2025 Current Fiscal Year Report: Pediatric Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Pediatric Advisory Committee	21515

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	07/11/2022		

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
Public Law 107-109, Public Law 108-155, FDAAA	01/07/2003	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End

On July 9, 2025, the PAC met to discuss post-marketing pediatric-focused safety reviews of the following products: 1. Center for Devices and Radiological Health a. LIPOSORBER LA-15 SYSTEM (Humanitarian Device Exemption (HDE)) b. MEDTRONIC ACTIVA NEUROSTIMULATOR FOR DYSTONIA TREATMENT (HDE) c. MINIMALLY INVASIVE DEFORMITY CORRECTION (MID-C) SYSTEM (HDE) d. REFLECT SCOLIOSIS CORRECTION SYSTEM (HDE) e. THE TETHER—VERTEBRAL BODY TETHERING SYSTEM (HDE) 2. Center for Biologics Evaluation and Research a. DENGVAXIA (Dengue Tetravalent Vaccine, Live) b. EPICEL (cultured epidermal autografts) (HDE) c. FLUZONE QUADRIVALENT (Influenza Vaccine) d. GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) 3. Center for Drug Evaluation and Research a. AUVI-Q AUTO-INJECTOR (epinephrine) b. DIOVAN (valsartan) c. ENTRESTO (sacubitril and valsartan) d. ERAXIS (anidulafungin) e. EUCRISA (crisaborole) f. EXJADE (deferasirox), JADENU (deferasirox), and JADENU SPRINKLE (deferasirox) g. FIASP (insulin aspart) h. JAKAFI (ruxolitinib phosphate) and OPZELURA (ruxolitinib) i. LATUDA (lurasidone hydrochloride) j. LILETTA (levonorgestrel-releasing intrauterine system) k. MYCAMINE (micafungin) l. NITYR (nitisinone) m. POTASSIUM PHOSPHATES (potassium phosphate, dibasic injection; potassium phosphate, monobasic) n. REPATHA (evolocumab) o. ROZLYTREK (entrectinib) p. STELARA (ustekinumab) q. SUTENT (sunitinib malate) r. TASIGNA (nilotinib) s. TOPICORT (desoximetasone) t. TRIUMEQ (abacavir, dolutegravir, lamivudine) and TRIUMEQ PD (abacavir, dolutegravir, lamivudine) u. XYREM (sodium oxybate)	07/09/2025 - 07/09/2025	

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$12,200.00	$46,800.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$1,197,498.00	$1,106,570.00

18a(4). Personnel Pmts to Non-Member Consultants	$2,806.00	$3,120.00
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)	$307,054.00	$307,675.00
18e. Total Costs	$1,519,558.00	$1,464,165.00
19. Federal Staff Support Years (FTE)	5.50	5.30

20a. How does the Committee accomplish its purpose?

The committee makes recommendations to the Commissioner of Food and Drugs in response to specific questions posed by the FDA. Recommendations for regulatory or policy decisions are reviewed by FDA staff and by the Commissioner, who then implements changes or forwards recommendations to the Department of Health and Human Services.

20b. How does the Committee balance its

membership?

Members are authorities knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. Members also include a patient-family representative , one technically qualified consumer representative, and may include one non-voting industry representative and one non-voting representative from a pediatric health organization.

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

The Committee met 1 time during FY-25 (prior to October 30, 2025). The committee plans to meet 2 to 3 times in FY 2026.

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

The Pediatric Advisory Committee is mandated by law. In addition, the committee will have advisory functions for many pediatric products regulated by the FDA. The committee will provide expert advice on specific regulatory and policy areas related to pediatric therapeutics, including (1) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501,502, 505, 505A, and 505B, 510K, 515, and 520m of the Federal Food, Drug, and Cosmetic Act; (2) identification of research priorities related to pediatric therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments of specific pediatric diseases or conditions, (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices, (4) pediatric labeling disputes as specified in Public Law 107-109, Public Law 110-85, and Public Law

112-144, (5) pediatric labeling changes as specified in Public Law 107-109, Public Law 110-85, and Public Law 112-144, (6) adverse event reports for drugs studied under Public Law 107-109, 110-85 and labeled, and Public Law 112-144 (7) any safety issues that may occur as specified Public Law 107-109, Public Law 110-85, and Public Law 112-144, (8) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products, (9) pediatric ethical issues including research involving children as subjects as specified in 21 CFR 50.54, (10) advise and make recommendations to the Secretary on the development of countermeasures for pediatric populations in H.R.307, Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, and (11) any other matter involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner of Food and Drugs on research involving children as subjects that is conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

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

There were no closed meetings to report in FY25.

