
The MDUFMA User Fee Program in 2005: A Critical Year

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This work was supported in part by a grant from the Center for Integration of Medicine and Innovative Technology (CIMIT), a non-profit consortium consisting of Massachusetts General Hospital, Brigham and Women's Hospital, Massachusetts Institute of Technology and Draper Laboratory. CIMIT is funded in part by the Department of the Army, under agreement

DAMD 17-02-2-0006. The information in this article does not necessarily reflect the position of the United States Government and no official endorsement should be inferred.

I. Introduction

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA)¹ represents one of the most significant device-related reforms to the Federal Food, Drug and Cosmetic Act (FDCA)² since passage of the Medical Device Amendments of 1976 (MDA).³ Intended to expedite the marketing of safe and effective device-based technology, the most notable of these reforms authorizes the Food and Drug Administration (FDA) to assess fees for the review of premarket submissions, a paradigm based on the previously enacted Prescription Drug User Fee Act.⁴ The long-term success of MDUFMA's user fee program is largely contingent on FDA's performance during the first five years of implementation, as measured by the Center for Devices and Radiological Health's (CDRH's) ability to meet predetermined performance goals.⁵ While only two performance goals have been in effect since 2002, beginning in fiscal 2005, the device center will be held to a total of 20. With additional responsibility for 18 new performance goals, a congressionally-mandated report from the Government Accountability Office (GAO) on CDRH performance due at the end of 2005, and uncertainty surrounding a legislative "trigger fix" to forgive the shortfall in congressional appropriations to date, user fee activities in the coming year will be closely monitored by all stakeholders, and will shape the long-term future of the user fee program and CDRH review of medical device submissions in the future.

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II. History of Medical Device Regulation in the United States

The significance of MDUFMA's user fee program towards enhancement of FDA's ability to provide efficient, timely, and effective reviews of medical device submissions is best understood in the context of the history of medical device regulation. Federal regulation of medical products began with the Food and Drugs Act,⁶ which provided for the regulation of medical drugs. Medical devices of the era, limited in number and rudimentary by today's standards, were not encompassed in this legislation. It was not until three decades later that the Food, Drug and Cosmetic Act of 1938 (FDCA) was enacted, instituting federal regulation of medical devices for the first time, though initial regulatory authority was limited to challenging legally marketed devices that were thought to be unsanitary, unsafe, or misbranded.⁷ The agency thus lacked explicit authority to require device manufacturers to demonstrate that a device was safe or effective prior to marketing the product to consumers.⁸ Such authority did not exist until the Medical Device Amendments of 1976 (MDA), which established the core of today's sophisticated medical device regulatory framework including explicit authority to require premarket notification and premarket approval.

The cornerstone of the MDA regulatory framework is a risk-based classification scheme based on the perceived risk a medical device poses to patients.⁹ Pursuant to this legislation, all devices legally on the market prior to MDA were to be assigned to one of three classes - class I, II or III - by expert advisory committees. Device class in turn dictates the level of regulatory scrutiny. Class I devices represent a low-risk of harm to patients and are subject to general controls - regulations that speak to the safe manufacturing of medical products. These products are not intended for uses that are of substantial importance in preventing impairment of health and do not present an unreasonable risk of injury. Class II products are considered to represent an intermediate risk of harm to patients. In addition to general controls, more specific categorical performance standards in the form of special controls may apply to address these risk concerns. Finally, class III devices are products that represent a potentially significant risk to patients, that are used to maintain life, or for which the risk profile is unknown. These high-risk products are subject to a demanding premarket approval process, which

requires demonstration of reasonable safety and effectiveness prior to commercial sale.¹⁰

In addition to establishment of the risk-based classification scheme, MDA distinguished between pre-MDA devices and post-MDA devices. Pre-MDA devices, devices already legally on the market when MDA was enacted, were placed into one of the three categories by expert panels and allowed to remain on the market regardless of classification status, though FDA reserved the right to request proof of safety and efficacy at any time for high-risk, class III products. Post-MDA devices did not enjoy this grandfathered status, and were subject to evaluation via a premarket notification requirement under FDCA section 510(k) which required manufacturers to notify the agency of their intent to market a device. Through this notification process, FDA determines whether the device is "substantially equivalent" to a pre-MDA "predicate" device, or whether the device lacks a predicate. Devices lacking a predicate are automatically placed in class III, unless their established risk profile qualifies the product for downclassification to class I or II. Devices found "substantially equivalent" to a pre-MDA device can be marketed under the same controls associated with the classification of the predicate device.¹¹ Importantly, a post-MDA device that is found "substantially equivalent" to a pre-MDA device may itself serve as a predicate, allowing for incremental change over time outside the PMA process.

