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STATEMENT BY

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FOOD AND DRUG ADMINISTRATION

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INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Jeffrey Shuren, Assistant Commissioner for Policy at the Food and Drug Administration (FDA or the Agency) and beside me is Daniel Schultz, Director of FDA's Center for Devices and Radiological Health. We are pleased to be here today to discuss the Agency's success in implementing the Medical Device User Fee and Modernization Act and to emphasize the importance of reauthorizing this law in advance of its October 1, expiration date.

BACKGROUND

MDUFMA I

As you know, in 2002, Congress enacted the Medical Device User Fee and Modernization Act (P.L. 107-250, October 26, 2002) (MDUFMA), aimed primarily at improving the timeliness, quality, and predictability of medical device application review. The House Report to the MDUFMA legislation commented that FDA's device review program lacked the resources to keep up with a rapidly growing industry and increasingly complex technology. (U.S. Congress, House Committee on Energy and Commerce, Medical Device User Fee and Modernization Act of 2002, report to accompany H.R. 3580, 107th Cong., 2nd sess., part 1 [Washington: GPO, 2002], pp.23).

Under MDUFMA, the industry provides additional funds through user fees that are available to FDA, to supplement appropriated funds, to spend on the device review process. Our

authority to collect and spend user fees is linked to – or "triggered" by – increased appropriations. We can collect and spend user fees only in years when the amount Congress appropriates for our entire medical device program keeps pace with a measure of inflation specified in MDUFMA.

The additional resources provided by medical device user fees allow FDA to meet performance goals defined in a letter from the Secretary of the Department of Health and Human Services to Congress. These goals include "FDA decision" goals, which require FDA to make a specific decision on most types of pre-market applications within a specified time (and similar goals that require FDA to "review and act on" certain biologics applications within a specified time), and cycle goals, which refer to FDA actions prior to a final Agency decision on a submission. These goals were progressively more ambitious each year for the duration of the legislation.

In addition to its provisions relating to medical device user fees and performance goals, MDUFMA contained other significant provisions. These include:

- Authorization for a program that allows establishment inspections to be conducted by third party accredited persons (APs), under carefully prescribed conditions.
- Establishment of a new office in the Office of the Commissioner to coordinate the review of combination products;

- Authorization to require electronic registration of device establishments, once FDA finds that electronic registration is feasible; and
- Explicit authorization for the "modular" review of pre-market approval applications (PMAs).

MDUFSA

In August 2005, Congress passed the Medical Device User Fee Stabilization Act (Public Law 109-43, August 1, 2005) (MDUFSA). MDUFSA modified several provisions of MDUFMA as follows:

- Repealed the fiscal year (FY) 2003 and FY 2004 appropriations trigger requirements;
- Modified the 2005-2007 minimum appropriation requirements for the device and radiological health line of FDA's appropriation to be within 1 percent of the calculated appropriations trigger;
- Specified user fee rates for FY 2006 and FY 2007, using 8.5 percent rate of increase each year;
- Expanded the definition of "small business" for FY 2006 and FY 2007, making more firms eligible for small business fees; and
- Repealed the "compensating adjustment" that allowed FDA to adjust user fee rates to make up for revenue lost when user fee revenues did not meet projections in a prior year.

MDUFMA ACHIEVEMENTS

The user fees provided by MDUFMA, and the annual appropriations, have allowed us to make significant improvements in the device review program. FDA's progress towards meeting MDUFMA's performance goals has been accomplished through:

- Targeted hiring, including medical specialists, statisticians, software experts, and engineers;
- Increased use of outside experts, particularly for novel technologies;
- Improvements to the IT systems, such as enhanced tracking of applications and reporting systems; and
- Additional guidance documents that assist industry in preparing their applications to better address regulatory and scientific issues, such as how to obtain expedited review of a pre-market submission, and how to use new statistical tools to enhance the value of clinical trial data.

These actions have led to improved FDA review times and greater predictability in the device review process.

