

the Social Security Act, and as amended, hereafter.

This delegation supersedes all previous delegations of authority to administer the Abstinence Education Program under Title V, section 510 of the Social Security Act. Except as provided above, the existing delegations of authority to officials within the Health Resources and Services Administration concerning Title V of the Social Security Act are unaffected.

This delegation shall be exercised under the Department's existing delegation and policy on regulations, and under financial and administrative requirements applicable to all Administration for Children and Families authorities.

I have ratified any actions taken by the Assistant Secretary for Children and Families, or any other Administration for Children and Families officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation.

This delegation is effective immediately.

Dated: June 9, 2004.

**Tommy G. Thompson,**  
Secretary.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): BECAUSE Kids Count (Building and Enhancing Community Alliances United for Safety and Empowerment), Program Announcement Number 04142

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): BECAUSE Kids Count (Building and Enhancing Community Alliances United for Safety and Empowerment), Program Announcement Number 04142.

*Times and Dates:* 4 p.m.-5:30 p.m., July 15, 2004 (Open), 9 a.m.-4:30 p.m., July 16, 2004 (Closed).

*Place:* Sheraton Buckhead, 3405 Lenox Road, NE, Atlanta, GA 30326, Telephone 404.261.9250.

*Status:* Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of

the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92-463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number 04142.

*For Further Information Contact:* La Tanya Butler, Deputy Branch Chief, Program Implementation Branch, DVP/NCIPC, 4770 Buford Highway, NE, MS-K60, Atlanta, GA 30310, Telephone 770.488.4653.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 15, 2004.

**Alvin Hall,**

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0254]

#### Possible Barriers to the Availability of Medical Devices Intended to Treat or Diagnose Diseases and Conditions that Affect Children; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), is requesting comments concerning the possible barriers to the availability of medical devices intended to treat or diagnose diseases and conditions that affect children. This action is being taken to assist the agency in preparing a report to Congress required by the Medical Devices Technical Corrections Act of 2004 (MDTCA).

**DATES:** Submit written or electronic comments by August 20, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Joanne Less, Center for Devices and Radiological Health, Food and Drug

Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

**SUPPLEMENTARY INFORMATION:** The President signed MDTCA (Public Law 108-214) into law on April 1, 2004. Section 3 of the MDTCA was added to address potential difficulties in bringing pediatric devices to market. Over the last few months, several professional organizations representing pediatric interests expressed concern about the availability of safe and effective devices intended for this population. Representatives from CDRH and the Office of Pediatric Therapeutics met with these organizations to explore the issue. The agency has also received anecdotal reports suggesting there is an unmet need in the pediatric population, but additional information is needed to assess the accuracy of these reports.

By October 1, 2004, the new law requires FDA to submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report addressing the "barriers to the availability of devices intended for treatment or diagnosis of diseases and conditions that affect children." The law also states that the report must include "any recommendations of the Secretary of Health and Human Services for changes to existing statutory authority, regulations, or agency policy or practice to encourage the invention and development of such devices."

Through this notice, FDA is soliciting comments that will help the agency draft its report to Congress under section 3 of MDTCA. In particular, FDA seeks input in response to the following questions:

1. What are the unmet medical device needs in the pediatric population (neonates, infants, children, and adolescents)? Are they focused in certain medical specialties and/or pediatric subpopulations?

2. What are the possible barriers to the development of new pediatric devices? Are there regulatory hurdles? Clinical hindrances? Economic issues? Legal issues?

3. What could FDA do to facilitate the development of devices intended for the pediatric population? Are there changes to the law, regulation, or premarket process that would encourage clinical investigators, sponsors, and manufacturers to pursue clinical trials and/or marketing of pediatric devices?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic