

Report to Congress

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

Fiscal Year 2020 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 (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 conflicts of interest on an annual basis. The reporting information was first mandated by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and subsequently modified by FDASIA.

As required in the statute, this report describes the following information for FY 2020:

- 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 2020 include:

- The number of waivers granted under 18 U.S.C. 208(b)(3) increased from seven in FY 2019 to nine in FY 2020 (less than two percent of total meeting participants in attendance at meetings);
- 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 as determined by the Agency;
- FDA received 258 applications through the Membership Nomination Portal. FDA identified 67 percent of the nominees received (175) 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, 2019, through September 30, 2020.

Scope of the FY 2020 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 2020, for each advisory 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. In order to

¹712(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).

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.

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 2019, the number of new vacancies during FY 2020, and the number of these vacancies filled during FY 2020, 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.

The number of vacancies on FDA Advisory Committees increased from 12% on September 30, 2019, to 14% on September 30, 2020 (see Table 1).

Table 1 - 712(e)(1)(A) Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing to Serve - FY 2020

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	New Vacancies During Reporting Period (10/01/19 - 9/30/20)	Vacancies Filled (10/01/19 - 9/30/20)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	Nominees Received (10/01/19 - 9/30/20)	Nominees Willing to Serve (10/1/19-9/30/20)
Total All Offices/Centers	547	65 (12%)	160	146	547	79 (14%)	254	175 (69%)
OFFICE OF THE COMMISSIONER	52	10 (19%)	17	12	52	15 (29%)	22	12 (55%)
Pediatric Advisory Committee	16	4	4	7	16	1	6	7
Risk Communication Advisory Committee	15	2	7	0	15	9	5	0
Science Board to the Food and Drug Administration	21	4	6	5	21	5	11	5
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	58	7 (12%)	18	24	58	2 (3%)	24	23 (96%)
Allergenic Products Advisory Committee	10	3	4	7	10	1	4	6
Blood Products Advisory Committee	18	1	6	6	18	1	7	6
Cellular, Tissue, & Gene Therapies Advisory Committee	14	2	4	6	14	0	6	6
Vaccines and Related Biological Products Advisory Committee	16	1	4	5	16	0	7	5

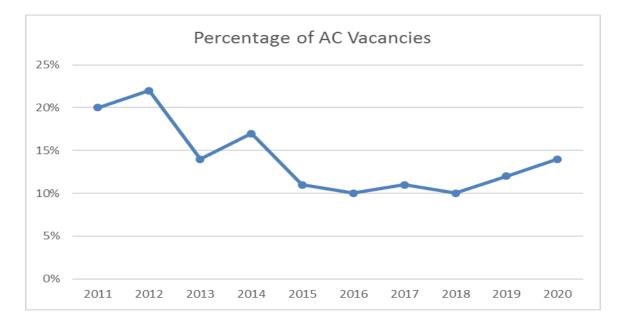
Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	New Vacancies During Reporting Period (10/01/19 - 9/30/20)	Vacancies Filled (10/01/19 - 9/30/20)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	Nominees Received (10/01/19 - 9/30/20)	Nominees Willing to Serve (10/1/19-9/30/20)
CENTER FOR DRUG EVALUATION AND RESEARCH	209	8 (4%)	74	70	209	12 (6%)	79	69 (87%)
Anesthetic and Analgesic Drug Products Advisory Committee	12	0	3	2	12	1	8	2
Antimicrobial Drugs Advisory Committee	14	0	5	5	14	0	7	5
Arthritis Advisory Committee	12	1	5	6	12	0	1	6
Bone, Reproductive and Urologic Drugs Advisory Committee	12	2	4	2	12	4	4	1
Cardiovascular and Renal Drugs Advisory Committee	12	0	6	6	12	0	6	6
Dermatologic and Ophthalmic Drugs Advisory Committee	10	0	4	4	10	0	2	4
Drug Safety and Risk Management Advisory Committee (DSARMAC)	12	0	4	3	12	1	11	3
Endocrinologic and Metabolic Drugs Advisory Committee	12	0	5	5	12	0	1	5
Gastrointestinal Drugs Advisory Committee	12	0	3	2	12	1	4	2
Medical Imaging Drugs Advisory Committee	13	0	5	5	13	0	2	б

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	New Vacancies During Reporting Period (10/01/19 - 9/30/20)	Vacancies Filled (10/01/19 - 9/30/20)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	Nominees Received (10/01/19 - 9/30/20)	Nominees Willing to Serve (10/1/19-9/30/20)
Nonprescription Drugs Advisory Committee	11	1	4	5	11	0	5	5
Oncologic Drugs Advisory Committee	14	1	5	2	14	4	7	2
Peripheral and Central Nervous System Drugs Advisory Committee	10	0	5	5	10	0	2	5
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	17	0	5	5	17	0	5	5
Pharmacy Compounding Advisory Committee	14	3	4	6	14	1	12	4
Psychopharmacologic Drugs Advisory Committee	10	0	5	5	10	0	1	5
Pulmonary-Allergy Drugs Advisory Committee	12	0	2	2	12	0	1	3

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	New Vacancies During Reporting Period (10/01/19 - 9/30/20)	Vacancies Filled (10/01/19 - 9/30/20)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	Nominees Received (10/01/19 - 9/30/20)	Nominees Willing to Serve (10/1/19-9/30/20)
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	207	39 (19%)	44	33	207	50 (24%)	98	64 (65%)
Device Good Manufacturing Practice Advisory Committee	9	5	0	1	9	4	6	4
National Mammography Quality Assurance Advisory Committee	15	2	6	6	15	2	5	15
Patient Engagement Advisory Committee	9	1	3	4	9	0	18	9
Technical Electronic Product Radiation Safety Standards Committee	15	4	б	0	15	10	1	15
				Advisory Commit 1 of 18 Panels)	tee			
Anesthesiology and Respiratory Therapy Devices Panel	9	1	1	0	9	2	7	3
Circulatory System Devices Panel	9	2	2	3	9	1	7	7
Clinical Chemistry and Clinical Toxicology Devices Panel	9	2	1	0	9	3	2	1
Dental Products Panel	10	3	2	2	10	3	11	4

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	New Vacancies During Reporting Period (10/01/19 - 9/30/20)	Vacancies Filled (10/01/19 - 9/30/20)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	Nominees Received (10/01/19 - 9/30/20)	Nominees Willing to Serve (10/1/19-9/30/20)
			Medical Devices Adv (Compos	isory Committee, ed of 18 Panels)	continued			
Ear, Nose, and Throat Devices Panel	9	0	0	0	9	0	1	1
Gastroenterology-Urology Devices Panel	9	1	2	0	9	3	2	2
General and Plastic Surgery Devices Panel	9	1	3	3	9	1	8	6
General Hospital and Personal Use Devices Panel	9	0	1	0	9	1	3	2
Hematology and Pathology Devices Panel	9	0	3	3	9	0	0	0
Immunology Devices Panel	9	5	2	1	9	6	2	1
Medical Devices Dispute Resolution Panel	5	0	1	0	5	1	6	6
Microbiology Devices Panel	9	1	2	0	9	3	3	3
Molecular and Clinical Genetics Panel	9	0	1	0	9	1	0	0

Advisory Committee Name (by Office/Center)	Authorized Membership as of 9/30/19	Vacancies as of 9/30/19	New Vacancies During Reporting Period (10/01/19 - 9/30/20)	Vacancies Filled (10/01/19 - 9/30/20)	Authorized Membership as of 9/30/20	Vacancies as of 9/30/20	Nominees Received (10/01/19 - 9/30/20)	Nominees Willing to Serve (10/1/19-9/30/20)				
	Medical Devices Advisory Committee, continued (Composed of 18 Panels)											
Neurological Devices Panel91209332												
Obstetrics and Gynecology Devices Panel	9	3	1	2	9	2	2	1				
Ophthalmic Devices Panel	9	2	1	0	9	3	2	1				
Orthopaedic and Rehabilitation Devices Panel	9	3	3	6	9	0	5	3				
Radiological Devices Panel	9	1	1	1	9	1	4	2				
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	9	0	3	3	9	0	6	3 (50%)				
Science Advisory Board to the National Center for Toxicological Research	9	0	3	3	9	0	6	3				
CENTER FOR TOBACCO PRODUCTS	12	0	4	4	12	0	25	4 (16%)				
Tobacco Products Scientific Advisory Committee	12	0	4	4	12	0	25	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. Table 2 also presents the number of waiver disclosures made in FY 2020 and the percentage of individuals to whom disclosures did not apply in FY 2020.

