



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

TO: The Secretary  
Through: DS \_\_\_\_\_  
COS \_\_\_\_\_  
ES \_\_\_\_\_

FROM: Commissioner of Food and Drugs

DATE: FEB 07 2013

SUBJECT: FY 2012 Annual Report on the Food and Drug Administration Advisory  
Committee Vacancies and Public Disclosures - **DECISION**

**BACKGROUND**

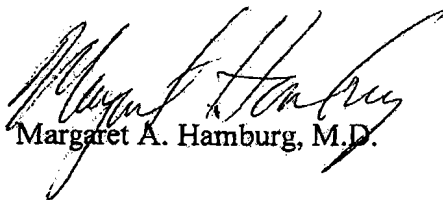
The Food and Drug Administration (FDA) is submitting this report under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The report covers fiscal year (FY) 2012 and summarizes how the FDA has met each of the conditions specified in Section 712(e) of the FD&C Act.

**HIGHLIGHTS**

The report describes, for FY 2012, the number of vacancies on each advisory committee, including new vacancies, the number of nominees considered for each committee, and the number of such nominees willing to serve. The report also describes the number of disclosures made in FY 2012 and the percentage of individuals to whom disclosures did not apply in FY 2012.


**RECOMMENDATION**

I recommend that you review and approve the report and forward it to Congress.

  
Margaret A. Hamburg, M.D.

**DECISION**

Approved  Disapproved \_\_\_\_\_ Need More Information \_\_\_\_\_



\_\_\_\_\_  
Kathleen Sebelius  
Secretary

MAR 20 2013

\_\_\_\_\_  
Date

**Attachments:**

Tab A – Transmittal Letters

Tab B – Report to Congress



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

March 21, 2013

The Honorable Fred Upton  
Chairman  
Committee on Energy and Commerce  
House of Representatives  
Washington, DC 20515

Dear Mr. Chairman:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. The Food and Drug Administration (FDA) is submitting this report under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The report covers fiscal year 2012 and summarizes how FDA has met each of the conditions specified in Section 712(e) of the FD&C Act, in response to this statutory requirement.

I hope you will find the report useful and informative.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is fluid and cursive.

Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

March 21, 2013

The Honorable Joseph Biden, Jr.  
President  
United States Senate  
Washington, DC 20510

Dear Mr. President:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. The Food and Drug Administration (FDA) is submitting this report under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The report covers fiscal year 2012 and summarizes how FDA has met each of the conditions specified in Section 712(e) of the FD&C Act, in response to this statutory requirement.

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Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

March 21, 2013

The Honorable Tom Harkin  
Chairman  
Committee on Health, Education, Labor, and Pensions  
United States Senate  
Washington, DC 20510

Dear Mr. Chairman:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. The Food and Drug Administration (FDA) is submitting this report under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The report covers fiscal year 2012 and summarizes how FDA has met each of the conditions specified in Section 712(e) of the FD&C Act, in response to this statutory requirement.

I hope you will find the report useful and informative.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is written in a cursive style with a large initial "K".

Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

March 21, 2013

The Honorable Lamar Alexander  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate  
Washington, DC 20510

Dear Senator Alexander:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. The Food and Drug Administration (FDA) is submitting this report under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The report covers fiscal year 2012 and summarizes how FDA has met each of the conditions specified in Section 712(e) of the FD&C Act, in response to this statutory requirement.

I hope you will find the report useful and informative.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Kathleen Sebelius

Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

March 21, 2013

The Honorable Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Waxman:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. The Food and Drug Administration (FDA) is submitting this report under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The report covers fiscal year 2012 and summarizes how FDA has met each of the conditions specified in Section 712(e) of the FD&C Act, in response to this statutory requirement.

I hope you will find the report useful and informative.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

March 21, 2013

The Honorable John Boehner  
Speaker of the House of Representatives  
Washington, DC 20515

Dear Mr. Speaker:

Attached is the annual Report on the Food and Drug Administration Advisory Committee Vacancies and Public Disclosures. The Food and Drug Administration (FDA) is submitting this report under Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The report covers fiscal year 2012 and summarizes how FDA has met each of the conditions specified in Section 712(e) of the FD&C Act, in response to this statutory requirement.

I hope you will find the report useful and informative.