In addition, we have made significant progress towards meeting other fundamental objectives of MDUFMA. For example, FDA established an Office of Combination Products that is improving coordination of combination product reviews. And, FDA met the statutory requirement to establish a third-party inspection program. This option may be particularly useful to U.S. firms who compete in international markets and are faced with multiple sets of

regulatory requirements, since a single third party inspection may satisfy both U.S. and foreign requirements and also may meet International Organization for Standardization (ISO) or other international standards requirements.

The program has produced significant benefits for public health. A better resourced device program has enhanced our abilities to keep pace with the increasing complexity of technology and changes in clinical practice. Since MDUFMA was enacted, FDA has approved more than 150 original PMAs. These have included devices intended to address unmet needs in the pediatric population, such as the first pediatric left-ventricular assist device, a cooling cap to treat severe hypoxic-ischemic encephalopathy in infants, and an expandable prosthetic rib to treat growing children with Thoracic Insufficiency Syndrome.

The device program also has approved important new laboratory tests, including the first test for use as an aid in diagnosing West Nile Virus, tests for diabetes management and newborn screening, tests for diagnosing cystic fibrosis, and a rapid screening test for lead poisoning that can be used at health care clinics, mobile health units, and schools. Device reviews have significantly contributed to the very important trend towards personalized medicine through clearance of test systems that can identify an individual's DNA to evaluate likely response to drug therapy.

In the area of women's health, FDA's device program approved an optical detection system to identify areas of potential cervical cancer, a non-invasive therapy system to treat uterine

fibroids with high-frequency ultrasound, and a clinical laboratory test to determine if a woman with breast cancer is a good candidate for Herceptin therapy.

Other important devices include the first carotid-stenting systems, a hip resurfacing system intended to treat younger patients who are not ready for hip replacements, and the first over-the-counter automatic external defibrillators.

REAUTHORIZATION

The user fee provisions of MDUFMA will sunset on October 1, 2007, if not reauthorized. In preparing our proposed recommendations for MDUFMA reauthorization, we have conducted technical discussions with regulated industry and have consulted each year with stakeholders at a public meeting as required by law. We published proposed recommendations for reauthorization on April 18, 2007; the comment period closes on May 18, 2007. We also held a public meeting on April 30, 2007, to obtain public input from all interested parties, including regulated industry, appropriate scientific and academic experts, health care professionals, and representatives of patient and consumer advocacy groups, on the proposed recommendations. Testimony at that meeting was generally supportive of our published recommendations.

PROPOSALS FOR MDUFMA II

Our goal for the legislative package to reauthorize medical device user fees and to make other improvements (MDUFMA II) is to build upon the performance goals we are pursuing for FY 2007 while providing reasonable and predictable user fees for industry and adequate and stable funding for FDA. Our proposed recommendations fall into two major categories: proposals to ensure sound financial footing for the device review program and proposals to enhance the process for pre-market review of device applications. We also are recommending modifications to the third party inspection program authorized by MDUFMA.

Proposed Recommendations to Ensure Sound Financial Footing

Although user fees have provided additional resources to FDA since the beginning of the program, resources for device review have not kept up with increasing costs. FDA as a whole has experienced an increase in its costs per FTE (including pay, benefits, and contract support) averaging 5.8 percent per year over the most recent five years. Non-salary costs, including the costs of rent and contract support, have also increased at the same rate per FTE. At the same time, our user fee revenue, which has been entirely dependent on the number of fee-paying applications submitted by industry, has not reached the levels anticipated when MDUFMA was enacted. These factors have impeded our business planning and delayed additional improvements to the device review program. We are proposing changes to the financial provisions of MDUFMA to place FDA on more sound financial footing, while providing industry with lower fees per application for most submissions. We believe these changes will help us continue and enhance the program.

