FOOD AND DRUG ADMINISTRATION
Office of the Commissioner
MINUTES OF THE PEDIATRIC ADVISORY COMMITTEE MEETING
The public meeting was convened virtually on September 16, 2026

PAC Members Present (voting) David Callahan, MD Douglas Diekema, MD, MPH Charleta Guillory, MD, MPH Richard Holubkov, PhD Roberto Ortiz-Aguayo, MD, MMM Laura Schanberg, MD **Temporary Members (voting)** Kathryn Cullen, MD Robert Dracker, MD, MHA, MBA, CPI Liza-Marie Johnson, MD, MPH, MSB Randi Oster, MBA Ricardo Quinonez, MD Lesha Shah, MD Lynn Sleeper, MS, ScD	**Chairperson** Premchand Anne, MD, MBA, MPH **Designated Federal Officer (DFO)** Shivana Srivastava, RN, MS, PMP **Industry Representative (non-voting)** Tara Frenkl, MD, MPH **Pediatric Health Organization Representative (non-voting)** Jennifer Goldman, MD, MS

*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)
An Massaro, MD

Center for Drug Evaluation and Research (CDER)
Ivone Kim, MD
CDR Quocbao Pham, PharmD, MBA, BCPS

Center for Devices and Radiological Health (CDRH)
Douglas Silverstein, MD

Center for Biologics Evaluation and Research (CBER)
Brendan Day, MD, MPH

Call to Order and Introduction of the Committee
Premchand Anne, MD

- Dr. Premchand Anne called to order the Pediatric Advisory Committee (PAC) meeting at 10:00 am. EDT on September 16, 2026, 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 Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and the Center for Biologics Evaluation and Research (CBER). Dr. Anne noted that the committee's role would be to provide input on ongoing safety surveillance measures for these products.

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
An Massaro, MD

- Dr. An Massaro, Director of the Office of Pediatric Therapeutics, delivered opening remarks. She announced three upcoming pediatric workshops, provided updates on Pediatric Research Equity Act non-compliance letters issued since the last PAC meeting on November 13, 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.

Overview of Adverse Event Reporting to FDA: A CDER Perspective
CDR Quocbao Pham, PharmD, MBA, BCPS

- Dr. "Bao" Pham provided an overview of how adverse event data flows to FDA, noting that a majority of reports are submitted mandatorily by manufacturers. Reports are loaded into the FDA Adverse Event Monitoring System (AEMS) which serves as an integrated ecosystem for collecting, managing, and analyzing safety reports across all intake channels. The "Report a Problem" portal is a recently launched, centralized interface designed to simplify the reporting process for patients and caregivers and is intended to be user-friendly. In response to a question about data quality, Dr. Pham noted that the new portal uses a streamlined set of targeted required fields with further technological enhancements planned. On the question of literature surveillance, Dr. Pham clarified that literature review is a mandatory requirement for manufacturers, and that FDA reviewers independently search databases such as PubMed and Embase to identify reports not captured by manufacturers. Any such reports identified by FDA are flagged and must subsequently be submitted by the manufacturer.

Open Public Hearing

- There were no open public hearing speakers.

Center for Drug Evaluation and Research (CDER)

Listing of products and clarifying questions

Ivone Kim, MD

- Dr. Ivone Kim presented the list of 15 pediatric-focused post-market safety reviews. Of the 15 reviews, 14 identified no new safety signals. The exception was a newly identified safety signal (NISS) for a potential drug-drug interaction between dasatinib (Sprycel) and methotrexate, which is currently under active Agency evaluation. During the clarifying questions segment, Dr. Kim reiterated that these reviews reflect the clinical complexity of the patient population (e.g., underlying diseases/comorbidities, and concurrent medications) making it difficult to attribute causality to any single drug and noted that FDA does not currently have routine access to patients' full electronic health records. Additional clarifications touched on FDA's routine pharmacovigilance evaluation of non-serious and serious adverse events and vast explanation/discussion on the technical term "unassessable" as it relates to adverse event attribution determination.

Committee Discussions and Votes

1.) Voting Question: FDA did not identify new safety signals in 14 of the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee (excluding Sprycel). As such for these 14 CDER products, FDA recommends continuing routine, ongoing post-market safety monitoring.

Does the Pediatric Advisory Committee concur?

The results of the vote for CDER 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 post-market safety monitoring for 14 of the CDER products under discussion. There were zero "No" votes, six "Abstain" and three recorded "Recused" votes. Committee members read their vote into the record.