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Kathleen Sebelius

Enclosure



**Report to Congress**

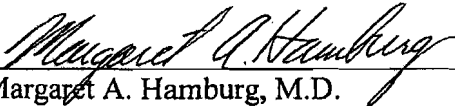
**Food and Drug Administration Amendments Act of 2007  
Section 712 (e) of the Federal Food, Drug, and Cosmetic Act**

**Fiscal Year 2012 Annual Report on the Food and Drug Administration  
Advisory Committee  
Vacancies and Public Disclosures**

**Department of Health and Human Services**

**Food and Drug Administration**

Submit to HHS for review and concurrence before final signature:

 Date **FEB 07 2013**  
Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs

## **EXECUTIVE SUMMARY**

This report on the Food and Drug Administration Amendments Act (FDAAA) of 2007, Section 712(e) of the Federal Food, Drug, and Cosmetic Act, provides the information required by the Food and Drug Administration (FDA) on its advisory committee vacancies and public disclosures of information for fiscal year 2012.

This report describes the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of nominees willing to serve. This report also describes the aggregate number of waiver disclosures for each meeting of each advisory committee and the percentage of individuals who served on a committee for each meeting to whom waiver disclosures did not apply, and how the Secretary plans to reduce the number of vacancies and mechanisms to encourage the nomination of individuals for service on an advisory committee.

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## **Background**

Section 712(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)<sup>1</sup> requires the Food and Drug Administration (FDA or Agency) to report annually on its advisory committee vacancies and public disclosures of information. Specifically, section 712(e)<sup>2</sup> requires a report that describes:

- (1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;*
- (2) with respect to such year, the aggregate number of disclosures required under subsection (c)(3) [section 712(c)(3)] for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;*
- (3) with respect to such year, the number of times the disclosures required under subsection (c)(3) [section 712(c)(3)] occurred under subparagraph (B) of such subsection; and*
- (4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.*

## **Reporting Period**

This report covers the period from October 1, 2011, through September 30, 2012.

## **Scope of the FY 2012 Annual Report**

In response to the information to be reported under section 712(e)(1), Table 1 (on page 2) presents the data on the number of vacancies, the number of nominees received,<sup>3</sup> and the number of such nominees willing to serve<sup>4</sup> in FY 2012, for each advisory committee.

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<sup>1</sup> 21 U.S.C. 379d-1(e). This annual report requirement was added by the Food and Drug Administration Amendments Act (FDAAA) of 2007, signed into law on September 27, 2007. Title VII of FDAAA added new conflict of interest provisions applicable to FDA advisory committees, effective October 1, 2007. The 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) further amended section 712 of the FD&C Act, as of October 1, 2012. The initial annual report under section 712(e), as amended by FDASIA, is due on February 1, 2014.

<sup>2</sup> References to “sections” in this report are to sections of the FD&C Act unless otherwise specified.

<sup>3</sup> FDA considers a nomination as “received” when the submission includes all of the following information for the nominee: complete *curriculum vitae*, a current address and telephone number, the advisory committee(s) or advisory panel(s) for which the nominee is recommended, and a written confirmation that the nominee is aware of the nomination.

<sup>4</sup> See section 712(c)(3)(B) of the FD&C Act. The nominees that FDA received were counted as “willing to serve” if a review of the submission indicated that the nominee appeared to meet qualifications to serve and the nominee confirmed his/her willingness to serve after being contacted by FDA and informed of the committee requirements for service, including conflict of interest requirements.

The number of vacancies on an FDA advisory committee may vary within any given year depending on when openings are filled and when new vacancies occur. In order to provide a complete picture of this dynamic process, FDA lists the total number of vacancies for each advisory committee at the start of FY 2012, the number of new vacancies during FY 2012, and the number of these vacancies filled during FY 2012. See Table 1.

