

## **FDA NEWS RELEASE**

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### **FDA issues two draft guidance documents to facilitate investigational medical device studies in humans**

The U.S. Food and Drug Administration today issued a draft guidance aimed at fostering early-stage development of medical devices within the United States. Doing early-stage development is important to help stimulate U.S.-based innovation and contribute to medical research.

The guidance document contains new approaches towards early feasibility studies, which are conducted in a small number of patients early in device development, while providing appropriate human subject protections. Such studies are necessary to resolve final design issues before the device is ready for a large clinical trial that is typically required for product approval. The FDA is seeking a small number of companies that could pilot the new approaches in the guidance. The results of the pilot will help to inform the final guidance.

Also today, the FDA issued guidance regarding clinical trials and medical devices. It describes the FDA's process for approving applications from companies that want to conduct clinical trials involving medical devices.

"Approaches to regulation that facilitate early clinical experience with investigational medical devices can result in safe and effective devices that reach patients sooner and create incentives to innovate in the United States," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "Today's guidance documents give sponsors and FDA device reviewers more flexibility to start investigational studies sooner while maintaining appropriate human subject protections, and they propose efficient ways to support product or study design changes once the study begins."

Before investigators can proceed with a clinical study involving a medical device that poses significant risks to human subjects, the FDA must approve an Investigational Device Exemption (IDE). IDE approval allows a medical device to be studied on subjects who consent to being part of the investigation.

The draft guidance "FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations" clarifies the FDA's process for approving clinical trials of medical devices and includes:

- When the FDA might allow patients to enroll in a study while issues are resolved, an

approach called "approval with conditions." Appropriate issues might include data analysis methods that can be resolved prior to gathering the data or minor divergences from study endpoints or study design assumptions.

- When the FDA might allow studies to begin with a smaller group of subjects while companies gather additional data, prior to the larger general enrollment, an approach called "staged approval."

The draft guidance "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, including First in Human (FIH) Studies" applies to medical devices in the early stages of development to better inform the final design of the device. It would allow studies to start earlier in the device development process than previously allowed. It would also permit for select device modifications to be made without FDA approval.

Participation in the pilot, announced in a Federal Register notice today, will be limited to nine sponsors. To qualify they should focus on innovative, early-stage development technologies that are most likely to benefit from the efficiencies of the program. Enrollment will begin on Dec. 12, 2011 and continue for 180 days from today's Federal Register notice or until a final guidance is published, whichever occurs first.

For more information:

FDA: Medical Devices

<http://www.fda.gov/MedicalDevices/default.htm>

Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff: FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm277669.htm>

Draft Guidance for Industry and Food and Drug Administration Staff: Investigational Device Exemptions (IDE) for Early Feasibility and Medical Device Clinical Studies, Including First in Human (FIH) Studies

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm277670.htm>

Pilot Program for Early Feasibility Investigational Device (IDE) Exemption Review

<http://www.gpo.gov/fdsys/pkg/FR-2011-11-10/pdf/2011-29116.pdf>

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

