

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)

July 9, 2025

FINAL QUESTIONS FOR THE COMMITTEE

I. Center for Devices and Radiological Health

FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDRH products under discussion. Does the Pediatric Advisory Committee concur?

- 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)

II. Center for Biologics Evaluation and Research

FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CBER products under discussion. Does the Pediatric Advisory Committee concur?

- a. DENG VAXIA (Dengue Tetravalent Vaccine, Live)
- b. EPICEL (cultured epidermal autografts) (HDE)
- c. FLUZONE QUADRIVALENT (Influenza Vaccine)
- d. GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

III. Center for Drug Evaluation and Research

FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDER products under discussion. Does the Pediatric Advisory Committee concur?

- a. AUVI-Q AUTO-INJECTOR (epinephrine)
- b. DIOVAN (valsartan)
- c. ENTRESTO (sacubitril and valsartan)

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- d. ERAXIS (anidulafungin)
- e. EUCRISA (crisaborole)
- f. EXJADE (deferasirox), JADENU (deferasirox) and JADENU SPRINKLE (deferasirox)
- g. FIASP (insulin aspart)
- h. JAKAFI (ruxolitinib phosphate), 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)