**Table 1 - 712(e)(1) Pre-existing Vacancies, New Vacancies, Nominees Received, and Nominees Willing To Serve FY 2012**

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/11	New Vacancies during reporting period (10/01/11- 9/30/12)	Vacancies Filled (10/01/11-9/30/12)	Vacancies as of 9/30/12	Nominees Received (10/01/11- 9/30/12)	Nominees Willing to Serve (10/1/11- 9/30/12)
<b>Total All Centers</b>	<b>118</b>	<b>157</b>	<b>140</b>	<b>135</b>	<b>603</b>	<b>304</b>
Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/11	New Vacancies during reporting period (10/01/11- 9/30/12)	Vacancies Filled (10/01/11- 9/30/12)	Vacancies as of 9/30/12	Nominees Received (10/01/11- 9/30/12)	Nominees Willing to Serve (10/01/11- 9/30/12)
Science Board to the FDA	3	3	4	2	39	6
FDA Pediatric AC	5	5	3	7	10	4
Risk Communication Advisory Committee	0	4	3	1	43	36
Allergenic Products	1	4	5	0	9	7
Blood Products	4	1	5	0	17	14
Cellular, Tissue, & Gene Therapies	2	5	7	0	13	11
Transmissible Spongiform Encephalopathies	2	5	4	3	1	1
Vaccines and Related Biological Products	1	4	5	0	10	7
Anesthetic and Life Support Drugs	7	3	8	2	11	0
Anti-Infective Drugs	2	4	5	1	9	0
Antiviral Drugs	0	5	5	0	5	0
Arthritis	5	4	7	2	2	0
Cardiovascular and Renal Drugs	5	5	6	4	9	2
Dermatologic and Ophthalmic Drugs	3	5	1	7	6	1
Drug Safety and Risk Management	0	4	1	3	13	2
Endocrinologic and Metabolic Drugs	2	4	3	3	9	0
Gastrointestinal Drugs	3	4	5	2	8	3
*Medical Imaging Drugs	13	0	1	12	74	33
Nonprescription Drugs	8	6	6	8	19	0
Oncologic Drugs	3	6	3	6	8	0
Peripheral and Central Nervous System Drugs	4	3	2	5	9	1
Pharmaceutical Science and Clinical Pharmacology	8	10	7	11	9	1

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/11	New Vacancies during reporting period (10/01/11- 9/30/12)	Vacancies Filled (10/01/11- 9/30/12)	Vacancies as of 9/30/12	Nominees Received (10/01/11- 9/30/12)	Nominees Willing to Serve (10/01/11- 9/30/12)
**Pharmacy Compounding	0	13	0	13	0	0
Psychopharmacologic Drugs	1	5	2	4	6	0
Pulmonary-Allergy Drugs	0	5	1	4	9	4
Reproductive Health Drugs	5	3	3	5	10	2
<b>CENTER FOR DEVICES AND RADIOLOGICAL HEALTH</b>	<b>23</b>	<b>29</b>	<b>35</b>	<b>17</b>	<b>179</b>	<b>137</b>
Device Good Manufacturing Practice Advisory Committee	0	3	1	2	1	1
<b>Medical Devices Advisory Committee (Comprised of 18 Panels)</b>						
- Anesthesiology and Respiratory Therapy Devices Panel	1	2	3	0	11	7
- Circulatory System Devices Panel	0	2	0	2	28	25
- Clinical Chemistry and Clinical Toxicology Devices Panel	0	3	2	1	7	4
- ***Dental Products Panel	1	0	0	1	7	5
- Ear, Nose, and Throat Devices Panel	0	0	0	0	3	2
- Gastroenterology-Urology Devices Panel	0	3	3	0	4	3
- General and Plastic Surgery Devices Panel	1	2	1	2	10	7
- General Hospital and Personal Use Devices Panel	1	0	1	0	1	1
- Hematology and Pathology Devices Panel	0	0	0	0	1	1
- Immunology Devices Panel	2	1	3	0	3	2
- Medical Devices Dispute Resolution Panel	0	0	0	0	0	0
- Microbiology Devices Panel	0	2	0	2	8	5
- Molecular and Clinical Genetics Panel	1	2	1	2	4	2
- Neurological Devices Panel	1	1	2	0	7	5
- Obstetrics-Gynecology Devices	0	1	1	0	9	4
- Ophthalmic Devices Panel	2	0	2	0	30	30
- Orthopedic and Rehabilitation Devices Panel	0	2	0	2	9	9
- Radiological Devices Panel	0	1	0	1	13	8
National Mammography Quality Assurance Advisory Committee	0	4	3	1	15	10
Technical Electronic Product Radiation Safety Standards Committee	13	0	12	1	8	6

