

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0485]

### Regulatory Process for Pediatric Mechanical Circulatory Support Devices (Ventricular Assist Devices)

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

**ACTION:** Notice of public meeting.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public meeting: Regulatory Process for Pediatric Mechanical Circulatory Support Devices (Ventricular Assist Devices). The topics of discussion are the agency's activities regarding the regulation and approval of circulatory support devices used for temporary support in pediatric patients.

*Date and Time:* The public meeting will be held on January 20, 2006, from 9 a.m. to 12 p.m. The agency is requiring registration by December 30, 2005.

*Location:* The public meeting will be held at the Center for Devices and Radiological Health, rm. 20B, 9200 Corporate Blvd., Rockville, MD 20850.

*Contact:* Eric Chen, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., 301-443-8262, ext. 146, e-mail: [eac@cdrh.fda.gov](mailto:eac@cdrh.fda.gov), or Michael Berman (HFZ-170), 12725 Twinbrook Pkwy., 301-827-4744, e-mail: [mrb@cdrh.fda.gov](mailto:mrb@cdrh.fda.gov). If you need special accommodations due to a disability, please contact Eric Chen, at least 7 days in advance of the meeting.

*Registration:* There is no fee to attend the workshop; however, because space is limited, registration is required. Please submit registration information

(including name, title, firm name, address, e-mail address, telephone number, and fax number) by December 23, 2005 (see *Contact*). Background information for the workshop will be available to the public on the Internet at <http://www.fda.gov/cdrh/meetings/012006workshop/index.html>.

**SUPPLEMENTARY INFORMATION:** This workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by providing the medical device community with guidance on the approval process for mechanical circulatory support devices (ventricular assist devices) used in pediatric patients in need of temporary support (left side, right side, or both sides). During the public workshop, FDA will present information regarding the approval process for these devices. Specifically, FDA will address applications for premarket approval, humanitarian use designations, humanitarian device exemptions, and investigational device exemptions. FDA will also present information regarding preclinical engineering qualification of pediatric mechanical circulatory support devices and invited experts will discuss medical and surgical topics. Following each presentation, and at the close of the meeting, FDA will conduct a question and answer session with the participating audience. After the workshop, presentations can be accessed by the public on the Internet at <http://www.fda.gov/cdrh/meetings/012006workshop/index.html>.

This workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which include working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness

Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: December 12, 2005.

**Linda S. Kahan,**

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