⁵712(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 2020

Committee Name	Meeting Date	# 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 Participant s Attending (Voting & Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participan ts With No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
FDA TOTALS		34	757	31	193	532	9	523	98.31%
OFFICE OF THE COMMISSIONER		2	39	0	0	38	1	37	97.37%
Science Board to the Food and Drug Administration	10/7/2019	1	15	0	0	14	0	14	100.00%
Pediatric Advisory Committee	9/15/2020	1	24	0	0	24	1	23	95.83%
CENTER FOR BIOLOGICS EVALUATION & RESEARCH		5	74	4	16	54	0	54	100.00%
Allergenic Products Advisory Committee	11/22/2019	1	15	2	2	11	0	11	100.00%
Blood Products Advisory Committee	5/8/2020	1	15	0	1	14	0	14	100.00%

Committee Name	Meeting Date	# 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 Participant s Attending (Voting & Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participan ts With No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
	CENTER I	FOR BIOLO	GICS EVALU	JATION & RE	ESEARCH, CO	ONTIUNED			
Vaccines and Related Biological Products Advisory Committee	10/9/2019	1	16	0	7	9	0	9	100.00%
Vaccines and Related Biological Products Advisory Committee	11/8/2019	1	14	2	4	8	0	8	100.00%
Vaccines and Related Biological Products Advisory Committee	3/4/2020	1	14	0	2	12	0	12	100.00%
CENTER FOR DRUG EVALUATION & RESEARCH		21	513	20	145	348	6	342	98.28%
Anesthetic and Analgesic Drug Products Advisory Committee	1/16/20	1	15	1	2	12	0	12	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting with DSARMAC	1/14/20	1	45	0	18	27	0	27	100.00%
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting with DSARMAC	1/15/20	1	40	0	14	26	0	26	100.00%

Committee Name	Meeting Date	# 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 Participant s Attending (Voting & Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participan ts With No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
	CENTE	R FOR DRU	JG EVALUAT	TION & RESE	ARCH, CONT	TINUED			
Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting with DSARMAC	1/15/20	1	41	0	15	26	0	26	100.00%
DSARM with Anesthetic and Analgesic Drug Products Advisory Committee Joint Meeting	1/15/20	1	35	1	6	28	0	28	100.00%
Antimicrobial Drugs Advisory Committee	10/16/19	1	25	0	9	16	0	16	100.00%
Bone, Reproductive, and Urologic Drugs Advisory Committee	10/29/2019	1	29	2	11	16	0	16	100.00%
Bone, Reproductive, and Urologic Drugs Advisory Committee	10/30/2019	1	32	3	12	17	1	16	94.12%
Cardiovascular and Renal Drugs Advisory Committee	7/15/2020	1	17	1	1	15	0	15	100.00%
Cardiovascular and Renal Drugs Advisory Committee	12/10/2019	1	17	1	2	14	0	14	100.00%
Endocrinologic and Metabolic Drugs Advisory Committee	11/13/2019	1	16	0	0	16	0	16	100.00%