Advisory Committee Name (by Office/Center)	Vacancies as of 9/30/11	New Vacancies during reporting period (10/01/11- 9/30/12)	Vacancies Filled (10/01/11-9/30/12)	Vacancies as of 9/30/12	Nominees Received (10/01/11-9/30/12)	Nominees Willing to Serve (10/1/11-9/30/12)
	0	3	0	3	32	17
Food Advisory Committee	0	3	0	3	32	17
	6	4	0	10	5	0
Veterinary Medicine Advisory Committee	6	4	0	10	5	0
	0	0	0	0	1	0
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH Science Advisory Board to the National Center for Toxicological Research	0	0	0	0	1	0
	2	1	3	0	28	15
Tobacco Products Scientific Advisory Committee	2	1	3	0	28	15

\*Number of vacancies for Medical Imaging Drugs Advisory Committee vacancies for 9/30/11 was reported incorrectly. The correct number was 13

\*\*On April 5, 2012, the charter for the Pharmacy Compounding Advisory Committee was filed, re-establishing the Committee. Announcement of the formation of the Committee and the solicitation of nominations for the 13 member vacancies is on hold pending discussions about the role of the Committee, which is described in a statutory provision currently under discussion in Congress for amendment.

\*\*\*Vacancies for 9/30/11 was corrected for Dental Products Panel, from 0 to 1

Section 712(e)(2) of the FD&C Act mandates an annual report of the aggregate number of waiver disclosures required under section 712(c)(3) for each advisory committee meeting and the percentage of advisory committee members to whom such disclosures did not apply to those who served on the committee for each meeting. Under section 712(c)(3), 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 conflict of interests laws<sup>5</sup> that apply to all advisory committees or under FDA<sup>6</sup>, and the reasons for granting the waiver.<sup>7</sup> This information is posted on FDA's website prior to each meeting. Table 2 presents the number of waiver disclosures made in FY 2012 and the percentage of individuals to whom disclosures did not apply in FY 2012.

**Table 2 - 712(e)(2) Number of Meetings, Participants, and Waivers Granted FY 2012**

	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Section 712(c)(2)(B) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
<b>TOTAL</b>	<b>82</b>	<b>1328</b>	<b>14</b>	<b>7</b>	<b>1320</b>	<b>98.95%</b>

\* Not including Industry Representatives, FDA Employees or Guest Speakers

<sup>5</sup> 18 U.S.C. 208

<sup>6</sup> 712(c)(2)(B), 21 USC 379d-1(c)(2)(B)

<sup>7</sup> 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 FDA, 21 USC 379d-1(c)(2) a waiver may be granted if necessary to afford the advisory committee essential expertise.

Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Section 712(c)(2)(B) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
<b>OFFICE OF THE COMMISSIONER</b>		<b>7</b>	<b>116</b>	<b>0</b>	<b>0</b>	<b>116</b>	<b>100.00%</b>
Science Board to the FDA	1/6/12	1	14	0	0	14	100.00%
Science Board to the FDA	5/2/12	1	13	0	0	13	100.00%
Pediatric	1/30-31/2012	1	24	0	0	24	100.00%
Pediatric	5/7-8/2012	1	19	0	0	19	100.00%
Pediatric	9/10-11/2012	1	19	0	0	19	100.00%
Risk Communication	11/17-11/18	1	14	0	0	14	100.00%
Risk Communication	6/29/12	1	13	0	0	13	100.00%
<b>CENTER FOR BIOLOGICS EVALUATION &amp; RESEARCH</b>		<b>0</b>	<b>144</b>	<b>0</b>	<b>0</b>	<b>144</b>	<b>100.00%</b>
Allergenic Products	10/25/11	1	10	0	0	11	100.00%
Blood Products	5/15-16/12	1	21	0	0	21	100.00%
Blood Products	6/12/12	1	15	0	0	15	100.00%
Blood Products	9/20-21/12	1	24	0	0	24	100.00%
Cellular Tissue & Gene Therapies	11/17/11	1	15	0	0	15	100.00%
Cellular Tissue & Gene Therapies	2/10/12	1	8	0	0	8	100.00%
Transmissible Spongiform Encephalopathies	N/A	0	0	0	0	0	0.00%
Vaccines and Related Biologics	11/16/11	1	16	0	0	16	100.00%
Vaccines and Related Biologics	2/28-29/12	1	19	0	0	19	100.00%
Vaccines and Related Biologics	9/19/12	1	16	0	0	16	100.00%
<b>DRUG EVALUATION AND RESEARCH</b>		<b>0</b>	<b>111</b>	<b>0</b>	<b>0</b>	<b>111</b>	<b>100.00%</b>
Anesthetic and Life Support Drugs	2/9/12	1	12	0	0	12	100.00%
Anti-Infective Drugs	11/3/11	1	18	0	0	18	100.00%
Anti-Infective Drugs	11/4/11	1	17	0	0	17	100.00%
Anti-Infective Drugs	4/2/12	1	26	0	0	26	100.00%
Anti-Infective Drugs	4/3-4/12	1	10	0	0	10	100.00%
Anti-Infective Drugs	9/5/12	1	14	0	0	14	100.00%
Antiviral Drugs	12/14-15/2011	1	20	0	0	20	100.00%
Antiviral Drugs	5/10/12	1	22	0	0	22	100.00%
Antiviral Drugs	5/11/12	1	14	0	0	14	100.00%
Arthritis	3/12/12	1	22	0	0	22	100.00%
Arthritis	5/8/12	1	11	0	0	11	100.00%
Arthritis	5/9/12	1	10	1	0	9	90.00%
Cardiovascular and Renal Drugs	2/23/12	1	13	0	0	13	100.00%
Cardiovascular and Renal Drugs	5/23/12	1	11	0	0	11	100.00%
Cardiovascular and Renal Drugs	9/13/12	1	12	0	0	12	100.00%
Dermatologic and Ophthalmic Drugs	2/27/12	1	11	0	0	11	93.33%
Dermatologic and Ophthalmic Drugs	7/26/12	1	10	0	0	10	100.00%
Drug Safety and Risk Management	12/1/11	1	30	0	0	30	100.00%



Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Section 712(c)(2)(B) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
Endocrinologic and Metabolic Drugs	11/2/11	1	16	0	0	16	100.00%
Endocrinologic and Metabolic Drugs	2/22/12	1	23	0	0	23	100.00%
Endocrinologic and Metabolic Drugs	3/28-29/2012	1	24	0	0	24	100.00%
Endocrinologic and Metabolic Drugs	5/10/12	1	23	1	1	22	95.65%
Gastrointestinal Drugs	11/16/11	1	12	0	0	12	100.00%
Gastrointestinal Drugs	11/17/11	1	22	0	0	22	100.00%
Gastrointestinal Drugs	3/13/12	1	21	1	1	20	95.24%
Gastrointestinal Drugs	8/28/12	1	17	0	0	17	100.00%
Medical Imaging Drugs	N/A	0	0	0	0	0	0.00%
Nonprescription Drugs	N/A	0	0	0	0	0	0.00%
Oncologic Drugs (Pediatric Oncology Subcommittee)	11/1/11	1	12	0	0	12	100.00%
Oncologic Drugs (Pediatric Oncology Subcommittee)	11/2/11	1	14	0	0	14	100.00%
Oncologic Drugs	12/7/11	1	19	0	0	19	100.00%
Oncologic Drugs	2/8/12	1	13	0	0	13	100.00%
Oncologic Drugs	2/9/12	1	14	0	0	14	100.00%
Oncologic Drugs	3/20/12	1	15	1	1	14	93.33%
Oncologic Drugs	3/21/12	1	13	0	0	13	100.00%
Oncologic Drugs	6/20/12	1	17	0	0	17	100.00%
Oncologic Drugs	7/24/12	1	19	0	0	19	100.00%
Oncologic Drugs	7/25/12	1	17	0	0	17	100.00%
Peripheral and Central Nervous System Drugs	10/17/11	1	17	0	0	17	100.00%
Peripheral and Central Nervous System Drugs	5/24/12	1	17	0	0	17	100.00%
Pharmaceutical Science and Clinical Pharmacology	3/14/12	1	14	4	4	10	71.43%
Pharmaceutical Science and Clinical Pharmacology	8/8/12	1	8	0	0	8	100.00%
Pharmaceutical Science and Clinical Pharmacology	8/9/12	1	8	0	0	8	100.00%
Psychopharmacologic Drugs	12/12/11	1	18	0	0	18	100.00%
Pulmonary-Allergy Drugs	2/23/12	1	14	0	0	14	100.00%
Reproductive Health Drugs	12/8/11	1	27	0	0	27	100.00%
Reproductive Health Drugs	12/9/11	1	24	0	0	24	100.00%
Reproductive Health Drugs	1/20/12	1	17	0	0	17	100.00%
Reproductive Health Drugs	4/5/12	1	12	0	0	12	100.00%
Device Good Manufacturing Practice Advisory Committee	N/A	0	0	0	0	0	0.00%
Medical Devices Advisory Committee (Comprised of 18 Panels)							
- Anesthesiology and Respiratory Therapy Devices Panel	N/A	0	0	0	0	0	0.00%
- Circulatory System Devices Panel	10/13/11	1	14	0	0	14	100.00%
- Circulatory System Devices Panel	10/26-27/11	1	13	0	0	13	100.00%
- Circulatory System Devices Panel	12/7-8/11	1	15	0	0	15	100.00%