Under the MDA, FDA's ability to ensure the safety and effectiveness of medical devices was considerably expanded, though the framework raised new issues resulting in the Safe Medical Device Act of 1990 (SMDA)¹² and the Medical Device Amendments of 1992.¹³ Through the MDA as amended, FDA worked to implement the complex regulatory framework, a process which imposed significant administrative and resource burdens on the agency.¹⁴

The evolving device regulatory system became notably stressed in the late 1980's and early 1990's, when an explosion in medical technology and increased regulatory scrutiny linked to the silicone breast implant controversy combined to produce major delays in gaining product approval or clearance.¹⁵ Ultimately, these factors drove passage of the Food and Drug Administration Modernization Act (FDAMA) of 1997.¹⁶ FDAMA amended the FDCA to improve the general efficiency of FDA medical product review, and represented a growing

consensus that FDA's mandate included not only ensuring that safe and effective products reached consumers, but that such products reached consumers in a timely manner.¹⁷

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), signed into law by President Bush on October 26, 2002, represents the latest legislation following FDAMA aimed at improving prompt approval and clearance of safe and effective medical devices for improved public health.¹⁸ Among its various device-related provisions, the legislation establishes the medical device user fee program, which authorizes FDA to assess fees for the review of certain types of premarket submissions, while additionally authorizing congressional appropriations, as needed, to support postmarket surveillance efforts.¹⁹ In exchange for the increased revenue from user fees and congressional appropriations, MDUFMA requires CDRH to satisfy a set of performance goals - statutorily mandated review timeframes and review quality standards - over the course of a five-year period ending in 2007. At the conclusion of the five-year period, Congress will determine if the MDUFMA user fee program will be extended or expire under a "sunset" provision in the legislation.²⁰

III. The Medical Device User Fee Program under MDUFMA

Beginning in fiscal year 2003, FDA began assessing user fees for certain premarket submissions.²¹ Exact fee amounts are set annually, contingent on whether user fee revenue targets were met in previous years. Depending on the category of submission and type of sponsor, the exact fee amount will vary. Generally, the most resource-intensive submissions are subject to the highest user fee rate, and theoretically reflect FDA resource expenditures required for reviewing that particular type of application. While user fees are generated by premarket submissions with rates dependent on submission type, revenue from user fees may be utilized by CDRH toward the satisfaction of broader improvement initiatives and are not directly tied to exact resource expenditures for review of the particular device submission with which it was submitted.²²

A. Submissions Subject to User Fees

MDUFMA section 102 authorizes FDA to assess user fees for the following premarket submissions:

- *Original Premarket Approval Applications (PMAs)* - the most stringent pathway to market, this submission often includes human clinical trial data to establish the safety and effectiveness of a device.²³ This category includes premarket approvals (PMAs), biologics licensing applications (BLAs), and product development protocols (PDPs).
- *Premarket Reports (PMRs)* - a newly established type of submission under a separate MDUFMA provision concerning regulatory requirements for high-risk devices meant for single-use that have been reprocessed for additional uses.^{24 25}
- *PMA Panel-Track Supplements* - required in cases where a sponsor is seeking to expand the indication of an approved PMA or PMR to request a significant change in design or performance of a device, and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness.²⁶
- *PMA 180-day Supplements* - a request for a significant change in components, materials, design, specification, software, color additive, or labeling of an already approved device.
- *PMA Real-Time Supplements* - supplements required when the sponsor is requesting a minor change to the device, such as a minor change to the design of the device, software, manufacturing, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.²⁷
- *Biologics License Application (BLA) Efficacy Supplements* - supplements accompanying an approved BLA, required when the sponsor seeks to change the design, performance, or indication for use of the device, for which substantial clinical data is needed to demonstrate safety and effectiveness.²⁸
- *Modular PMAs* - a compilation of sections submitted at different times that together become a complete submission application, for which the

entire fee is due when the first portion is submitted.²⁹

- *Premarket Notifications or 510(k)s* – submitted for marketing a device that is substantially equivalent to a legally-marketed device.