TABLE 1: CDER Voting Results

CDER Product List:	Yes	No	Abstain	Recused
Aranesp (darbepoetin alfa)	11	0	2	0
Dalvance (dalbavancin)	13	0	0	0
Fragmin (dalteparin sodium)	10	0	1	2
Isopto Atropine (atropine sulfate)	13	0	0	0
Kloxxado nasal spray, Zimhi injection, Naloxone hydrochloride autoinjector, Naloxone hydrochloride nasal spray, RiVive nasal spray, Rezenopy nasal spray (naloxone hydrochloride)	13	0	0	0

Lymphoseek (technetium Tc 99m tilmanocept)	13	0	0	0
Nextstellis (drospirenone/estetrol)	12	0	1	0
Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate)	13	0	0	0
Tecentriq (atezolizumab)	12	0	1	0
Veklury (remdesivir)	12	0	1	0
Vemlidy (tenofovir alafenamide)	13	0	0	0
Zelsuvmi (berdazimer)	13	0	0	0
Zevtera (ceftobiprole medocaril sodium)	13	0	0	0
Zinplava (bezlotoxumab)	12	0	0	1

2.) Voting Question: FDA identified a new safety signal in the pediatric-focused postmarketing safety review for Sprycel. As such, FDA is conducting additional evaluation surveillance.

Does the Pediatric Advisory Committee support our further investigation of this product?

The results of the vote are displayed in TABLE 2 below. All PAC members voted "Yes" that they support FDA's further investigation of this product. There were zero "No" votes, zero "Abstain" and zero recorded "Recused" votes. Committee members read their vote into the record.

TABLE 2: CDER Voting Results

CDER Product List:	Yes	No	Abstain	Recused
Sprycel (dasatinib)	13	0	0	0

Center for Devices and Radiological Health

Listing of products and clarifying questions

Douglas Silverstein, MD

- Dr. Silverstein presented the list of CDRH devices under review. Main discussion topics included the completeness of Medical Device Report (MDR) data, rate of infective endocarditis observed with the Contegra device, and device-related questions for spinal tethering systems. FDA actively monitors device redesigns and maintains engagement with patient advocacy groups/surgeon networks to ensure ongoing awareness of developments in this area. Overall, FDA subject matter experts indicated that the current safety profiles for these devices remain consistent with their original approvals, that ongoing monitoring and manufacturer

collaborations are in place, and that no new safety signals have been identified at this time.

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 post-market 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 3 below. Most of the PAC members voted "Yes" that they concur with FDA's recommendation to continue routine, ongoing post-market safety monitoring of each of the CDRH products under discussion. There were eight "No" votes, one "Abstain" and zero recorded "Recused" votes. Committee members read their vote into the record.

TABLE 3: CDRH Voting Results

CDRH Product List:	Yes	No	Abstain	Recused
Enterra Therapy System (Humanitarian Device Exemption (HDE))	12	1	0	0
Liposorber LA-15 System (HDE)	12	1	0	0
Activa Neurostimulator for Dystonia Treatment (HDE)	12	1	0	0
Contegra Pulmonary Valved Conduit (HDE)	11	1	1	0
Minimally Invasive Deformity Correction (MID-C) System (HDE)	11	2	0	0
Pleximmune (HDE)	13	0	0	0
Reflect Scoliosis Correction System (HDE)	12	1	0	0
Sonalleve MR-HIFU (HDE)	13	0	0	0
The Tether – Vertebral Body Tethering System (HDE)	12	1	0	0

Center for Biologics Evaluation and Research (CBER)

Listing of products and clarifying questions

Brendan Day, MD, MPH

- Dr. Day presented the list of CBER products under review. Regarding Epicel, Dr. Day noted that reported incidents have declined over time (from 21 in 2023 to 9 in 2025) and that FDA will continue safety monitoring. For Quelimmune, Dr. Day emphasized that FDA was in agreement with post-approval study sample size adjustments given feasibility constraints. He noted that complementary surveillance mechanisms — including the MDR database or passive surveillance, manufacturer annual reports, and published literature reviews — remain in place, and that no bloodstream infection safety signal has been identified to date. Both products will continue to be monitored, with updates expected at the next Pediatric Advisory Committee meeting.

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 post-market 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 4 below. All PAC members voted "Yes" that they concur with FDA's recommendation to continue routine, ongoing post-market safety monitoring of each of the CBER products under discussion. There were zero "No" votes, zero "Abstain" and zero recorded "Recused" votes. Committee members read their vote into the record.

TABLE 4: CBER Voting Results

CBER Product List:	Yes	No	Abstain	Recused
Epicel (cultured epidermal autografts) (HDE)	13	0	0	0
Quelimmune (HDE)	13	0	0	0

ADJOURNMENT

Premchand Anne, MD, MBA, MPH

The September 16, 2026, the Pediatric Advisory Committee 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 September 16, 2026, meeting of the Pediatric Advisory Committee (PAC) was approved on October 14, 2026.

I certify that I attended the September 16, 2026, 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/

Premchand Anne, MD, MBA, MPH
PAC Chairperson