21. Remarks

There were no reports required for FY25. As provided in section 14(d) of the Best Pharmaceuticals for Children Act as amended by section 507 of the Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. 112-144, notwithstanding section 14 of the Federal Advisory Committee Act, the Pediatric Advisory Committee (PAC) will continue to

operate to carry out the advisory committee's responsibilities under sections 505A, 505B, and 520(m) of the Federal Food, Drug, and Cosmetic Act. During FY2025, the Pediatric Advisory Committee convened once for a 1-day meeting. On July 9, 2025, the PAC met to discuss post-marketing pediatric-focused safety reviews for several products, biologics, and devices.

Designated Federal Officer

Shivana Srivastava Lead Public Health Specialist/Designated Federal Officer, Office of Pediatric Therapeutics

Committee Members	Start	End	Occupation	Member Designation
Anne, Premchand	07/09/2025	07/09/2025	Pediatric Cardiology	Special Government Employee (SGE) Member
Baker, Susan	07/01/2023	06/30/2027	The State University of New York	Special Government Employee (SGE) Member
Callahan, David	07/01/2024	06/30/2028	Washington University School of Medicine	Special Government Employee (SGE) Member
Czaja, Angela	07/01/2021	06/30/2025	Department of PEdiatric, Criticial Care University of Colorado School of Medicine Children's Hospital Colorado Aurora CO	Special Government Employee (SGE) Member
Diekema, Douglas	07/01/2023	06/30/2027	University of Washington, Department of Pediatrics, Divisions of Bioethics and Emergency Medicine	Special Government Employee (SGE) Member
Fischer, Gwenyth	07/01/2022	06/30/2026	University of Minnesota College of Medicine, Minneapolis, MN	Special Government Employee (SGE) Member
Goldman, Jennifer	07/01/2020	06/30/2028	Children's Mercy Hospital Kansas City, MO	Representative Member
Guillory, Charleta	07/01/2023	06/30/2027	Texas Children's Hospital	Special Government Employee (SGE) Member

Hoehn, K. Sarah	07/09/2025	07/09/2025	Pediatric Critical Care Medicine	Special Government Employee (SGE) Member
Holubkov, Richard	07/01/2020	06/30/2028	University of Utah Department of Pediatrics, Salt Lake City, UT	Special Government Employee (SGE) Member
Johnson, Liza-Marie	07/09/2025	07/09/2025	Pediatric Hematology-Oncology and Bioethics	Special Government Employee (SGE) Member
Jones, Bridgette	07/01/2021	06/30/2025	Children's Mercy Hospital 2401 Gillham Rd. Kansas City MO	Special Government Employee (SGE) Member
Krug, Steven	07/01/2022	06/30/2026	Ann & Robert H. Lurie Children’s Hospital of Chicago, Chicago, IL	Special Government Employee (SGE) Member
McMillan, Gianna	11/03/2020	06/30/2028	Patient-Family Rep	Special Government Employee (SGE) Member
Nelson, Robert	08/30/2022	06/30/2026	Johnson and Johnson	Representative Member
Ortiz-Aguayo, Roberto	07/01/2020	06/30/2028	The Children's Hospital of Philadelphia, Philadelphia, PA	Special Government Employee (SGE) Member
Oster, Randi	04/24/2018	06/30/2026	CEO, Help Me Health, Fairfield, CT	Representative Member
Schanberg, Laura	07/01/2024	06/30/2027	Duke Clinical Research Institute	Special Government Employee (SGE) Member
White, Michael	07/01/2022	06/30/2025	Ochsner Health System	Special Government Employee (SGE) Member

Number of Committee Members Listed: 19

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 Pediatric Advisory Committee supports FDA's strategic priorities by providing advice and making recommendations to the Commissioner of Food and Drugs on matters relating to pediatric therapeutics, pediatric research, and any other matter involving pediatrics for which the Food and Drug Administration has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary pursuant to 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services. The recommendations of this committee support the agency by improving patient and consumer safety.

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

	Checked if Applies
Improvements to health or safety	☑
Trust in government	☑
Major policy changes	☑
Advance in scientific research	☑
Effective grant making	☐
Improved service delivery	☐
Increased customer satisfaction	☑
Implementation of laws or regulatory requirements	☑
Other	☐

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐

$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments
The utilization of the Pediatric Advisory Committee (and subcommittees) enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed bases 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?
640

Number of Recommendations Comments
The committee made 640 recommendations from June of FY03 through October FY25.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
84%

% of Recommendations Fully Implemented Comments
Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice. This number represents an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments
Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, 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

When appropriate, information is made available to the public. Actions related to guidance documents or other general matters or 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	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

The agency has made product labeling changes as a result of committee recommendations.

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

No

Grant Review Comments

NA

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

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A