



The Pediatric Device Consortia Grant Program Fact Sheet

What: A statutory two million dollar grant program dedicated to stimulating the development and availability of medical devices for children.

Why: The development of medical devices for children currently lags five to ten years behind the development of devices for adults. Children differ from adults in terms of their size, growth, development, and body chemistry.

When: Fiscal Year 2009

May 1, 2009 GOAL DATE for Request For Applications to be published in Federal Register and NIH Guide.

Where: The Office of Orphan Products Development in OC will administer this program. The OPD will coordinate with CDRH, OPT, OCC, NIH, and Grants Management to carry out this program.

Who: Contacts in OOPD: Linda.Ulrich@fda.hhs.gov and Debra.Lewis@fda.hhs.gov @ (301) 827-3666

The Law:

The Pediatric Medical Device Safety and Improvement Act of 2007 established demonstration grants for non-profit consortia to stimulate pediatric device development.

- A consortium receiving a grant or contract under Section 305 will facilitate the *development, production, and distribution* of medical devices by
 - Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers.
 - Mentoring and managing device projects through the development process.
 - Connecting innovators and physicians to existing Federal and non-Federal Resources.
 - Assessing the scientific and medical merit of proposed pediatric device projects.
 - Providing assistance as needed on business development, personnel training, prototype development, post-market needs and other activities
- Each consortium will coordinate with the FDA Commissioner and device companies to facilitate applications for approval or clearance of devices labeled for pediatric use.
- Each consortium will coordinate with the NIH as well.