While certain premarket submissions are subject to user fees, others are specifically exempt from user fee assessment, and for others, user fees have been waived. These submissions include:

- *Humanitarian Device Exemption (HDE)* – an application, similar to a PMA, for the marketing of a Humanitarian Use Device, or a device “that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.” These devices do not need to meet the effectiveness requirements of a PMA because of the limited feasibility of a clinical trial.³⁰
- *Any original PMA or PMA supplement that is intended solely for a pediatric population.* The exemption is no longer valid if the sponsor proposes conditions of use for an adult population at a later time.³¹
- *Biologics License Application (BLA) for a product licensed for further manufacturing use only.*
- *Third Party 510(k)s* – any submission reviewed by a third party under the Third Party Review Program. Although exempt from an FDA fee, the sponsor may be required to pay a fee to the third party reviewer.
- *Any first time premarket submission for a qualified small business.*
- *The first PMR submission by the sponsor of a device for which a PMA was submitted on the same date.* This exemption exists to minimize the penalty that sponsors of previously PMA-approved reprocessed devices face from MDUFMA provisions.
- *Any application submitted by a State or Federal Government entity, unless the device is to be distributed commercially.*³²

- *Certain submissions that fall outside of MDUFMA’s definition of a real-time supplement because they are not reviewed jointly with the applicant.* As defined by MDUFMA, a real time supplement “requests a minor change to the device, such as a minor change to the design of the device, software, manufacturing, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.”³³ Submissions excluded by this definition include post approval protocols, post approval study results, modification of the post approval protocol, trade name changes, request for approval of a private label distributor, and manufacturing site change.

B. User Fee Rates

User fee rates for each submission type discussed above are set annually in August, and announced in the Federal Register. Adjusted for inflation, workload changes, and various other factors, fees also reflect whether revenue targets from the previous year(s) where met, and by how much.³⁴ Recognizing that small device sponsors would be especially impacted by assessment of user fees generally, MDUFMA includes provisions establishing reduced fees for qualified small businesses. Eligibility turns on whether a sponsor’s gross annual revenue exceeds \$30 million, which includes revenue from all affiliates, partners and parent firms. Applicants who show gross revenue of \$30 million or less are eligible for the small business fee structure.³⁵

The following chart provides the established user fee rates for fiscal years 2003, 2004, and 2005, including both full fee rates and small business rates:

Submission Type	FY 2003 Fees		FY 2004 Fees		FY 2005 Fees	
	Standard	Small Business	Standard	Small Business	Standard	Small Business
Premarket Application	\$154,000	\$58,520	\$206,811	\$78,588	\$239,237	\$90,910
Premarket Report	\$154,000	\$58,520	\$206,811	\$78,588	\$239,237	\$90,910
Panel-Track Supplement	\$154,000	\$58,520	\$206,811	\$78,588	\$239,237	\$90,910
180-day Supplement	\$33,110	\$12,582	\$44,464	\$16,896	\$51,436	\$19,546
Real-Time Supplement	\$11,088	\$4,213	\$14,890	\$5,658	\$17,225	\$6,546
BLA Efficacy Supplement	\$154,000	\$58,520	\$206,811	\$78,588	\$239,237	\$90,910
Premarket Notification	\$2,187	N/A	\$3,480	\$2,784	\$3,502	\$2,802

Generally, the PMA fee is used to calculate the baseline for all the other fee rates. Premarket report, panel-track supplement, and BLA efficacy supplement fees are set at 100 percent of the baseline, while the 180-day supplement, real-time supplement, and premarket notification fees are set at 21.5 percent, 7.2 percent, and 1.42 percent, respectively. Small business fees are set at 38 percent of standard fee rates, with the exception of 510(k) fees, which are set at 80 percent of the standard starting in fiscal year 2004.

