

2025 Current Fiscal Year Report: Risk Communication Advisory Committee

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2025

3. Committee or Subcommittee

Risk Communication Advisory Committee

3b. GSA Committee No.

31951

4. Is this New During Fiscal Year? 5. Current Charter 6. Expected Renewal Date 7. Expected Term Date

No 07/17/2009

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Terminate

10a. Legislation Req to Terminate?

Yes

10b. Legislation Pending?

Pending

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority

21 U.S.C. 360bbb-6

13. Effective Date

09/27/2007

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports

No Reports for this Fiscal Year

17a. Open 0 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$0.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$0.00	\$0.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$0.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	\$0.00	\$0.00
18d. Other (all other funds not captured by any other cost category)	\$0.00	\$0.00
18e. Total Costs	\$0.00	\$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

Members' comments and discussion provide advice to the Agency on improving communications practices, from both a basis of scientific research and practical experience, in matters ranging from specific types of agency communications to more general strategies and research needs, in order to help the agency

accomplish its goal of improving patient and consumer safety by providing risk-benefit information that is clear, timely, and usable by the audience. The meetings also facilitate the RCAC purpose of interactive sharing of information between the FDA and the public.

20b. How does the Committee balance its membership?

The RCAC consists of 15 voting members including the Chair. Members are selected among authorities in fields such as risk communication, social marketing, health literacy, and other relevant areas. Some members will be selected to provide experiential insight on the communications needs of various groups who use FDA-regulated products such as patients, healthcare professionals, consumer or patient advocacy organizations. Depending on the topic, the commissioner or designee may select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. FDA will give close attention to distribution with respect to members' geographic region, minority status, and sex, so long as the effectiveness of the Committee is not impaired.

20c. How frequent and relevant are the Committee Meetings?

The committee is considered Administrative Inactive.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

FDA strives to communicate with many audiences using many instruments, but in the past not all were developed or evaluated in ways consistent with established best practices in risk

communication. The RCAC is necessary in order to bring expertise on current research and established best practices to the Agency, to help the agency interact with the public for more effective risk communication. This need was recognized both in the Congress (HR 3580) and the National Academies' Institute of Medicine (The Future of Drug Safety, recommendation 6.1).

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

This committee is Administratively Inactive as the committee has completed the work that was required by the originating statute.

Designated Federal Officer

Ashlee N Januszewicz DFO

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Risk Communication Advisory Committee supports FDA's strategic priorities by providing expert advice on FDA strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products, review and evaluate scientific research relevant to risk

communication, and facilitate the interactive sharing between FDA and the public of information on risks and benefits of FDA-regulated products.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

Cost Savings Comments

The utilization of the Risk Communication Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical, scientific and communications experts not otherwise available to the Agency and to obtain the services

of these experts only on an as needed basis rather than on a full time basis. The service of the committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

188

Number of Recommendations Comments

The committee made 188 recommendations from FY03 through FY21.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

20%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

70%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

Feedback is usually provided. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities	<input checked="" type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

The committee does not advise on resource allocation, but prioritization may be reflected in resource allocation. The other actions boxes above that are checked applicable are showing that the Agency is actively engaged in developing internal strategy, process, and capacity to implement recommendations more fully, but none of this is complete at this time. The boxes above that are blank are, to date, inapplicable.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Access Comments

N/A