



**FOR IMMEDIATE RELEASE**

P06-184

November 9, 2006

**Media Inquiries:**

Heidi Valetkevitch, 301-827-6242

**Consumer Inquiries:**

888-INFO-FDA

## **FDA Announces Actions to Strengthen its Postmarket Program for Medical Devices**

*Effort Will Improve Management of Adverse Events, Enhancing Patient Safety*

The U.S. Food and Drug Administration (FDA) today announced its action plan for strengthening the way it monitors the safety of medical devices after they reach the marketplace.

"Many of today's medical devices are smaller and more complex than ever, offering new medical opportunities that have benefited literally millions of people," said Scott Gottlieb, M.D., Deputy Commissioner for Medical and Scientific Affairs, FDA. "But this technical sophistication sometimes means that the margin for error with device manufacturing shrinks and so we need to be working even harder, after devices and engineering changes are approved, to monitor for potential safety problems."

FDA's Center for Devices and Radiological Health (CDRH) last year completed a comprehensive assessment of the tools used to monitor the safety of medical devices after the agency approves them for marketing. In January, the agency formed a Postmarket Transformation Leadership Team to develop an action plan focusing on four main areas: enhancing the center's culture of collaboration; developing world class data systems; enhancing risk/benefit communication efforts; and collaborating on improved enforcement strategies and outcomes.

"The agency is committed to improving its medical device safety program and ensuring that medical devices and radiation-emitting products remain safe and effective once they are in the hands of health professionals and the public," said Daniel Schultz, M.D., Director, CDRH. "Postmarket systems that enable constant learning and feedback not only help support best medical practices to ensure safe use of devices with maximum effectiveness but they also spur continued innovation. This plan is a major step in that direction."

Today's Postmarket Transformation Leadership Team report outlines actions to transform the postmarket program. These efforts will increase the agency's ability to identify, analyze, and act on the risks that may be posed by the thousands of devices used by health professionals and consumers every day. The action items include the following:

- creating a cross-cutting organizational structure within CDRH to better integrate premarket, postmarket and enforcement efforts;
- developing internal performance measurements to track the center's handling of postmarket issues, such as recalls;
- pursuing the development of a unique identifier system to identify a device and the information associated with that device throughout its lifetime;
- proposing mandatory use of electronic reporting for required adverse event reports and revising the current system that records reported adverse events for devices (the Manufacturer and User Facility Device Experience Database or MAUDE system);

- increasing the use of Medical Product Safety Device Network (MedSun) programs—a network comprised of more than 350 hospitals that have been recruited and specifically trained to identify and report device problems, and help provide "real time" data on signals and safety problems;
- enhancing risk/benefit communication efforts so health practitioners, patients and consumers receive clearer and more timely information on public health news; and
- increasing the coordination among the agency's compliance and enforcement programs.

For further information on the initiative, including a copy of the "Postmarket Transformation Leadership Team: Strengthening FDA's Postmarket Program for Medical Devices" report and the January 2006 "Medical Device Postmarket Safety Program – Synopsis and Recommendations," visit: [www.fda.gov/cdrh/postmarket/mdpi.html](http://www.fda.gov/cdrh/postmarket/mdpi.html).