As provided under MDUFMA, user fees are to be used to reach predetermined revenue targets, which range from \$25,125,000 in 2003 to \$35,000,000 in 2007, unadjusted for inflation. These targets are subject to adjustment to account for inflation, increased workload, shortfalls in fee revenue, a final year adjustment in 2007, and possible legislation requiring the Department of Health and Human Services (DHHS) to fund additional employee retirement costs.³⁶

C. Refunds

Under some circumstances, user fees may be refunded in whole or in part. In a case where FDA refuses to file a submission under circumstances where an application does not meet standards of acceptability,³⁷ or where an applicant withdraws the application before the submission is filed, a refund of 75 percent of the fee will be issued upon written request, if submitted within 180 days after the fee due date for traditional PMA and Panel-Track supplements.³⁸ FDA may refund a portion of the fee if an applicant withdraws a PMA or Panel-Track supplement after filing, but before a first action.³⁹ The refund amount is determined by assessing the

effort expended on the review, in proportion to the number of days the application was in review. Generally, FDA will refund 50 percent of the fee when the application is withdrawn within 90 days and refund 25 percent if the application is withdrawn between 91 and 135 days. After 135 days, FDA does not expect to refund any of the fee, though the agency will take additional factors into consideration when unusual circumstances exist.⁴⁰

Importantly for the sponsor, FDA is not required to refund user fees and the agency’s determination of whether a particular case qualifies for a refund as well as the refund amount, is not reviewable.⁴¹ Generally, refunds will not be made following a first action. For 180-day or Real-Time supplements, FDA will not refund user fees, based on the rationale that these submissions are considered filed on request, cost significantly less than original PMAs, and have a much shorter review time.

D. Performance Goals

The crux of the user fee program is FDA’s ability to satisfy a set of predetermined performance goals. In exchange for the assessment of fees as authorized by MDUFMA, CDRH has been charged with meeting performance goals, as set forth in the Congressional Record.⁴² These goals essentially set specific timeframes within which premarket submission reviews should be completed. Notably, with each passing year, these goals must be met with greater frequency, thus increasing their performance with regard to timely review of applications.⁴³ The following chart provides the performance goals for different types of submissions and includes goals for both first actions and final FDA decisions:

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Submission Type	Action Goals and % Compliance				Decision Goals and % Compliance			
	First Action Issuance	FY 2005	FY 2006	FY 2007	FDA Decision	FY 2005	FY 2006	FY 2007
Original PMA, Panel-Track Supplement, or PMR	180 days (major deficiency within 150)	75%	80%	90%	320 days	N/A	80%	90%
Expedited Original PMA	170 days (major deficiency within 120)	70%	80%	90%	300 days	70%	80%	90%
180-day Supplement	180 days (not approvable within 120)	80%	85%	90%	180 days	80%	80%	90%
Premarket Notification	75 days	70%	80%	90%	90 days	75%	75%	80%
BLA Efficacy Supplement	N/A	N/A	N/A	N/A	10 months	N/A	75%	90%

The original PMA submission goals and the premarket notification goals for fiscal year 2007 are subject to review by FDA and relevant stakeholders at the end of fiscal year 2005.⁴⁴

Importantly, FDA is required to satisfy MDUFMA performance goals if salary and account appropriations for a given year, excluding revenue generated by collection of user fees, meet a target level specific to that fiscal year. If such appropriations do not meet required levels, FDA will not be held to satisfaction of performance goals for the corresponding year.⁴⁵ The base target level of appropriations, with fee revenue amounts excluded, is \$205,720,000 or greater, when multiplied by the relevant yearly adjustment factor. If appropriations fall below this level in fiscal year 2005, FDA will only be required to meet performance goals to the “extent practicable.”⁴⁶ If appropriations fall below this level in fiscal years 2006 or 2007, FDA will not be required to meet performance goals to any extent, though user fees cannot be assessed during this time.⁴⁷ Accordingly, FDA appropriation levels are critical to the long-term sustainability of the user fee program.