Committee Name	Meeting Date	Number of Meetings	Total Number of Meeting Participants Attending (voting & nonvoting)*	18 USC 208(b)(1) and (b)(3) Waivers Granted	Section 712(c)(2)(B) Waivers Granted	Total Meeting Participants with No Waivers	% of Meeting Participants Not Issued Waivers
- Circulatory System Devices Panel	5/24/12	1	18	2	0	16	88.89%
- Circulatory System Devices Panel	6/13/12	1	16	1	0	15	93.75%
- Clinical Chemistry and Clinical Toxicology Devices Panel	N/A	0	0	0	0	0	0.00%
- Dental Products Panel	N/A	0	0	0	0	0	0.00%
- Ear, Nose, and Throat Devices Panel	N/A	0	0	0	0	0	0.00%
- Gastroenterology-Urology Devices Panel	1/11/2012	1	12	0	0	12	93.33%
- Gastroenterology-Urology Devices Panel	05/10-11/2012	1	16	0	0	16	100.00%
- General and Plastic Surgery Devices Panel	6/21/12	1	15	0	0	15	100.00%
- General Hospital and Personal Use Devices Panel	N/A	0	0	0	0	0	0.00%
- Hematology and Pathology Devices Panel	N/A	0	0	0	0	0	0.00%
- Immunology Devices Panel	N/A	0	0	0	0	0	0.00%
- Medical Devices Dispute Resolution Panel	N/A	0	0	0	0	0	0.00%
- Microbiology Devices Panel	N/A	0	0	0	0	0	0.00%
- Molecular and Clinical Genetics Panel	N/A	0	0	0	0	0	0.00%
- Neurological Devices Panel	2/10/2012	1	13	0	0	13	100.00%
Neurological Devices Panel	3/23/2012	1	15	3	0	12	80.00%
- Obstetrics-Gynecology Devices	N/A	0	0	0	0	0	0.00%
- Ophthalmic Devices Panel	9/28/12	1	22	0	0	22	100.00%
- Orthopedic and Rehabilitation Devices Panel	6/27-28/12	1	18	0	0	18	100.00%
Orthopedic and Rehabilitation Devices Panel	9/21/12	1	15	0	0	15	100.00%
- Radiological Devices Panel	04/11-12/2012	1	27	0	0	27	100.00%
National Mammography Quality Assurance Advisory Committee	11/4/11	1	15	0	0	15	100.00%
Technical Electronic Product Radiation Safety Standards Committee	N/A	0	0	0	0	0	0.00%
Food Advisory Committee	N/A	0	0	0	0	0	0.00%
Veterinary Medicine Advisory Committee	N/A	0	0	0	0	0	0.00%
Science Advisory Board to the National Center for Toxicological Research	11/8-9/11	1	7	0	0	7	100.00%
Tobacco Products Scientific Advisory Committee	1/18/12-1/20/12	1	15	0	0	18	100.00%
Tobacco Products Scientific Advisory Committee	3/1/12-3/2/12	1	13	0	0	16	100.00%

\*Not including Industry Representatives, FDA Employees or Guest Speakers

Under section 712(e)(3) of the FD&C Act, FDA is to provide the number of times a financial interest triggering the public disclosure requirement became known to FDA less than 30 days prior to an advisory committee meeting and the applicable disclosure was posted to FDA's website less than 15 days prior to a meeting.<sup>8</sup> There were five waiver disclosures posted less than 15 days prior to a meeting for FY 2012.