1. Adjustment of Total Revenue for Device Review to Ensure a 6.4 percent Increase From Year to Year Over the Next Five Years

Detailed analysis of FDA's recent costs history, and increased costs FDA is anticipating over the next five years due to increased costs related to moving the Center for Devices and Radiological Health to the new White Oak facility necessitate annual increases of 6.4 percent just for FDA to maintain the current level of staff to support the device review process. The primary drivers of this rate of increase are rent, security, and statutorily mandated payroll and benefit increases. The industry has agreed to a fee structure designed to provide $287 million over the next five years. This will provide an approximately 31 percent increase in total fee revenue for 2008 and an 8.5 percent increase each subsequent year through 2012.

2. More Stable Fee Structure

Under MDUFMA I, fee revenues repeatedly fell short of expectations. All fee revenues were derived solely from application fees, which fluctuated significantly from year to year. For MDUFMA II, industry has agreed to two new fees that will generate about 50 percent of the total fee revenue and that will create a more stable structure than relying solely on application fees. They are an annual establishment registration fee and an annual fee for filing periodic reports. The addition of these new fees will allow for a significant reduction of existing application fees.

The establishment fee will be paid once each year by each device manufacturer, single-use device reprocessor, and specification developer. It is proposed to start at $1,706 in 2008 and

will generate about $21.8 million for FY 2008 (45 percent of total revenues), assuming that 12,750 establishments pay this fee. A firm will not be considered to be legally registered each year without the payment of this fee. An establishment's registration, listing, and registration fee payment would be completed electronically through a single on-line system.

The standard annual fee for filing periodic reports is proposed to start at $6,475 in 2008 and will generate about $2.5 million in FY 2008, or about 5 percent of fee revenues, assuming that we receive reports on 425 devices subject to periodic reporting and 10 percent pay the reduced small business fee of $1,619.

The remaining 50 percent of revenues will come from application fees. All proposed application fees will be significantly lower than they were in FY 2007. For example, the proposed fee for a Pre-Market Application (PMA) or Biologics Licensing Application (BLA) will be reduced from $281,600 in FY 2007 to $185,000 in FY 2008 and the fee for a 510(k) pre-market notification submission will be reduced from $4,158 in FY 2007 to $3,404 in FY 2008.

FDA is proposing two new application fees. They are (1) a fee for 30-day notices (making modifications to manufacturing procedures or methods) that will be 1.6 percent of the fee for a full PMA, and (2) a fee for a request for classification information under section 513(g) that will be 1.35 percent of the cost of a full PMA. Both of these applications require significant work for FDA, and the proposed fees reflect the work that they involve, on average. As

stated above, all of the fees will increase each year by 8.5 percent to ensure that fee revenues contribute their expected share to total program costs.

3. Changes in the Fee Structure for Small Businesses

To reduce the burden on small businesses, FDA is proposing to reduce small business fee rates for certain submissions. We are proposing to reduce the rates for small businesses for pre-market application, panel-track PMA applications, BLA efficacy supplements, 180-day PMA supplements, real-time PMA supplements, and annual reports from 38 percent to 25 percent of the full fee. We also are proposing to reduce the rates for small businesses for 30-day notices, 510(k) pre-market notification submissions, and 513(g) requests for classification information from 80 percent to 50 percent of the full fee. We are not proposing to change the criteria to qualify for small business status. However, we are proposing to expand the small business provisions to provide a way for foreign firms that do not file tax returns with the United States Internal Revenue Service to qualify for small business rates.

4. Electronic Registration and Listing

FDA believes electronic registration and listing are essential for efficient implementation of any proposal for an establishment registration fee. Therefore, we are proposing to change section 510(p) of the FD&C Act (21 U.S.C. 360(p)) to require all establishments to submit their registration and listing information by electronic means, except in those situations where FDA agrees that electronic registration is not reasonable. Electronic registration and listing will be faster and more efficient for industry and FDA.

5. Technical Changes to Increase Administrative Efficiency of the User Fee Program

We are also proposing to change the current offset provision of MDUFMA which requires us to reduce fees in a subsequent year if collections in any year exceed the amount appropriated. There currently is no parallel provision in MDUFMA to increase fees in a subsequent year if collections fall short of amounts appropriated from fees. We propose to aggregate all fees paid over the first four years of MDUFMA II and compare that amount to aggregate appropriations for the same period. A reduction will be made in fees in the final year only if the amount collected in the four-year period exceeds the amount appropriated for the same period. We believe aggregation over four years is fairer than treating each year separately. There would still be no parallel provision for increasing revenues if fees collected fall below appropriated amounts in aggregate.