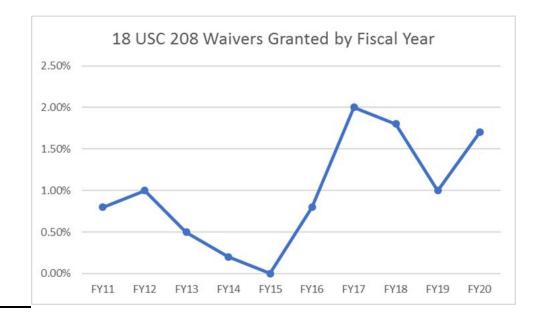
Committee Name	Meeting Date	# of Meetings	# of Persons Contacted (Attending and Not Attending) *	# of Persons Contacted and Not Serving Due to Potential Conflicts of Interest	# of Persons Contacted and Not Serving Due to Reasons Other Than Potential Conflicts of Interest	Total Number of Meeting Participant s Attending (Voting & Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participan ts With No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
	CENT	ER FOR DRU	JG EVALUAT	TION & RESE	ARCH, CON	TINUED			
Endocrinologic and Metabolic Drugs Advisory Committee	11/14/2019	1	20	0	4	16	0	16	100.00%
Oncologic Drugs Advisory Committee	12/17/2020	1	14	0	2	12	0	12	100.00%
Oncologic Drugs Advisory Committee	12/17/2020	1	19	2	3	14	0	14	100.00%
Oncologic Drugs Advisory Committee	12/18/2020	1	17	3	3	11	0	11	100.00%
Oncologic Drugs Advisory Committee	2/26/20	1	26	2	9	15	0	15	100.00%
Oncologic Drugs Advisory Committee	2/26/20	1	21	1	9	11	0	11	100.00%
Oncologic Drugs Advisory Committee	7/14/2020	1	21	2	5	14	0	14	100.00%

Committee Name	Meeting Date	# 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 Participant s Attending (Voting & Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participan ts With No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
	CENTE	R FOR DRU	JG EVALUAT	TION & RESE	CARCH, CON	TINUED			
Oncologic Drugs Advisory Committee	8/13/2020	1	21	1	7	13	0	13	100.00%
Pediatric Sub-Committee/Oncologic Drugs Advisory Committee	6/17-18/2020	1	21	0	7	14	5	9	68.75%
Pulmonary-Allergy Drugs Advisory Committee	8/31/20	1	21	0	6	15	0	15	100.00%

Committee Name	Meeting Date	# 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 Participant s Attending (Voting & Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participan ts With No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		3	99	7	32	60	2	58	96.67%

Medical Devices Advisory Committee (Composed of 18 Panels)									
General Hospital and Personal Use Devices Panel	11/6-7/2019	1	31	2	7	22	0	22	100.00%
Immunology Devices Panel	11/13-14/2019	1	40	5	13	22	2	20	90.91%
Orthopedic and Rehabilitation Devices Panel	10/8-9/2020	1	28	0	12	16	0	16	100.00%

Committee Name	Meeting Date	# 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 Participant s Attending (Voting & Nonvoting) *	18 USC 208(b)(1) and (b)(3) Waivers Granted	Total Meeting Participan ts With No Waivers	% of Meeting Participants <u>Not</u> Issued Waivers
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		2	18	0	0	18	0	18	100.00%
Science Advisory Board to the National Center for Toxicological Research	8/18- 19/2020	1	9	0	0	9	0	9	100.00%
Science Advisory Board to the National Center for Toxicological Research	12/3-4/2019	1	9	0	0	9	0	9	100.00%
CENTER FOR TOBACCO PRODUCTS		1	14	0	0	14	0	14	100.00%
Tobacco Products Scientific Advisory Committee	2/14/2020	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 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 2020, 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.
- To encourage diversity and inclusion among our advisory committee members, FDA's public announcements of vacancies (Federal Register notices, website, etc.) include the following language: "FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups."

- FDA's advisory committee staff participate in FDA-TRACK, an Agency-wide performance tracker 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 as well as 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, 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.
- The COVID-19 pandemic had a significant effect on FDA's traditional in-person recruitment activities (e.g., attendance at meetings of professional scientific organizations, meetings with relevant consumer-oriented organizations and distribution of brochures at various public meetings). In FY 2020 these activities were replaced with telephone communications, e-mail and physical mailing of brochures.