MEDICAL DEVICE PREMARKET REVIEW

Desired Outcome

To improve the quality and reduce the cumulative review time required to approve 510(k) and traditional Pre-Market Approval Applications (PMA), while ensuring the safety of products approved for the market.

Program Objective

To achieve the Agency's FY 2006 Medical Device User Fee and Modernization Act (MDUFMA) performance goals for prompt review, so patients can enjoy the benefits of safe and effective medical devices to diagnose, treat, and prevent disease.

The medical device review program supports the FDA Strategic Plan in the area of "Using Risk Based Management Practices." This goal is aimed at providing the most health protection at the least cost to the public by making the review process more efficient through the use of a third party review program.

Why is FDA's Contribution so Important?

Sound, risk-based review processes are imperative to ensure that medical devices on the market are safe and effective. These devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices.

Because of the complexity of many medical devices, a 510(k) or PMA is required to market the product. A 510(k) is a premarketing submission made to FDA 90 days before a company proposes to begin marketing a new or modified device. A 510(k) demonstrates that a device to be marketed is safe and effective, and is substantially equivalent to a device that is currently legally marketed.

The PMA is required for new Class III medical devices that must be approved by FDA before the products can be marketed. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Premarket review entails the scientific and regulatory evaluation of the PMA to assure the safety and effectiveness of the product.

To strengthen FDA's Premarket review process, Congress enacted MDUFMA as a multi-year effort to improve the quality and timeliness of the medical device review process. It authorizes the collection of user fees to supplement the appropriated portion of the medical device review program for the review of medical device applications. The user fee is collected from device manufacturers that submit premarket applications, certain supplements to those applications, and premarket notifications.

The implementation of MDUFMA makes available new revenue for completing more timely and complete device reviews, reducing the cumulative approval time, reducing the number of review cycles, encouraging and supporting high quality applications, and providing a more efficient resolution of outstanding issues. The viability of the MDUFMA program is essential for the success of the medical device review program.

Requested Increases - Budget Authority

MDUFMA specifies a minimum amount of budget authority that must be provided each year in the Device and Radiological Health line of FDA's appropriation. FDA's budget has undergone a structure change since the passage of MDUFMA and the Device and Radiological Health line of FDA's appropriation is equivalent to the Center for Devices and Radiological Health (without Rent) plus the Devices and Radiological Health Estimate under the Office of Regulatory Affairs.

The minimum amount is the FY 2003 base appropriation of $205,720,000, multiplied by the April Consumer Price Index for Urban areas for each year thereafter. FDA estimates that adjustment factor for FY 2006 is 1.0734 percent, [1/] which would yield a minimum that must be appropriated for the Devices and Radiological Products Program for FY 2006 of $220,823,000 plus the $138,000 in FY 2005 make up funds for a total of $220,961,000.

This legislation also requires that any appropriation shortfalls below the specified level in fiscal years 2003, 2004 and 2005 be made up, or the program will cease to operate on October 1, 2005. Recognizing this requirement, the OMB Director issued a letter on October 29, 2003 to the Speaker of the House, committing the Administration to budget requests at a level that would satisfy this MDUFMA requirement for FY 2005 through 2007. For FY 2005 Congress appropriated a level approaching the trigger level in the FY 2005 Omnibus Appropriation and the Administration anticipates that Congress will take up the legislation during FY 2005 that will forgive the Appropriation triggers for FY 2003 and FY 2004, thus allowing the MDUFMA program to maintain operations and continue to efficiently review the safety and effectiveness of medical devices.

[1/] As specified in MDUFMA, the adjustment factor for FY 2006 is the Consumer Price Index for all urban consumers, U.S. city average (CPI/U) for April of FY 2005 divided by the CPI/U for April of 2002 (179.8). The adjustment factor for FY 2006 is based on the CPI/U for FY 2005 from the Economic Assumptions for the FY 2006 Budget. This estimate will be adjusted for actuals in mid May of FY 2005 when the Bureau of Labor and Statistics releases the April 2005 CPI/U.

FY 2005 Request
Budget Authority Increase
(Dollars in $000)

Program	Center	Field	Total
Devices and Radiological Health	$1,796	$4,200	$5,996

The requested budget authority increase of $5,996,000 will allow FDA to:

- Meet all of the performance goals specified in MDUFMA for FY 2005-2007;
- Maintain the level of investigators conducting inspections; and,
- Allow the field to meet the third party inspection trigger for the MDUFMA program.

Consequences of Not Achieving the Objective

Without the ability to collect fees, FDA would lack the resources needed to meet agreed upon performance goals from FY 2003 to 2007. Failing to meet these goals would negatively impact public health by delaying improvements in the medical device review process and denying patients access to innovative new medical

procedures and treatments. The current request, in conjunction with the MDUFMA user fees, will allow FDA to meet the aggressive FY 2005-2007 medical device review performance goals.

How are we Doing?

Overall the requested budget authority of $5,996,000 for the Devices and Radiological Health Program, in conjunction with the $40,300,000 in MDUFMA user fees, will allow FDA to:

- Acquire and train staff to meet a set of aggressive FY 2005 - 2007 performance goals to expedite the review of medical device applications, which were formally submitted by the Secretary of Health and Human Services to the Congress;

- Promote public health with major improvements in the review of breakthrough medical technologies and improvements in review of expedited device submission; and,

- Make major improvements in review performance in areas where fees are collected, while maintaining performance in other areas.

Specifically, the FY 2006 FDA premarket device review performance goals include:

- Complete review and decision on 80 percent of Expedited PMA Actions within 300 days;

- Complete Review and Decision on 80 percent of 180 day PMA supplement actions within 180 days;

- Complete Review and Decision on 75 percent of 510(k) (Premarket Notification) within 90 days; and,

- Conduct 295 domestic and 15 foreign BIMO inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.

In FY 2006 a total of $220,961,000 is requested for the Devices and Radiological Health Program (CDRH (without rent) and the Devices and Radiological Health Estimate under the Office for Regulatory Affairs) for both premarket and postmarket activities related to MDUFMA.