FOOD AND DRUG ADMINISTRATION
Office of the Commissioner
MINUTES OF THE PEDIATRIC ADVISORY COMMITTEE MEETING
The public meeting was convened virtually on November 13, 2025

PAC Members Present (voting)
Susan S. Baker, MD, PhD
David Callahan, MD
Douglas Diekema, MD, MPH
Charleta Guillory, MD, MPH
Steven Krug, MD

Patient Family Representative (voting)
Gianna McMillan, DBe, MFA

Temporary Members (voting)
Premchand Anne, MD, MBA, MPH
Randall Flick, MD, MPH
K. Sarah Hoehn, MD, MBe
Liza-Marie Johnson, MD, MPH, MSB
Sandra Juul, MD, PhD
Jennifer Lee-Summers, MD
Wael Sayej, MD, MBA

Chairperson
Gwenyth Fischer, MD

Designated Federal Officer (DFO)
Shivana Srivastava, RN, MS, PMP

Industry Representative (non-voting)
Robert Nelson, MD, PhD

*All PAC members and consultants in attendance, with the exception of the Industry Representative, received background materials in advance *

U.S. Food and Drug Administration (FDA participants)

Office of the Commissioner (OC)
Prabha Viswanathan, MD, FAAP
Mohamed Mohamoud, PharmD, MPH

Center for Drug Evaluation and Research (CDER)
Ivone Kim, MD

Center for Devices and Radiological Health (CDRH)
George Van Hare, MD

Center for Biologics Evaluation and Research (CBER)
Craig Zinderman, MD, MPH

Call to Order and Introduction of the Committee
Gwenyth Fischer, MD

- Dr. Gwenyth Fischer called to order the Pediatric Advisory Committee (PAC) meeting at 10:00 am. EST on November 13, 2025, by welcoming all committee members, FDA staff, and public attendees. The meeting was focused on reviewing pediatric-focused post-market safety data for products regulated by the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), and the Center for Drug Evaluation and Research (CDER). Dr. Fischer noted that the FDA's review of adverse event reports for the products under discussion did not identify any new pediatric safety concerns. Therefore, no product-specific presentations from the FDA or industry were planned, and the committee's role would be to provide input on ongoing safety surveillance measures.

Conflict of Interest Statement
Shivana Srivastava, RN, MS, PMP

- Shivana Srivastava, the Designated Federal Officer for the PAC, read the conflict-of-interest statement. She confirmed that all voting members of the committee had been screened for potential conflicts and were found in compliance with federal ethics regulations.

FDA Opening Remarks
Prabha Viswanathan, MD, FAAP

- Dr. Prabha Viswanathan, Deputy Director of the Office of Pediatric Therapeutics, delivered opening remarks. She announced two upcoming pediatric workshops, provided updates on Pediatric Research Equity Act non-compliance letters issued since the last PAC meeting on July 9, 2025, and summarized PAC members' comments from the last meeting. The remainder of her opening remarks summarized the meeting flow and voting procedures for the day.

FDA Pediatric Safety and Monitoring Framework Presentation and Q&A
Mohamed Mohamoud, PharmD, MPH

- Dr. Mohamoud provided a comprehensive overview of pediatric drug safety and regulatory oversight at the FDA. The session covered pediatric product development legislation pertinent to the PAC's review of pediatric-focused postmarket safety reviews, including the Best Pharmaceuticals for Children Act (BPCA, 2002), Pediatric Research Equity Act (PREA, 2003), and Pediatric Medical Device Safety and Improvement Act (PMDSIA, 2007). The presentation also addressed pediatric advisory committee functions, post-marketing adverse event reporting systems, surveillance mechanisms, and the definition of safety signals. Additionally, the session covered post-marketing data sources, the process for safety signal detection and evaluation/verification, FDA efforts to promote adverse event (AE) reporting, and emphasized that continuous safety monitoring occurs year-round at the FDA beyond formal committee activities.

