

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)

November 13, 2025

FINAL QUESTIONS FOR THE COMMITTEE

Non-voting Discussion Question

FDA encourages the public to submit adverse event reports when safety concerns arise. However, there are many factors that may impact reporting.

What steps can patients/consumers, providers, and healthcare systems take to optimize reporting of pediatric adverse events?

Voting Questions

I. 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. CONTEGRA PULMONARY VALVED CONDUIT (HDE)
- c. PLEXIMMUNE (HDE)
- d. SONALLEVE MR-HIFU (HDE)

Does the Pediatric Advisory Committee concur?

II. 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. QUELIMMUNE (HDE)
- b. SEVENFACT (coagulation factor VIIa (recombinant)-jncw)
- c. VAXCHORA (Cholera Vaccine, Live, Oral)

Does the Pediatric Advisory Committee concur?

III. Center for Drug Evaluation and Research

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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.

- a. ABRIXANE (paclitaxel)
- b. ARMONAIR RESPICLICK (fluticasone propionate), ARMONAIR DIGIHALER (fluticasone propionate), AIRDUO RESPICLICK (fluticasone propionate and salmeterol xinafoate), AIRDUO DIGIHALER (fluticasone propionate and salmeterol xinafoate)
- c. AUBAGIO (teriflunomide)
- d. AUSTEDO (deutetrabenazine)
- e. BREXAFEMME (ibrexafungerp)
- f. BYDUREON (exenatide), BYDUREON BCISE (exenatide), BYETTA (exenatide)
- g. CIBINQO (abrocitinib)
- h. COSENTYX (secukinumab)
- i. DESCOVY (emtricitabine and tenofovir alafenamide)
- j. DUPIXENT (dupilumab)
- k. EDURANT (rilpivirine), EDURANT PED (rilpivirine)
- l. ENBREL (etanercept)
- m. EVOTAZ (atazanavir and cobicistat)
- n. LIALDA (mesalamine)
- o. LINZESS (linaclotide)
- p. LITFULO (ritlecitinib)
- q. MYRBETRIQ EXTENDED-RELEASE TABLETS (mirabegron), MYRBETRIQ GRANULES (mirabegron)
- r. NUCYNTA (tapentadol), NUCYNTA ER (tapentadol)
- s. OPANA (oxymorphone hydrochloride)
- t. PIFELTRO (doravirine), DELSTRIGO (doravirine, lamivudine, and tenofovir disoproxil fumarate)
- u. RAPIVAB (peramivir)
- v. REXULTI (brexpiprazole)
- w. RYALTRIS (olopatadine hydrochloride and mometasone furoate)
- x. SELZENTRY (maraviroc)
- y. SIMPONI ARIA (golimumab)
- z. SMOFLIPID (lipid injectable emulsion)
- aa. SOLOSEC (secnidazole)
- bb. TAYTULLA (norethindrone acetate/ethinyl estradiol capsules and ferrous fumarate capsules)
- cc. TEZSPIRE (tezepelumab-ekko)
- dd. TRINTELLIX (vortioxetine)
- ee. VIIBRYD (vilazodone hydrochloride)
- ff. XOFLUZA (baloxavir marboxil)

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- gg. YCANTH (cantharidin)
- hh. ZEGALOGUE (dasiglucagon)
- ii. ZEPATIER (elbasvir and grazoprevir)
- jj. ZERBAXA (ceftolozane and tazobactam)
- kk. ZOSYN (piperacillin and tazobactam)

Does the Pediatric Advisory Committee concur?