MDUFMA requires that the Government Accountability Office (GAO) annually report on the status of the user fee program and efforts towards

meeting performance goals, as measured against the goals set forth in Secretary Thompson’s commitment letters.⁴⁸ Oversight procedures are clearly defined in the Act, and the commitment letters require an annual stakeholders’ meeting beginning in fiscal year 2004 to evaluate the implementation of MDUFMA. In addition, FDA is required to submit annual reports to Congress regarding progress, how the revenue from collected user fees are being used, and implementation of the authority for fees.⁴⁹ FDA’s authority to collect user fees expires October 1, 2007. However, at the conclusion of fiscal year 2005, the GAO is scheduled to submit a report to Congress regarding the extent performance goals have been met, and, based on these findings, whether future performance goals will likely be met.⁵⁰

IV. The Future of the User Fee Program

The first two years following implementation of the MDUFMA user fee program have established a foundation for significantly improving the review of medical device submissions. They have also highlighted critical issues which stand to impact the success of the program through 2007 and beyond. Fiscal year 2005 will be a defining year for the program: 18 additional performance goals are in effect, a double-digit user fee rate hike has been implemented straining relations with the industrial community, uncertainty remains in revenue projections, and the potential of a legislative “trigger

fix” for past appropriation shortfalls remains uncertain and may be jeopardized by lack of a unified front.

A. The First Two Years

Fiscal years 2002 and 2003 were essentially designed to allow the agency a ramp-up period, with a focus on strengthening CDRH staff and infrastructure towards ensuring satisfaction of future performance goals. Though not statutorily mandated, CDRH and the Center for Biologics Evaluation and Research (CBER) convened a meeting in late 2003, seeking feedback on progress during the first year following MDUFMA implementation, including progress on the user fee program as well as other provisions of the MDUFMA legislation. In assessing performance under the user fee program, CDRH reported 67 new hires, bringing the total number of review staff members dedicated to reviewing device submissions from 681 to 748.⁵¹ Also during this year, a scorecard system was developed and implemented to assist CDRH in tracking premarket review performance and measuring progress towards performance goals.⁵² In addition, the device center issued 18 guidance documents related to MDUFMA provisions, many of which addressed various aspects of user fee program implementation.⁵³

Fiscal year 2004 saw continuing progress in bolstering CDRH staff and infrastructure, supporting both the user fee program as well as other MDUFMA provisions. As of June 2004, CDRH reported over 100 additional staff members hired under MDUFMA, with 76 CDRH hires projected through fiscal 2004, the majority of which are engineers and scientists. CDRH spent \$632,000 on training and professional development for these additional employees throughout this second year. CDRH also invested in its information technology infrastructure, with \$3.7 million in funding committed to strengthen this important component of Center activities.

Despite progress in these areas, a number of challenges have been identified following initial implementation of the program and two years of ramp-up efforts. In fiscal year 2003, CDRH experienced a shortfall in user fee revenue by several million dollars, highlighting the difficulty of accurately budgeting this new revenue stream and the consequences of significant errors in budget projections. That year, FDA collected \$21.9 million in user fees, substantially less than the revenue target of \$25.1 million.⁵⁴ To compensate for the \$3.2

million shortfall, FDA increased user fee rates for fiscal year 2004, while making a \$1.2 million adjustment for inflation.⁵⁵ Fees for PMAs, PMA panel-track supplements, and biologic license applications were thus set 34 percent higher than 2003 rates, while fees for 510(k)s increased 59 percent, and the small business rate rose 47 percent. With these increases, FDA expected to collect \$27.2 million in fiscal year 2004. However, again FDA experienced a shortfall in projected user fee revenues, with a preliminary estimate of roughly \$26.8 million collected versus the roughly \$33.9 projected. Despite this shortfall, the fiscal year 2005 revenue target has been set at \$32.4 million, which includes a mandatory inflation adjustment, but no compensating adjustment for previous revenue shortfalls. Fluctuating increases in user fee rates and the expected continuation of such increases in the coming fiscal years should the current compensating adjustment be utilized, have the potential to cause significant financial problems for device firms, particularly smaller firms whose resources are already constrained. There is also the broader risk of straining industry’s satisfaction with the program, particularly if CDRH fails to meet statutorily set review timeframes.

