U.S. FOOD & DRUG ADMINISTRATION

Pediatric Advisory Committee Meeting

July 9, 2025

10:00 a.m. – 3:30 p.m. EST

Meeting notice and materials are available on the PAC website

2025 Meeting Materials, Pediatric Advisory Committee | FDA

Please direct all technical inquiries to the email listed below

Virtual-WOCC-Support@fda.hhs.gov

Information for Media/Press and Public

- For press inquiries, please contact the HHS Press Room at *www.hhs.gov/ press-room/ index.html* or 202-690-6343 to document your attendance, ask questions, or make interview requests for any FDA speakers

- For Open Public Hearing speakers, industry and the press, please sign in by sending an email to PAC@fda.hhs.gov

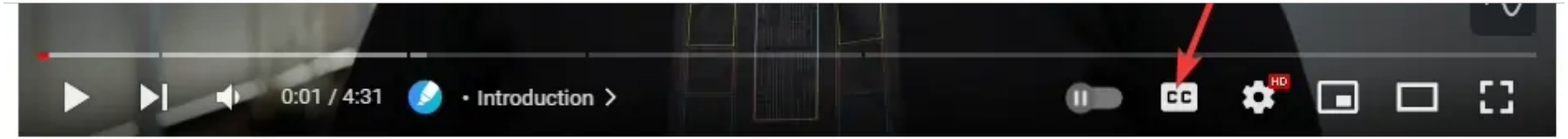
- Please direct all technical inquiries to the email listed below
  - Virtual-WOCC-Support@fda.hhs.gov

Closed Captioning

- Closed captioning can be accessed by clicking on the icon pictured here within YouTube

<u>How to enable closed captions on YouTube:</u>

- On the video player: Click the "CC" (Closed Captioning) icon at the bottom right of the video player.
- If you are signed into your YouTube account, you may access closed captioning through default settings: Navigate to your YouTube account settings, navigate to "Playback and performance," and select "Always show captions"



Pediatric Advisory Committee Meeting

July 9, 2025

Call to Order

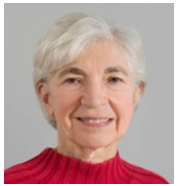
Gwenyth Fischer, MD

Chairperson, PAC

Pediatric Advisory Committee Meeting Roster

Gwenyth Fischer, MD
PAC Chairperson

Premchand Anne, MD, MBA, MPH



Susan Baker, MD, PhD

Douglas Diekema, MD, MPH

Jennifer Goldman, MD, MS
Pediatric Health Organization Representative

Charleta Guillory, MD, MPH

Sarah Hoehn, MD, MBe

Richard Holubkov, PhD

Liza-Marie Johnson, MD, MPH, MSB

Gianna McMillan, D. Be
Patient/Family Representative

Robert Nelson, MD, PhD
Industry Representative

Roberto Ortiz-Aguayo, MD

Randi Oster, MBA
Consumer Representative

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Introduction of FDA Representatives

Shivana Srivastava, RN, MS, DCPM, PMP

Designated Federal Officer, PAC

Conflict of Interest Statement

Shivana Srivastava, RN, MS, DCPM, PMP
Designated Federal Officer, PAC

FDA Opening Remarks

Dionna Green, MD, FCP
Director, Office of Pediatric Therapeutics
Office of the Chief Medical Officer
Office of the Commissioner, FDA

Purpose of the Meeting

- The Pediatric Advisory Committee (PAC) is meeting to discuss pediatric-focused postmarket safety reviews as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109), the Pediatric Research Equity Act of 2003 (Pub. L. 108-155), and the Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110-85, title III)

PREA Non-Compliance Letters

- Center for Biologics Evaluation and Research (CBER, n=7)
  - https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/prea-non-compliance-letters
- Center for Drug Evaluation and Research (CDER, n=174)
  - https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act
- The websites list the sponsor, product, a copy of the non-compliance letter, the sponsor's response (if available), and the status of the PREA requirement (e.g., released, replaced, fulfilled)

CBER PREA Non-Compliance Letters

- Seven letters issued by CBER overall
  - 1 new letter since the last Pediatric Advisory Committee Meeting

Sponsor	Product	Date of Letter
Pfizer, Inc.	Respiratory Syncytial Virus Vaccine (ABRYSVO ®)	3/24/25

CDER PREA Non-Compliance Letters

- 174 letters issued by CDER overall
  - 15 new letters since the last Pediatric Advisory Committee Meeting

Sponsor	Product	Date of Letter
Gilead Sciences, Inc.	Sovaldi (sofosbuvir) tablets	5/22/24
Gilead Sciences, Inc.	Harvoni (ledipasvir; sofosbuvir) tablets	5/22/24
Genentech, Inc.	Xofluza (baloxavir marboxil) tablet and granules for oral suspension	5/22/24
Genentech, Inc.	Xofluza (baloxavir marboxil) granules for oral suspension and tablets	5/22/24
CMP Development, LLC	potassium phosphates injection	8/16/24
Innocoll Pharmaceuticals, Limited	Xaracoll (bupivacaine hydrochloride) implant	9/10/24
Keryx Biopharmaceuticals, Inc.	Auryxia (ferric citrate) tablets	9/20/24
Heron Therapeutics, Inc.	Cinvanti (aprepitant) injection emulsion	10/2/24

