

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Meeting of the Pediatric Advisory Committee (PAC)

September 18, 2024

FINAL QUESTIONS

I. Center for Drug Evaluation and Research (CDER):

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

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| 1. AZSTARYS (serdexmethylphenidate/dexmethylphenidate) | 17. MULTRY'S (trace elements), TRALEMENT (trace elements), ZINC SULFATE, SELENIUM ACID |
| 2. CAFKIT (caffeine citrate) | 18. MYDAYIS (mixed salts of a single-entity amphetamine) |
| 3. CHANTIX (varenicline) | 19. NATROBA (spinosad) |
| 4. CIMDUO, TEMIXYS (lamivudine/tenofovir disoproxil fumarate) | 20. PRADAXA (dabigatran etexilate) |
| 5. CLEOCIN HYDROCHLORIDE (clindamycin hydrochloride), CLEOCIN PHOSPHATE (clindamycin phosphate), CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER (clindamycin phosphate), CLINDAMYCIN PHOSPHATE IN 0.9% SODIUM CHLORIDE (clindamycin phosphate) | 21. QELBREE (viloxazine extended-release) |
| 6. DYANAVEL XR (amphetamine) | 22. RIOMET ER (metformin hydrochloride extended-release) |
| 7. EVEKEO ODT (amphetamine sulfate) | 23. TEFLARO (ceftaroline fosamil) |
| 8. GATTEX (teduglutide) | 24. TIROSINT-SOL (levothyroxine sodium) |
| 9. GILENYA (fingolimod) and TASCENSO ODT (fingolimod) | 25. TYBOST (cobicistat) |
| 10. JANUVIA (sitagliptin) and JANUMET (sitagliptin/metformin HCl), JANUMET XR (sitagliptin/metformin hydrochloride extended release) | 26. ULTRAVATE (halobetasol propionate), LEXETTE (halobetasol propionate) |
| 11. KAPSPARGO SPRINKLE (metoprolol succinate extended release) | 27. VEKLURY (remdesivir) |

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| 12. LITHIUM (lithium carbonate), (lithium oral solution) | 28. VYVANSE (lisdexamfetamine dimesylate) |
| 13. LOTEMAX (loteprednol etabonate) | 29. XACIATO (clindamycin phosphate) |
| 14. LUMASON (sulfur hexafluoride lipid-type A microspheres) | 30. XEGLYZE (abametapir) |
| 15. MAVYRET (glecaprevir/pibrentasvir) | 31. XELSTRYM (dextroamphetamine) |
| 16. MIRCERA (methoxy polyethylene glycol-epoetin beta) | 32. YERVOY (ipilimumab) |

II. Center for Devices and Radiological Health (CDRH):

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

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| 1. CONTEGRA PULMONARY VALVED CONDUIT (Humanitarian Device Exemption (HDE)) | 4. PLEXIMMUNE IN-VITRO DIAGNOSTIC TEST (HDE) |
| 2. ENTERRA THERAPY SYSTEM (HDE) | 5. PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE (HDE) |
| 3. FLOURISH PEDIATRIC ESOPHAGEAL ATRESIA DEVICE (HDE) | 6. SONALLEVE MR-HIFU (HDE) |

III. Center for Biologics Evaluation and Research (CBER):

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

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| 1. AGRIFLU (influenza virus vaccine) | 3. XYNTHA (antihemophilic factor (recombinant), plasma/albumin Free) |
| 2. CUTAQUIG (immune globulin subcutaneous (human)-hipp, 16.5%) | |