Beyond the difficulty with projecting revenue targets is the challenge of satisfying review time performance goals as the user fee provisions take full effect. According to a status report for fiscal year 2003, CDRH met the 320-day processing target for PMA and PMA panel-track supplements 44 percent of the time. As soon as fiscal year 2006, CDRH will be required to meet the processing target 80 percent of the time.⁵⁶ While it is important to note that the device center was not operating at full funding levels during this period, a recently released GAO report is not optimistic in its assessment, identifying a number of shortfalls in the limited data available.⁵⁷

B. Looking Ahead

Perhaps the most significant challenge facing the user fee program going forward is CDRH’s ability to accurately project resources necessary to meet an ever-changing product review environment. In order to set user fee rates that generate enough revenue to support timely and quality reviews, FDA must estimate the number of submissions expected during the upcoming fiscal year, a projection that may be extremely difficult given the volatility of the technology-driven device market and the lack of submission data from periods when MDUFMA user

fees were in effect. Should the agency underestimate submissions, it will likely encounter difficulty in meeting MDUFMA performance standards; inflated projections would artificially raise user fees, negatively impacting the medical device industry. Still, given that submission data will likely improve with time, and considering the success of FDA's Center for Drug Evaluation and Research (CDER) in calculating its user fees using five years of submission data, there is the suggestion that CDRH's projections will become more accurate with time.⁵⁸

Adding to problems with user fee revenue target projections, particularly in the early years of the program, is variability of congressional appropriations in any given year. These appropriations, authorized for salaries and expenses for devices and radiological health must meet certain levels under MDUFMA for CDRH to be held to performance goals each year. A minimum level of congressional appropriations is not guaranteed and any funding is subject to congressional approval. Such fluctuations and uncertainty from year to year will undoubtedly affect the ability of FDA to maximize the potential of the program if lower-than-expected appropriations put performance goals on hold. Likewise, such uncertainty impacts the device center's ability to proceed with review performance initiatives on many fronts, particularly to hire new review staff with confidence.

Of particular importance going into 2005 is the pursuit of a legislative "trigger fix." FDA is currently pursuing legislation that would forgive the failure of Congress to grant \$32 million in appropriations over fiscal years 2003 and 2004. However, competing interests among stakeholders, voiced at the second MDUFMA Stakeholders' Meeting this past November, may sideline the process. CDRH officials are urging industry to support the current trigger fix and wait to pursue additional legislative changes to the user fee program, such as a cap on user fee annual increases and a corresponding "forgiveness" of the \$4.8 million shortfall in industry user fee revenues, which would essentially eliminate the compensating adjustment rate hikes. CDRH leadership fears such renegotiations of the program at this point in time could jeopardize the entire program, as failure to pass the legislation may result in sunset of the program. Furthermore, reinstatement of the user fee program following sunset would be unlikely, a result that would seriously impact the device center's improvement initiatives and its ability to effectively

and efficiently handle increasingly complex device submissions in the future.

Despite early implementation issues with the user fee program, there is reason to expect that CDRH will be able to perform at expected levels in the coming years, particularly as the bolstered review teams and infrastructure take hold for greater effect.⁵⁹ Increased staff, professional development measures, and better device review infrastructure - all changes mandated by MDUFMA and already implemented by FDA - should contribute to more efficient and effective review processes going forward. CDRH's ability, however, to generate appropriate revenue from user fees to support its pursuit of ambitious performance goals will continue to remain a crucial aspect of the success of the user fee program, and may be the crux of the device center's performance in the coming year.

V. Conclusion

There is little doubt that the application of additional resources generated from user fees will allow the device center to more efficiently and effectively process medical device review submissions. However, the question of whether, or to what extent FDA can satisfy the 20 MDUFMA performance goals in effect beginning in fiscal year 2005 depends on the confluence of many factors. Fiscal 2005 is poised to be a defining year in terms of the potential success of the user fee program, particularly if the legislative "trigger fix" is not passed and performance goals go unmet. Despite what may be considered a slow start, FDA remains committed to the success of the program, and as such, there is good reason to expect that the MDUFMA user fee program can develop into an effective system of ensuring timely and effective review of important medical product submissions to the benefit of all stakeholders.