PAC Committee Discussion on Non-Voting Question: *What steps can patients/consumers, providers, and healthcare systems take to optimize reporting of pediatric adverse events?*

- The committee engaged in robust discussion and provided feedback on the existing barriers and methods for improved adverse event reporting to the Agency. A few barriers reported include healthcare providers' lack of understanding about what happens after submission, time burden on practitioners, and limited Electronic Medical Record (EMR) integration. The committee identified possible solutions including revising the intake forms, integrating reporting directly into hospital systems and EMRs, developing mandatory reporting training for advanced practitioners, partnering with professional societies such as the American Academy of Pediatrics for educational outreach, and incorporating reporting education into residency training and continuing medical education requirements. Additional recommendations include providing feedback to reporters (e.g., one PAC member reflected that the FDA had provided a follow-up phone call after filing a report), adding FDA reporting website information to product labels (especially for caregivers), creating take-home educational materials for parents, and reframing the conversation to emphasize that quality reports at the system's beginning are essential for effective post-market safety monitoring. The overarching goal conveyed was to make reporting easier, more integrated into clinical workflows, and better understood by all stakeholders.

Open Public Hearing

- One registered open public hearing speaker spoke about her personal experience with a deep brain stimulation device.

Center for Devices and Radiological Health

Listing of products and clarifying questions

George Van Hare, MD

- Dr. Van Hare presented the list of CDRH devices under review. There were no questions from the committee and the chair proceeded to the vote.

Committee Discussions and Votes

Voting Question: FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDRH products under discussion.

Does the Pediatric Advisory Committee concur?

The results of the vote for CDRH product reviews presented at the meeting are displayed in TABLE 1 below. Most of the PAC members voted “yes” that they concur with FDA’s recommendation to continue routine, ongoing postmarket safety monitoring of each of the CDRH products under discussion. There were no “No” votes, no “Abstains” and three recorded “Recused” votes. There were no comments from committee members upon reading their vote into the record.

TABLE 1: CDRH Voting Results

CDRH Product List:	Yes	No	Abstain	Recused
ENTERRA THERAPY SYSTEM (Humanitarian Device Exemption (HDE))	12	0	0	1
CONTEGRA PULMONARY VALVED CONDUIT (HDE)	12	0	0	1
PLEXIMMUNE (HDE)	13	0	0	0
SONALLEVE MR-HIFU (HDE)	12	0	0	1

Center for Biologics Evaluation and Research (CBER)

Listing of products and clarifying questions

Craig Zinderman, MD, MPH

- Dr. Zinderman presented the list of CBER products under review. Committee members questioned AE reporting requirements for off-label use. Dr. Zinderman explained that providers and sponsors are required to report AEs for off-label use and off-label AEs are included in CBER safety reviews. For the Quelimmune device, Dr. Zinderman explained the function of the selective cytopheretic device (SCD) while addressing a question on how this device differs from plasmapheresis. Dr. Anam Tariq addressed the question concerning the non-sterile portion of the Quelimmune device. There was one question concerning AE reports from outside the U.S. for Vaxchora. Dr. Zinderman explained that manufacturers are required to report all AE reports regardless of location and that there are no limitations for consumers and healthcare providers outside the U.S. to report AEs in VAERS.

Committee Discussions and Votes

Voting Question: FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CBER products under discussion.

Does the Pediatric Advisory Committee concur?

The results of the vote for CBER product reviews presented at the meeting are displayed in TABLE 2 below. Most of the PAC members voted "yes" that they concur with FDA's recommendation to continue routine, ongoing postmarket safety monitoring of each of the CBER products under discussion. There were no "No" votes, no "Abstains" and two recorded "Recused" votes. There were no comments from committee members upon reading their vote into the record.

TABLE 2: CBER Voting Results

CBER Product List:	Yes	No	Abstain	Recused
QUELIMMUNE (HDE)	12	0	0	1
SEVENFACT (coagulation factor VIIa (recombinant)-jncw)	12	0	0	1

VAXCHORA Cholera Vaccine, Live, Oral	13	0	0	0

Center for Drug Evaluation and Research (CDER)

Listing of products and clarifying questions

Ivone Kim, MD

- Dr. Kim presented the list of CDER products under review. A question was raised on how AEs are monitored for combination products using Airduo Digihaler as an example. Dr. Kim responded that CDER looks at medication errors and in some cases CDER works with CDRH to conduct complete evaluations if needed. A question was presented concerning tracking overall overdose deaths from oxymorphone from a public safety perspective and if these victims were given a rescue medicine. Dr. Kim explained that not all reports included information of co-administration of a rescue medicine but the reporting form allows for inclusion of concomitant medications but there is no data to confirm that they were prescribed at the same time. Dr. Kim also addressed a question on the withdrawal of Armonair Digihaler from the market. Committee members raised concerns on the number of unassessable reports and the quality of the data in some safety reviews presented.

