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Corresponding Author. E-mail address: smacleod@cw.bc.ca. Department of Pediatrics, Child & Family Research Institute, University of British Columbia, Vancouver, British Columbia, Canada ...

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Modeling & simulation in pediatric drug development and regulation Carl Peck, MD UCSF Center for Drug Development Science UC-Washington Center, Washington DC Department of Biopharmaceutical Sciences School of Pharmacy, University of

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complex nature of pediatric formulations presents challenges in the development of a  
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requires multiple considerations. Therefore, it is appropriate that drug developers  
consider possible pediatric formulations early in the drug development process. A  
natural point in time would be at the same time a solid oral form is being considered  
for adults.

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Development, in Pediatric Drug Development: Concepts and Applications (eds A. E.  
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Here's How Pediatric Drug Development is Changing  
Pediatric Drug Development: Concepts and Applications. S M MacLeod.  
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Pediatric Drug Development: Regulatory Expectations  
Pediatric drug development continues to be a vexing challenge, yet pediatric research  
is increasingly being mandated by regulators and patients alike. Traditional  
development methods can be problematic for ethical and logistical reasons.

Pediatric Drug Development: Challenges and Opportunities  
Many drugs have received pediatric labeling under this provision, such that the  
FDAMA could be considered as the major legislative initiative that progressed  
pediatric drug development in the U.S. In 2001, the FDA's Report to Congress  
identified some drawbacks, for example, that the incentive legislation was only  
applicable to some drugs [ 11 ].

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