As required by section 712(e)(4) of the FD&C Act, the following is a description of FDA strategies to reduce the number of vacancies on advisory committees to encourage the nomination of individuals for service on an advisory committee.

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. FDAAA added new requirements for recruiting potential members and evaluating their expertise and potential for financial conflicts of interest. FDA requests that nominees under consideration for appointment to FDA advisory committees complete confidential disclosure reports using either Form FDA 3410 or Form OGE<sup>9</sup> 450 so that FDA may evaluate the individual's potential for financial conflicts of interest, as well as his/her expertise prior to the final selection for appointment.

Under section 712(b)(1)(A), FDA is to consider the advisory committees with the greatest number of vacancies, and 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 also directed to seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. The statute lists a number of suggested recruitment activities.

With these suggested strategies in mind, the Agency is currently employing the following outreach practices:

- FDA 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.
- FDA regularly notifies the public about vacancies on advisory committees through *Federal Register* notices approximately four times annually. Many professional societies use these notices to share news of potential vacancies among interested professionals. In FY 2012, FDA issued ten such notices. FDA also uses its Advisory Committee website [www.fda.gov/AdvisoryCommittees/default.htm](http://www.fda.gov/AdvisoryCommittees/default.htm) to display such vacancies.
- 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.

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<sup>7</sup> See Section 712(c)(3)(B) of the FD&C Act.

<sup>9</sup> Office of Government Ethics (OGE)

- Individuals may submit their *curriculum vitae* and nomination information directly to FDA's ACOMS e-mailbox and receive prompt acknowledgement of their application. During FY 2012, FDA received more than 600 submissions to this e-mailbox.
- In FY 2012, FDA's Office of Minority Health continued recruitment activities targeting groups based on committee needs with a goal to enhance participation from underrepresented groups.
- 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.
- Agency representatives met with the following organizations to solicit nominations for FDA advisory committees and to establish an effective recruitment strategy:
  1. National Medical Association
  2. National Organization for Rare Diseases
  3. National Council of Asian & Pacific Islander Physicians
  4. National Hispanic Medical Association
- FDA Centers participated in 250 outreach activities, targeting recruitment to geographical locations and committees where vacancy rates were the highest.
- 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 distributed recruitment brochures at the following professional meetings:
  1. International Society for Cellular Therapy, Bethesda, MD
  2. 6<sup>th</sup> Annual Asian American, Native Hawaiian, and Pacific Islander Health Conference, NYC, NY
  3. American Society on Aging annual Conference, Washington, D.C.
  4. Office of Minority Health, "Health Month", Silver Spring, MD
  5. American Public Health 139<sup>th</sup> Annual Expo, Washington, D.C.
  6. Nat'l Minority Quality Forum 9th Annual Health Disparities Leadership Summit, Washington, D.C.
  7. Patient Network Annual Meeting "Patient Input into FDA Benefit –Risk", Silver Spring, MD
  8. American Association of Family & Consumer Sciences, Indianapolis, IN
  9. American Society of Nutrition in Bethesda, MD
  10. National Council of Asian Pacific Islander Physicians (NCAPID), Crystal City, VA

11. Drug Information Association, Philadelphia, PA
  12. National Hispanic Medical Association, Washington, D.C.
  13. National Medical Association, New Orleans, LA
  14. The American Council on Consumer Interests, Memphis, TN
- FDA publishes articles to support recruitment and outreach efforts. In FY 2012, articles appeared in the following organizations' newsletters/journals or conference bulletins:
    1. National Health Policy Conference (February 2012)
    2. Association of Asian Pacific Community Health Organizations (February 2012)
    3. American Pharmacists (March 2012)
    4. American Medical Women's Association (March, 2012)
    5. Consumer Bell (March 2012)
    6. 11th Native Women and Men's Wellness Annual Conference (March 2012)
    7. American College of Physicians (April 2012)
  - FDA Centers and advisory committee staff participate in both FDA and other government/organization-sponsored scientific training sessions, where FDA requests nominations for potential candidates.
  - FDA has an ongoing relationship with the National Institutes of Health to discuss recruitment strategies and identify experts in specialized areas of research.