A LETTER FROM THE CENTER DIRECTOR

To the American Public:

Today, the Food and Drug Administration is taking steps to foster medical device innovation and assure the safety and effectiveness of medical technologies used by and on patients in the United States. To keep the United States the leader in medical device innovation, the U.S. government must be innovative as well.

The new actions we are announcing will strengthen our most commonly-used pathway to market for medical devices, called the 510(k) program. The FDA's Center for Devices and Radiological Health uses this program to clear some 3,000 new medical devices for patients each year.

By increasing the predictability, reliability, and efficiency of our regulatory pathways, we can help provide better treatments and diagnostics to patients more quickly, stimulate investment in and development of promising new technologies to meet critical public health needs, and increase the global market position of U.S. medical devices.

Medical devices in the U.S. have a strong track record of safety and effectiveness. The 510(k) program, which the FDA created approximately 30 years ago, has helped support a robust medical device industry in the U.S. and helped stimulate innovation by providing a pathway for mostly lower-risk devices to come to market without the complexity of the approach used for high-risk devices.

For the past several years, however, the FDA's medical device center has been hearing major concerns about the 510(k) program from industry, consumers, healthcare professionals and others.

We've heard from industry that the program has become unpredictable, inconsistent and opaque. An unpredictable environment discourages investment and stifles innovation, which, in turn, can spur companies to go overseas.

We've also heard from consumers, third-party payers, and some healthcare professionals that the 510(k) program isn't sufficiently robust to assure that some devices cleared under the program are safe and effective nor does it provide enough information on safety and effectiveness to make well-informed decisions.

And we've heard from our own doctors and scientists that the 510(k) program in its current form is not well-suited to handle the increasingly complex devices under review.

To address these concerns, the agency started an internal and external evaluation of the 510(k) program.

The FDA created two staff working groups—one to review the program and make recommendations to strengthen it; the other to review how the agency incorporates new science into its decision making process and recommend how it can do so more predictably. We have engaged in extensive public outreach in developing and receiving feedback on the preliminary proposals developed by the working groups, including two public meetings, three town hall meetings, three public dockets and many smaller meetings with different stakeholder groups.

Today, we are announcing new steps that will lead to a smarter medical device program that supports innovation, keeps jobs here at home, and brings important, safe, and effective technologies to patients quickly.

Facilitating innovation is a critical part of the agency's responsibility to promote the public health, but this can happen only if the U.S. can support a robust, innovative medical device industry. The steps we are announcing today remove roadblocks to innovation while protecting patient safety.

To facilitate innovation in medical devices, the FDA will:

- Streamline the review process for innovative, lower-risk products, called the "de novo" process;
- Publish guidance for industry to clarify when clinical data should be submitted to increase predictability and transparency;
- Develop a network of external experts who can use their knowledge and experience to help the agency address important scientific issues regarding new medical device technologies; and
- Establish a new Center Science Council of senior FDA experts within the agency's medical device center to assure more timely and consistent science-based decision making.

While no medical device is completely risk-free, the FDA is strengthening its capacity to assess medical devices and monitor their safety once they are on the market and being used.

To bolster the safety of medical devices, the FDA will:

- Establish a public database of important device information, such as medical device labeling and summaries of the basis for the FDA's decision to clear specific devices; and
- Require a brief description of scientific information regarding the safety and effectiveness known to the manufacturer for select higher-risk devices on a case-by-case basis through device-specific guidance.

The accompanying implementation plan outlines 25 specific actions and the timelines for completion or reaching a major milestone in 2011 to make the 510(k) program a blueprint

for smarter medical device oversight; one that drives innovation and brings important technologies to the public.

Here at the FDA, we want safe and effective devices brought quickly to market, too—not only are we doctors, nurses and other healthcare professionals but we, our friends and our families are also patients.

We look forward to implementing these changes in support of our overall mission: improving the health of the American public.

Sincerely,

Jeffrey Shuren, M.D., J.D.
Director
FDA's Center for Devices and Radiological Health