Enhancing the Process for Pre-market Review

In the area of pre-market review, FDA is proposing enhancements in a number of areas:

- Improved performance goals;
- Interactive review;
- Guidance document development;
- Diagnostic imaging products;
- In vitro diagnostics;
- Meetings;
- Quarterly performance reports; and
- Reviewer training.

1. Improved Performance Goals

FDA is proposing goals for MDUFMA II that build on the progress made in MDUFMA I, taking into account the presence of more seasoned review staff and efficiencies accomplished in MDUFMA I and planned for in MDUFMA II. These efficiencies include additional scientific, regulatory and leadership training; additional staff, including those with expertise demanded by increasingly complex device reviews; expanded use of outside experts; and IT improvements.

In MDUFMA II, we propose to eliminate cycle goals, which we believe serve as an impediment to reaching the ultimate objective of getting safe and effective devices to patients and health care professionals more quickly. We believe that an unintended consequence of the cycle goals is that, because we must determine whether or not to send a major deficiency letter, "not approvable" letter, or other interim action earlier in the review process, we are less likely to have sufficient time to engage in informal interactions with industry to resolve outstanding questions before making that determination. Consequently, we are more likely to issue a formal interim letter. Because both FDA and industry would like to see greater informal interactions, we propose to eliminate cycle goals and focus our performance goals more closely on FDA decisions.

In MDUFMA II, we propose to improve our performance in reaching a final decision for expedited and non-expedited PMAs, panel track PMA supplements, and 510(k)s. We also propose to add a goal for PMA modules in MDUFMA II. And, where specific quantitative

goals have not been established (for example, Investigational Device Exemptions, or IDEs), we propose to maintain current review performance.

2. Interactive Review

We will continue to incorporate an interactive review process using all forms of communication and intended to: (a) prevent unnecessary delays in the completion of the review; (b) avoid surprises to the sponsor at the end of the review process; (c) minimize the number of review cycles and extent of review questions conveyed through formal requests for additional information; and (d) ensure timely and adequate responses from sponsors. Strengthening interactive review can help sponsors address Agency concerns and provide additional data, when necessary, earlier in the review process.

3. Guidance Document Development

We will continue to develop guidance documents to the extent possible without adversely impacting the review timeliness on MDUFMA-related submissions. In addition, FDA will post a list of guidance documents it is considering for development and provide stakeholders an opportunity to provide comments and suggestions for those topics as well as suggestions for new or different guidances.

4. Diagnostic Imaging Products

Diagnostic imaging devices are sometimes used concurrently with diagnostic drug and biological products (such as contrast agents and radiopharmaceuticals) in a way that does not meet the regulatory definition of a combination product. Nevertheless, such "concomitant

use products" present important questions of efficient regulation and consultation because multiple FDA review Centers and regulatory authorities may be involved as is often the case with combination products. To help ensure the timely and effective review of these products, and consistent and appropriate post-market regulation and product labeling requirements, FDA is proposing to develop a guidance document for diagnostic imaging devices used with approved imaging contrast agents and/or radiopharmaceuticals.

5. *In Vitro* Diagnostics (IVDs)

IVDs are devices used to diagnose diseases and other conditions. They will play an important role in personalized medicine. To facilitate the development of IVD devices, FDA will continue to explore ways to clarify the regulatory requirements and reduce regulatory burden. FDA proposes to:

- Draft or revise guidance on the conduct of clinical trials involving de-identified leftover specimens, clinical trial design issues for molecular diagnostic tests, migration studies, herpes simplex virus, enterovirus, and influenza testing;
- Conduct a pilot program of voluntary participants to evaluate the 510(k) review and Clinical Laboratory Improvement Amendments (CLIA) waiver application review processes for possible increased efficiencies through concurrent review;
- Consider industry proposals on acceptable CLIA waiver study protocols, develop acceptable protocol designs, and make them available by adding appendices to the CLIA waiver guidance or by posting redacted protocols on the OIVD website;

- Track our performance on CLIA waiver applications and evaluate whether CLIA waiver user fees and performance goals should be considered for MDUFMA III;
- Review a list of class I and II low risk IVD devices, provided by industry, to determine whether any could be exempted from pre-market notification and allow interested parties to petition for exemptions consistent with 510(m)(2); and
- Conduct a review of the pre-IDE program.

