 - 9/30/19)	Nominees Willing to Serve (10/1/18 - 9/30/19)
Medical Devices Advisory Committee, Continued (Composed of 18 Panels)								
Neurological Devices Panel	9	1	0	0	9	1	6	6
Obstetrics and Gynecology Devices Panel	9	0	3	0	9	3	5	0
Ophthalmic Devices Panel	9	3	3	4	9	2	8	3
Orthopaedic and Rehabilitation Devices Panel	9	1	2	0	9	3	8	0
Radiological Devices Panel	9	1	3	3	9	1	6	3
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	9	0 (0%)	3	3	9	0 (0%)	4	0 (0%)
Science Advisory Board to the National Center for Toxicological Research	9	0	3	3	9	0	4	0
CENTER FOR TOBACCO PRODUCTS	12	0 (0%)	4	4	12	0 (0%)	23	4 (17%)
Tobacco Products Scientific Advisory Committee	12	0	1	1	12	0	23	4



Section 712(e)(1)(D) calls for an annual report of the aggregate number of waiver disclosures required under section 712(d) and the percentage of individuals to whom such disclosures did not apply who served on an advisory committee. 712(d) requires FDA to ensure that the public record of an advisory committee includes the disclosure required under subsection 712(c).⁵ 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,⁶ which applies to all advisory committees, and its reasons for granting any such waiver.⁷ This information is posted on FDA’s website prior to each meeting. Table 2 presents the number of individuals contacted who did not serve because of 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 2019 and the percentage of individuals to whom disclosures did not apply in FY 2019.

⁵ 712(d) of the FD&C Act (21 U.S.C. 379d-1(d)) omits from its disclosure requirement information exempted from disclosure under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a).

⁶ 18 U.S.C. 208.

⁷ A waiver under 18 U.S.C. 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 U.S.C. 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 Who Did Not Serve, Participants, and Waivers Granted - FY 2019

Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Because of Potential Conflicts of Interest	# of Persons contacted and Not Serving Because of Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting)*	18 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
FDA TOTALS	-----	48	1295	48	334	811	7	863	99.14%
OFFICE OF THE COMMISSIONER		4	119	1	25	93	0	93	100.00%
Science Board to the Food and Drug Administration	10/22/2018	1	16	0	1	15	0	15	100.00%
Pediatric Advisory Committee	4/8/2019	1	24	0	5	19	0	19	100.00%
Pediatric Advisory Committee	9/26/2019	1	40	1	11	28	0	28	100.00%
Pediatric Advisory Committee	9/27/2019	1	39	0	8	31	0	31	100.00%
CENTER FOR BIOLOGICS EVALUATION & RESEARCH		6	106	3	21	82	1	81	98.78%
Allergenic Products Advisory Committee	9/13/2019	1	11	3	0	8	0	8	100.00%
Blood Products Advisory Committee	3/20-21/2019	1	24	0	6	18	0	18	100.00%

Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Because of Potential Conflicts of Interest	# of Persons contacted and Not Serving Because of Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting)*	18 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR BIOLOGICS EVALUATION & RESEARCH, CONTINUED...									
Vaccines and Related Biological Products Advisory Committee	10/3/2018	1	15	0	1	14	0	14	100.00%
Vaccines and Related Biological Products Advisory Committee	11/8/2018	1	13	0	4	9	0	9	100.00%
Vaccines and Related Biological Products Advisory Committee	3/6-7/2019	1	22	0	1	21	1	20	95.24%
Vaccines and Related Biological Products Advisory Committee	3/22/2019	1	21	0	9	12	0	12	100.00%
CENTER FOR DRUG EVALUATION & RESEARCH		28	754	25	180	542	6	538	98.99%
Anesthetic and Analgesic Drug Products Advisory Committee	10/11/18	1	14	0	1	13	0	13	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee	10/12/18	1	13	0	1	12	0	12	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee	11/14/18	1	36	0	19	17	0	17	100.00%

Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Because of Potential Conflicts of Interest	# of Persons contacted and Not Serving Because of Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting) *	18 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DRUG EVALUATION & RESEARCH, CONTINUED...									
Anesthetic and Analgesic Drug Products Advisory Committee	11/15/18	1	25	1	11	13	0	13	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting with DSARM.	12/17-18/2019	1	41	1	14	26	0	26	100.00%
Antimicrobial Drugs Advisory Committee	4/25/19	1	26	0	0	26	0	26	100.00%
Antimicrobial Drugs Advisory Committee	4/26/19	1	29	1	11	17	0	17	100.00%
Antimicrobial Drugs Advisory Committee	6/5/19	1	23	0	0	23	0	23	100.00%
Antimicrobial Drugs Advisory Committee	6/6/19	1	23	0	0	23	0	23	100.00%
Antimicrobial Drugs Advisory Committee	8/7/19	1	24	1	5	18	2	16	88.89%
Arthritis Advisory Committee	1/11/2019	1	28	4	2	22	1	21	95.45%

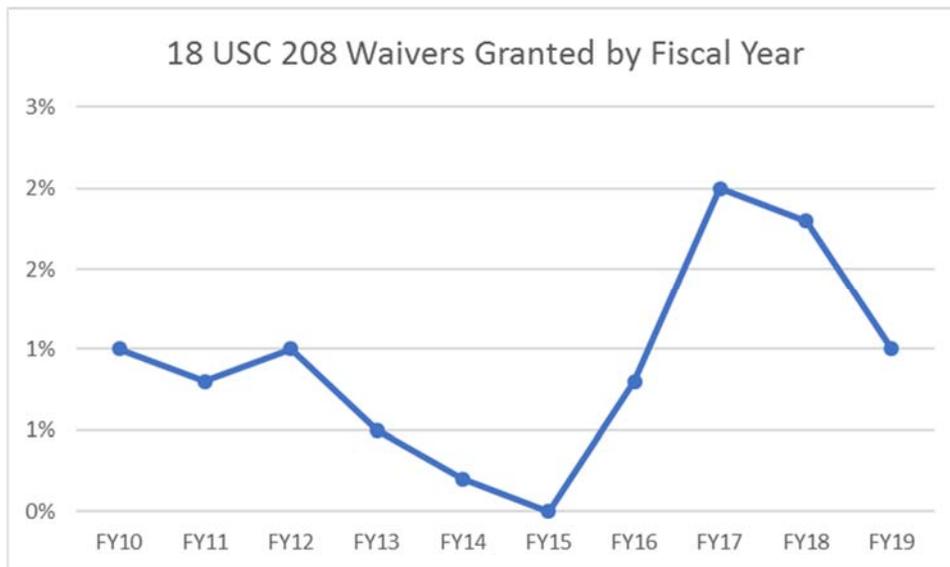
Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Because of Potential Conflicts of Interest	# of Persons contacted and Not Serving Because of Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting) *	18 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DRUG EVALUATION & RESEARCH, CONTINUED...									
Bone, Reproductive and Urologic Drugs Advisory Committee	1/16/2019	1	33	2	12	19	0	19	100.00%
Bone, Reproductive and Urologic Drugs Advisory Committee	1/16/2019	1	33	2	12	19	0	19	100.00%
Drug Safety and Risk Management Advisory Committee	6/11-12/2019	1	59	0	0	59	0	59	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	1/17/2019	1	17	0	2	15	0	15	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	10/24-25/2018	1	28	1	8	19	0	19	100.00%
Gastrointestinal Drugs Advisory Committee	10/18/2018	1	23	1	12	10	1	9	90.00%
Gastrointestinal Drugs Advisory Committee	10/17/2018	1	35	0	23	12	1	11	91.67%

Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Because of Potential Conflicts of Interest	# of Persons contacted and Not Serving Because of Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting) *	18 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DRUG EVALUATION & RESEARCH, CONTINUED...									
Nonprescription Drugs Advisory Committee	9/18/2019	1	21	0	0	21	0	21	100.00%
Oncologic Drugs Advisory Committee	5/14/19	1	29	0	0	29	0	29	100.00%
Oncologic Drugs Advisory Committee	10/10/2018	1	36	1	19	16	0	16	100.00%
Oncologic Drugs Advisory Committee	2/26/2019	1	23	6	3	14	0	14	100.00%
Pediatric Sub-Committee/ODAC	6/20/2019	1	16	2	4	10	1	9	90.00%
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	5/7/19	1	20	1	5	14	0	14	100.00%
Psychopharmacologic Drugs Advisory Committee	11/1/18	1	24	0	1	23	0	23	100.00%
Psychopharmacologic Drugs Advisory Committee	11/2/18	1	21	0	3	18	0	18	100.00%
Psychopharmacologic Drugs Advisory Committee	2/12/19	1	29	1	10	18	0	18	100.00%
Pulmonary-Allergy Drugs Advisory Committee	5/8/19	1	25	0	9	16	0	16	100.00%

Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Because of Potential Conflicts of Interest	# of Persons contacted and Not Serving Because of Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting) *	18 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		9	258	22	100	136	0	136	100.00%

Medical Devices Advisory Committee (Composed of 18 Panels)									
Circulatory System Devices Panel	12/4-5/2018	1	36	3	13	20	0	20	100.00%
Circulatory System Devices Panel	6/19-20/2019	1	37	4	17	16	0	16	100.00%
General and Plastic Surgery Devices Panel	3/25-26/2019	1	52	4	31	17	0	17	100.00%
General and Plastic Surgery Devices Panel	5/30-31/2019	1	33	0	23	10	0	10	100.00%
Microbiology Devices Panel	3/8/2019	1	23	1	5	17	0	17	100.00%
Neurological Devices Panel	3/21/2019	1	23	0	5	18	0	18	100.00%
Obstetrics and Gynecology Devices Panel	2/12-13/2019	1	28	10	5	13	0	13	100.00%

Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Because of Potential Conflicts of Interest	# of Persons Contacted and Not Serving Because of Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participants Attending (Voting & Nonvoting) *	18 U.S.C. 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, CONTINUED...									
Patient Engagement Advisory Committee	9/10/2019	1	13	0	1	12	0	12	100.00%
Patient Engagement Advisory Committee	11/15/2018	1	13	0	0	13	0	13	100.00%
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		1	9	0	4	5	0	5	100.00%
Science Advisory Board to the National Center for Toxicological Research	3/19/2019	1	9	0	4	5	0	5	100.00%
CENTER FOR TOBACCO PRODUCTS		1	14	0	0	14	0	14	100.00%
Tobacco Products Scientific Advisory Committee	2/6-7/2019	1	14	0	0	14	0	14	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 to 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 consider the levels of activity (including the numbers of annual meetings) of 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 notifies the public several times annually about vacancies on advisory committees through *Federal Register* notices. Many professional societies use these notices to share news of potential vacancies among interested professionals. In FY 2019, FDA issued nine 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 participate in FDA-TRACK, an Agency-wide performance plan that provides monthly reporting on measurable objectives on the Advisory Committees public website. As part of that effort, the advisory committee program reports on the monthly vacancy rates by committee as well as on the number of advisory committee meetings held per month.

- A staff member in FDA’s Advisory Committee Oversight and Management Staff, 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 engaging with consumer-oriented organizations.
- FDA participates in speaking opportunities at universities, conferences, workshops, and training sessions on FDA’s advisory committee process. FDA participated in seven such speaking opportunities in FY 2019.
- FDA meets with relevant organizations to explain the advisory committee program and the process for nominating candidates. FDA participated in four such activities in FY 2019.
- 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 meeting:
 - American Public Health Association, San Diego, California