THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS
AAP News

News Articles, FDA Update

FDA meetings address pediatric device development, drug safety

by from the Food and Drug Administration's Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, Pediatrics and Special Populations, Center for Devices and Radiologic Health, and the Office of Pediatric Therapeutics

Two recent public meetings highlight the Food and Drug Administration's (FDA's) efforts to address challenges in pediatric medical device development and post-marketing safety assessments.

The "Pediatric Medical Device Development" public meeting on Aug. 13-14 brought together AAP leaders, government officials, academicians, patient advocates and industry leadership to identify strategies to enhance innovation for pediatric medical devices.

Mandated under the Food and Drug Administration Reauthorization Act of 2017, the meeting included discussions on improving research infrastructure and research networks, appropriate use of pediatric extrapolation and post-marketing registries, identifying ways for the FDA to increase assistance to pediatric device developers, and addressing barriers with appropriate incentives. Important considerations verified by stakeholders included the interplay between early stage investment and reimbursement to support innovation for children.

The FDA will focus on integrating three fundamental areas to support pediatric medical device innovation: optimizing evidence generation, creating regulatory value and simplicity, and developing a supportive marketplace.

A public workshop on Sept. 14 titled "Advancing the Development of Pediatric Therapeutics 5 (ADEPT 5): Advancing Pediatric Pharmacovigilance" brought together regulators, academicians, industry stakeholders and technology representatives to discuss ways to advance pediatric pharmacovigilance through improved adverse event reporting, data systems and data analysis.

Presentations included an overview of legislation, how the FDA conducts pediatric pharmacovigilance, and the use of mobile technology and social media to collect pediatric adverse event reports. Presenters also reviewed pharmacovigilance data sources outside of voluntary reporting.

The potential role of technology in pediatric pharmacovigilance through natural language processing and artificial intelligence also was discussed; however, human expertise is still necessary to integrate these advanced technology systems.

Resources

- Pediatric Medical Device Development public meeting
- ADEPT 5 public workshop
- AAP News article "AAP brings need for pediatric medical devices to forefront"
- Additional FDA Update columns