

# Pediatric Device Issues Update

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# Outline

- FDAISA impact
- Guidance development
- OSEL activities
- Other activities
- Looking ahead



# FDAISA Implementation

- Pediatric Rare Diseases
- HDE
- Pediatric Device Consortia



# Guidance Development

- Tracking
- Extrapolation of Adult data
- Tanning
- Toy Laser
- Pediatric Information for X-ray Premarket notification
- Mattress Flammability



# OSEL Activities

- Dosing Devices
- Thermometers



# Other Activities

- Federal SIDS
- Pediatric Advisory Committee
- Newborn Screening using Pulse Ox
- Infant Positioners



# Looking Ahead

