

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)

September 16, 2026

FINAL QUESTIONS FOR THE COMMITTEE

Voting Questions

I. Center for Drug Evaluation and Research

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 postmarket safety monitoring.

- a. Aranesp (darbepoetin alfa)
- b. Dalvance (dalbavancin)
- c. Fragmin (dalteparin sodium)
- d. Isopto Atropine (atropine sulfate)
- e. Kloxxado nasal spray, Zimhi injection, Naloxone Hydrochloride Autoinjector, Naloxone hydrochloride nasal spray, RiVive nasal spray, Rezenopy nasal spray (naloxone hydrochloride)
- f. Lymphoseek (technetium Tc 99m tilmanocept)
- g. Nextstellis (drospirenone/estetrol)
- h. Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate)
- i. Tecentriq (atezolizumab)
- j. Veklury (remdesivir)
- k. Vemlidy (tenofovir alafenamide)
- l. Zelsuvmi (berdazimer)
- m. Zevtera (ceftobiprole medocaril sodium)
- n. Zinplava (bezlotoxumab)

Does the Pediatric Advisory Committee concur?

II. Center for Drug Evaluation and Research

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?

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III. Center for Devices and Radiological Health

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.

- a. Enterra Therapy System (Humanitarian Device Exemption (HDE))
- b. Liposorber LA-15 System (HDE)
- c. Medtronic Activa Neurostimulator for Dystonia Treatment (HDE)
- d. Medtronic Contegra Pulmonary Valved Conduit (HDE)
- e. Minimally Invasive Deformity Correction (MID-C) System (HDE)
- f. Pleximmune (HDE)
- g. Reflect Scoliosis Correction System (HDE)
- h. Sonalleve MR-HIFU (HDE)
- i. The Tether – Vertebral Body Tethering System (HDE)

Does the Pediatric Advisory Committee concur?

IV. Center for Biologics Evaluation and Research

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.

- a. Epicel (cultured epidermal autografts) Humanitarian Device Exemption (HDE)
- b. Quelimmune (HDE)

Does the Pediatric Advisory Committee concur?