6. Meetings

FDA will make every effort to schedule both informal and formal meetings, including pre-submission meetings, determination meetings, agreement meetings, and 100-day meetings, held both before and during the review process, in a timely way. Industry will make every effort to provide timely and relevant information to make the meetings as productive as possible.

7. Quarterly Performance Reports

FDA will report quarterly on its progress toward meeting the quantitative goals described in the commitment letter. In addition, for all submission types, we will track total time (time with FDA plus time with the company) from receipt or filing to final decision. We also will provide de-identified review branch performance data for 510(k)s, 180-day supplements, and real-time supplements on an annual basis.

8. Reviewer Training

As resources permit, FDA will apply user fee revenues to support reviewer training that is related to the process for the review of devices, including training to enhance scientific expertise. We will provide summary information on an annual basis of the types of training provided to staff.

Third Party Inspection Program

FDA is proposing changes to the Third Party Accredited Persons (AP) inspection program in three major areas. These proposals are intended to: increase industry participation in the program, which to date has been minimal, and increase the quantity of information FDA has about the compliance status of medical devices marketed in the United States. The freeing-up of FDA's own inspectional resources from routine inspections will permit FDA to focus instead on firms and products posing the greatest risk to public health.

First, FDA is proposing to streamline the administrative processes associated with qualifying for the program. For example, rather than having to petition FDA for clearance to use an AP, the proposal would require only that a firm provide FDA with prior notice of intent to use an AP, along with information about the date of last FDA inspection, identity of AP selected, and certification that the firm markets, or intends to market, at least one device in a foreign country that recognizes the AP as a person authorized to conduct device inspections. If FDA does not require additional information from the firm within 30 days of that notice, the firm is deemed to have clearance to participate in the program.

Second, we are proposing to expand participation in the program. For example, the current AP program restricts qualified manufacturers of class II and class III medical devices to two consecutive AP inspections. FDA must conduct the next inspection unless the manufacturer petitions and receives a waiver from us. We propose to eliminate that restriction and permit eligible firms to use APs for an unlimited number of consecutive inspections without seeking a waiver. We would continue to conduct "for cause" or follow-up inspections when appropriate.

Third, we are also proposing to permit the medical device industry, on a voluntary basis, to submit to FDA AP reports assessing conformance with an appropriate international quality systems standard set by the International Organization for Standardization (ISO). We would consider the information in these reports when establishing our inspectional priorities.

CONCLUSION

As you know, MDUFMA will sunset on October 1, 2007. It is essential for us to work together to ensure that FDA does not lose this critical source of funding and to ensure that we can undertake the other important improvements to medical device review and safety we are recommending in this legislation. MDUFMA II is a priority for the American public, the medical device industry, and the many talented staff at FDA that we rely upon to conduct medical device reviews. Delay in the reauthorization of this program could trigger personnel disruptions in our workforce, particularly among expert reviewers whose skills are in very

high demand. The repercussions of such losses would undermine the efforts and resources we have put into hiring and retaining skilled scientists.

We have achieved much under MDUFMA, and we are ready to work with you in any way we can to ensure that FDA has the resources and tools we need to build on that success. We appreciate the support of you and your staffs, the assistance of other Members of the Committee, and that of the Appropriations Committees, in helping us move forward toward the re-authorization of this vital program.

Thank you for your commitment to the mission of FDA, and the continued success of our medical device program, which helps get safe and effective technology to patients and practitioners on a daily basis. We are happy to answer questions you may have.