Committee Discussions and Votes

Voting Question: FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDER products under discussion.

Does the Pediatric Advisory Committee concur?

The results of the vote for CDER product reviews presented at the meeting are displayed in TABLE 3 below. Most of the PAC members voted "yes" that they concur with FDA's recommendation to continue routine, ongoing postmarket safety monitoring of each of the CDER products under discussion. There were no "No" votes, no "Abstains" and eight recorded "Recused" votes. Committee members read their vote into the record. One comment was made for the need to improve the quality of the reporting mechanism in the future.

TABLE 3: CDER Voting Results

CDER Product List:	Yes	No	Abstain	Recused
ABRAXANE paclitaxel	10	0	0	2
ARMONAIR RESPICLICK, ARMONAIR DIGIHALER, AIRDUO RESPICLICK, AIRDUO DIGIHALER fluticasone propionate / fluticasone propionate and salmeterol xinafoate	12	0	0	0
AUBAGIO teriflunomide	11	0	0	1
AUSTEDO deutetrabenazine	12	0	0	0

BREXAFEMME ibrexafungerp	12	0	0	0
BYDUREON, BYDUREON BCISE, BYETTA exenatide	12	0	0	0
CIBINQO abrocitinib	11	0	0	1
COSENTYX secukinumab	12	0	0	0
DESCOVY emtricitabine and tenofovir alafenamide	12	0	0	0
DUPIXENT dupilumab	11	0	0	1
EDURANT, EDURANT PED rilpivirine	12	0	0	0
ENBREL etanercept	12	0	0	0
EVOTAZ atazanavir and cobicistat	12	0	0	0
LIALDA mesalamine	11	0	0	1
LINZESS linaclotide	12	0	0	0
LITFULO ritlecitinib	12	0	0	0
MYRBETRIQ EXTENDED-RELEASE TABLETS, MYRBETRIQ GRANULES mirabegron	12	0	0	0
NUCYNTA, NUCYNTA ER tapentadol	12	0	0	0
OPANA oxymorphone hydrochloride	12	0	0	0
PIFELTRO, DELSTRIGO doravirine / doravirine, lamivudine, and tenofovir disoproxil fumarate	12	0	0	0
RAPIVAB peramivir	12	0	0	0
REXULTI brexpiprazole	12	0	0	0
RYALTRIS olopatadine hydrochloride and mometasone furoate	11	0	0	1
SELZENTRY maraviroc	12	0	0	0
SIMPONI ARIA golimumab	12	0	0	0
SMOFLIPID lipid injectable emulsion	12	0	0	0
SOLOSEC secnidazole	12	0	0	0

TAYTULLA norethindrone acetate / ethinyl estradiol capsules and ferrous fumarate capsules	12	0	0	0
TEZSPIRE tezepelumab-ekko	12	0	0	0
TRINTELLIX vortioxetine	12	0	0	0
VIIBRYD vilazodone hydrochloride	12	0	0	0
XOFLUZA baloxavir marboxil	12	0	0	0
YCANTH cantharidin	12	0	0	0
ZEGALOGUE dasiglucagon	12	0	0	0
ZEPATIER elbasvir and grazoprevir	12	0	0	0
ZERBAXA ceftolozane and tazobactam	12	0	0	0
ZOSYN piperacillin and tazobactam	11	0	0	1

ADJOURNMENT **Gwenyth Fischer, MD**
Chairperson, PAC

The November 13, 2025, PAC meeting was adjourned by the PAC chairperson after thanks and recognition of the hard work of the committee and staff supporting the PAC meeting.

The summary minutes for the November 13, 2025, meeting of the Pediatric Advisory Committee (PAC) was approved on December 4, 2025.

I certify that I attended the November 13, 2025, meeting of the meeting of the Pediatric Advisory Committee (PAC) and that these minutes accurately reflect what transpired.

_____**/s/**_____
Shivana Srivastava, RN, MS, PMP
Designated Federal Officer, PAC

_____**/s/**_____
Gwenyth Fischer, MD
PAC Chairperson