



News Articles, FDA Update

FDA releases guidance on extrapolating data to enhance pediatric device development

by from the Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health, and Center for Devices and Radiological Health

Coordinated efforts during the past few decades that have led to improved and increased pediatric drug labeling have not resulted in the increased availability of medical devices labeled for children. Off-label use of devices remains a prevalent and necessary practice in pediatrics. For example, nearly 90% of devices used for cardiac catheterization in children are not approved for use in pediatric patients.

The Food and Drug Administration (FDA) recognizes the unique and unmet needs of children. It also appreciates the numerous factors associated with relatively few medical devices having pediatric indications and labeling, including challenges in pediatric evidence generation and market economics. As part of continuing efforts to promote timely access to safe and effective medical care for children, the FDA Center for Devices and Radiological Health (CDRH) recently finalized its [Pediatric Extrapolation Guidance](http://bit.ly/2gZgqW2), <http://bit.ly/2gZgqW2>.

The guidance clarifies the FDA's perspective on leveraging existing data to support pediatric indications and labeling for medical devices. The guidance outlines the approach used to determine the appropriateness and extent of extrapolation and a description of relevant statistical methods. Extrapolation has the potential to enhance pediatric device development but should be used judiciously.

CDRH also is developing the Pediatric Extrapolation for Devices (PEDS) Team, a group of pediatric experts available for consultation. The PEDs Team will enhance consistency and standardization regarding extrapolation decisions.

The guidance and development of the PEDs Team reflect the FDA's commitment to the needs of pediatric patients. The FDA will continue to work with all stakeholders to address unmet medical device needs for children.

Resources

- [AAP News article "AAP policy clarifies acceptable off-label use of medical devices in children"](#)
- [AAP policy statement "Off-Label Use of Medical Devices in Children"](#)