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- ³² Pub. L. No. 107-250. §738(a)(1)(B), 116 Stat. at 1592
- ³³ Pub. L. No. 107-250, §737(4)(D), 116 Stat. at 1590
- ³⁴ FDA, *supra* note 5
- ³⁵ Pub. L. No. 107-250, § 738(d)(2)(A)(i), 116 Stat. at 1595
- ³⁶ Pub. L. No. 107-250, § 738(b), 116 Stat. at 1593
- ³⁷ For more details on FDA standards of acceptability for premarket submissions, see <http://www.fda.gov/cdrh/ode/guidance/297.html> (last updated June 25, 2003)
- ³⁸ Pub. L. No. 107-250, §738(a)(1)(D)(i) and (ii). 116 Stat. at 1593
- ³⁹ A first action is FDA’s initial characterization of an application and includes a range of potential statuses, from approval to denial.
- ⁴⁰ FDA, *Guidance for Industry and FDA Staff: User Fees and Refunds for Premarket Approval Applications* 7, 8 (Nov.2003) available at

<http://www.fda.gov/cdrh/mdufma/guidance/1224.htm>
1 (last updated Nov. 21, 2003)

⁴¹ Pub. L. No. 107-250, §738(a)(1)(D)(iii), 116 Stat. at 1593

⁴² *Performance Goals for the Medical Device User Fee and Modernization Act of 2002*, Cong. Rec. S1150 (Nov. 19, 2002) available at

<http://www.fda.gov/cdrh/mdufma/pgoals.html> (last accessed December 2, 2004)

⁴³ Pub. L. No. 107-250, § 738(g), 116 Stat. at 1597

⁴⁴ For a complete list of performance goals mandated by MDUFMA, see

<http://www.fda.gov/cdrh/mdufma/pgoals.html> (last accessed December 2, 2004)

⁴⁵ Pub. L. No. 107-250, § 738(g), 116 Stat. at 1597

⁴⁶ Pub. L. No. 107-250, § 738(g)(1)(A)(ii)(I), 116 Stat. at 1597

⁴⁷ Pub. L. No. 107-250, § 738(g), 116 Stat. at 1597

⁴⁸ *FDA*, *supra* note 5

⁴⁹ *CDRH*, *supra* note 22

⁵⁰ Pub. L. No. 107-250, 116 Stat. 1588 (2002)

⁵¹ *MDUFMA Update: FDA Tackles Performance Goals, Premarket Review Funding*, The Gray Sheet: 2003 Year-In-Review

⁵² *Id.*

⁵³ All published guidance documents are available at <http://www.fda.gov/cdrh/mdufma/guidance/> (last updated Nov. 23, 2004)

⁵⁴ *Medical Device User Fees Accepted By Vendors; New Technology*, HOSPITALS MATERIALS MANAGEMENT (Jan. 1, 2004)

⁵⁵ *Supra* note 50

⁵⁶ *Improvements Needed for MDUFAMA to Meet Future Goals*, Devices & Diagnostics Letter (April 5, 2004).

⁵⁷ General Accounting Office, *Data to Measure the Timeliness of Reviews of Medical Device Applications are Limited*, Report to Congressional Committees, GAO-04-0122 (August 2004) available at <http://www.gao.gov/new.items/d041022.pdf> (last accessed Dec. 2, 2004)

⁵⁸ Notice: Establishment of Prescription Drug User Fee Rates for Fiscal Year 2005, 69 Fed. Reg. 46165 (Aug. 2, 2004) available at

<http://www.fda.gov/cder/pdufa/default.htm> (last updated Nov. 18, 2004)

⁵⁹ FDA, *MDUFMA First Quarter FY 04 Report (3/31/04)*, available at

<http://www.fda.gov/cdrh/mdufma/mdufmaq1fy2004.html> (last updated March 31, 2004)