CDER PREA Non-Compliance Letters

Sponsor	Product	Date of Letter
Nalpropion Pharmaceuticals, LLC	Contrave (naltrexone hydrochloride/bupropion hydrochloride) extended-release tablets	10/8/24
Salix Pharmaceuticals, Inc.	Trulance (plecanatide) tablets	12/6/24
Hong Kong King-Friend Industrial Company Limited	Xenleta (lefamulin) tablets and Xenleta (lefamulin) injection	1/10/25
Impel Pharmaceuticals, LLC	Trudhesa (dihydroergotamine mesylate) nasal spray	3/5/25
Hikma Pharmaceuticals USA, Inc.	Phenylephrine hydrochloride injection	4/3/25
Bausch Health Americas, Inc.	DuobrII (halobetasol propionate and tazarotene) lotion	4/7/25
Acacia Pharma, Ltd.	Byfavo (remimazolam) for injection	4/15/25

Draft Meeting Agenda

- 10:30 a.m. Open Public Hearing
- 11:30 a.m. Products evaluated in the pediatric-focused postmarket safety reviews completed by the Center for Devices and Radiological Health (CDRH)
- 12:15 p.m. Products evaluated in the pediatric-focused postmarket safety reviews completed by the Center for Biologics Evaluation and Research (CBER)
- 1:00 p.m. Lunch
- 1:30 p.m. Products evaluated in the pediatric-focused postmarket safety reviews completed by the Center for Drug Evaluation and Research (CDER)
- 3:30 p.m. Closing Remarks and Adjournment

Voting Procedures

- 3 separate voting sessions will be held (one each for CDRH, CBER, and CDER)
- The voting question and answer choices will be the same for all Centers and all products
- Voting will occur via the Zoom platform
- A separate ballot will be launched for each Center's vote
- Each ballot will contain a series of voting questions – one for each of the products listed on the ballot
  - *Note*: Some CDER products were grouped into the same pediatric-focused postmarket safety review, and these products will be grouped for voting purposes as well

Voting Question and Meaning of Responses

FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the [CDER/CDRH/CBER] products under discussion

Does the Pediatric Advisory Committee concur?

- Yes – routine ongoing postmarket monitoring should continue
- No – additional evaluation/surveillance should be considered
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Voting Procedures

- Meeting participants trying to join the meeting during voting or vote tabulation will be placed in a waiting room until the meeting resumes, which may be ten minutes or more
- Once the meeting resumes, the vote results will be displayed and read into the record
- Each PAC member will be called upon to read out their individual vote for the record


FDA
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Pediatric Advisory Committee Meeting

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Open Public Hearing

All OPH Speakers, please sign in by sending an email to PAC@fda.hhs.gov

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Open Public Hearing
Speaker #1

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Center for Devices and Radiological Health

Scott Colburn, MS, BSN, RN

Center for Devices and Radiological Health

1. LIPOSORBER LA-15 SYSTEM*
2. MEDTRONIC ACTIVA NEUROSTIMULATOR FOR DYSTONIA TREATMENT*
3. MINIMALLY INVASIVE DEFORMITY CORRECTION (MID-C) SYSTEM*
4. REFLECT SCOLIOSIS CORRECTION SYSTEM*
5. THE TETHER – VERTEBRAL BODY TETHERING SYSTEM*

*(Humanitarian Device Exemption (HDE))

Clarifying Questions

Committee Vote

Voting Question

FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDRH products under discussion.

Does the Pediatric Advisory Committee concur?

Committee Voting in Progress

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Center for Biologics Evaluation and Research

Craig Zinderman, MD, MPH

Center for Biologics Evaluation and Research

1. DENGVAXIA (Dengue Tetravalent Vaccine, Live)
2. EPICEL (cultured epidermal autografts)*
3. FLUZONE QUADRIVALENT (Influenza Vaccine)
4. GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

*(Humanitarian Device Exemption (HDE))

Clarifying Questions

Committee Vote

Voting Question

FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CBER products under discussion.

Does the Pediatric Advisory Committee concur?

Committee Voting in Progress

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Lunch

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Center for Drug Evaluation and Research (CDER)

Ivone Kim, MD

Center for Drug Evaluation and Research

1. AUVI-Q AUTO-INJECTOR
(epinephrine)

2. DIOVAN
(valsartan)

3. ENTRESTO
(sacubitril and valsartan)

4. ERAXIS
(anidulafungin)

5. EUCRISA
(crisaborole)

6. EXJADE, JADENU, JADENU SPRINKLE
(deferasirox)

7. FIASP
(insulin aspart)

8. JAKAFI, OPZELURA
(ruxolitinib phosphate, ruxolitinib)

9. LATUDA
(lurasidone hydrochloride)

10. LILETTA
(levonorgestrel-releasing intrauterine system)

Center for Drug Evaluation and Research

11. MYCAMINE
(micafungin)

12. NITYR
(nitisinone)

13. POTASSIUM PHOSPHATES
(potassium phosphate, dibasic injection; potassium phosphate, monobasic)

14. REPATHA
(evolocumab)

15. ROZLYTREK
(entrectinib)

16. STELARA
(ustekinumab)

17. SUTENT
(sunitinib malate)

18. TASIGNA
(nilotinib)

19. TOPICORT
(desoximetasone)

20. TRIUMEQ, TRIUMEQ PD
(abacavir, dolutegravir, lamivudine)

21. XYREM
(sodium oxybate)

Clarifying Questions

Committee Vote

Voting Question

FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDER products under discussion.

Does the Pediatric Advisory Committee concur?

Committee Voting in Progress

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Wrap-Up

Adjournment