

An hourglass-shaped graphic with a globe in the top bulb and another globe in the bottom bulb. The hourglass is light blue and has a dark blue cap at the top. The globe in the top bulb is dark blue, while the globe in the bottom bulb is light blue. The text is centered within the hourglass shape.

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February 2, 2009

Congressional Research Service

Report RL34571

Medical Device User Fees and User Fee Acts

Erin D. Williams, Domestic Social Policy Division

July 14, 2008

Abstract. This report provides an overview of FDA and the medical device review process. It then presents the legislative history of user fees. Next, it explains the basics of FDA's medical device user fee system, noting the way in which various provisions have evolved. Finally, it provides an overview of non-user fee issues addressed in the device user fee acts.

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CRS Report for Congress

Medical Device User Fees and User Fee Acts

July 14, 2008

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<http://wikileaks.org/wiki/CRS-RL34571>



Prepared for Members and
Committees of Congress

Medical Device User Fees and User Fee Acts

Summary

The Food and Drug Administration (FDA) is the agency responsible for ensuring the safety and effectiveness of medical devices. An establishment may not market a device in the United States without FDA's prior approval or clearance.

In 2002, Congress first granted FDA the authority to collect user fees from medical device establishments. The authority was granted to help reduce the time required for the agency to review and make decisions about marketing applications. Lengthy review times harmed establishments, which waited to market devices, and patients, who waited to use them. User fee law provides a revenue stream for the agency, and also requires it to set *performance goals* for rapid application review.

The authority to collect medical device user fees has been authorized in five-year increments, and will expire next on October 1, 2012. In 2002, it was first established in the Medical Device User Fee and Modernization Act (MDUFMA; P.L. 107-250). Before reauthorization, it was amended by the Medical Device Technical Corrections Act (P.L. 108-214) and the Medical Device User Fee Stabilization Act of 2005 (P.L. 109-43). It has been reauthorized once, in the Medical Device User Fee Amendments of 2007 (MDUFA 2007), enacted as Title II of the Food and Drug Administration Amendments Act of 2007 (H.R. 3580; P.L. 110-85).

Since medical device user fees were first collected in FY2003, they have comprised an increasing proportion of FDA's device budget. In FY2003, \$14.8 million of user fees comprised 6.8% of the budget. In FY2007 (the year of the most recent reauthorization), \$35.2 million of user fees comprised 13.2% of the budget.

Medical device user fees have raised a number of issues. These have prompted Congress to determine the following: which activities should require fees; how user fees can be kept from supplanting federal funding, or being diverted from device review (through *triggers*); which activities the agency should fund with user fees; and how to qualify as a small business. (Small businesses pay reduced fee amounts.)

In addition to addressing the above issues, medical device user fee legislation has served a secondary purpose as a moving vehicle that legislators could use to address a range of issues related to medical devices. For example, MDUFA 2007 included provisions about the extent to which FDA can delegate activities to third parties (inspections and the review of premarket notifications); establishment registration requirements (timing and electronic submission); a unique device identification system; reporting requirements for devices linked to serious injuries or deaths; and requirements that FDA and GAO conduct certain studies. MDUFMA included provisions about reprocessed single use devices and other topics.

This report provides an overview of FDA and the medical device review process. It then presents the legislative history of user fees. Next, it explains the basics of FDA's medical device user fee system, noting the way in which various provisions have evolved. Finally, it provides an overview of non-user fee issues addressed in the device user fee acts. This report will be updated as events warrant.

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Medical Device User Fees and User Fee Acts

Medical device user fees consist of congressionally authorized private money, which is paid by medical device establishments to the Food and Drug Administration (FDA). FDA is an agency within the Department of Health and Human Services (HHS). User fee funds are one of the two revenue streams available to FDA for carrying out its mission with respect to medical devices: to ensure devices' safety and effectiveness. The second revenue stream is direct appropriations from Congress.

Medical device establishments, to whom most regulations and fees apply, are often device manufacturers, but can also be domestic companies and importers who prepare and/or propagate devices. Establishments must obtain FDA approval or clearance before marketing their medical devices in the United States. They must continue to abide by FDA's requirements, including the payment of certain user fees, while their devices are on the market.

The authority to collect medical device user fees has been authorized in five-year increments. The same is true for the two other FDA user fee programs for prescription drugs and animal drugs.¹ The agency's authority to collect medical device user fees is set to expire on October 1, 2012.

Medical device user fees were first authorized in 2002. The Medical Device User Fee and Modernization Act (MDUFMA; P.L. 107-250) created the authorization. It inserted two new medical device user fee sections in the Federal Food, Drug and Cosmetic Act (FFDCA §§737-738; 21 USC Chapter 9). MDUFMA was amended twice by smaller laws before its user fee authorities were reauthorized. These two laws were the Medical Device Technical Corrections Act (MDTCA; P.L. 108-214) and the Medical Device User Fee Stabilization Act of 2005 (MDUFSA; P.L. 109-43).

In 2007, MDUFMA's user fee authorities were reauthorized just before their expiration. The amendments came in the form of the Medical Device User Fee Amendments of 2007 (MDUFA 2007), enacted as Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA; H.R. 3580; P.L. 110-85).²

¹ See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): Background and Issues for PDUFA IV Reauthorization*, by Susan Thaul, and CRS Report RL34459, *Reauthorization of the Animal Drug User Fee Act (ADUFA)*, by Sarah A. Lister.

² See CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*, by Erin D. Williams and Susan Thaul.

FDAAA was the most significant and sweeping piece of FDA legislation since the Food and Drug Administration Modernization Act (FDAMA; P.L. 105-115). FDAAA addressed topics ranging from food safety, to postmarket surveillance of drugs, to pediatric medical devices, to the formation of a nonprofit organization to assist FDA.

Two key factors converged to enable the passage of the broad legislation. The first was that significant FDA revenue streams would have been lost if its medical device and prescription drug user fees had not been reauthorized before their expiration at the end of FY2007. A failure to reauthorize the legislation would have cost the agency more than \$280 million in user fees over five years. Reauthorization legislation was characterized as “must pass,” providing a moving vehicle for Congress to address other concerns about FDA.

The second key factor leading to FDAAA was the emergence of a landscape of criticisms about the agency’s response to safety concerns raised about a range of products the agency regulates. Publicized examples included adverse events related to products ranging from prescription drugs such as Vioxx, to medical devices such as cardiac stents, to imported items such as heparin and pet foods, to human foods such as spinach. Congress was able to address many of these threats to public safety in FDAAA.

Debates about which non-user fee topics were to be addressed in FDAAA and how they should be addressed slowed the process of reauthorization of FDA’s authority to collect user fees. Those delays sparked concern that FDA would have to lay off some 2,000 employees due to the resulting funding shortfall, or at least issue legally required notices to the employees 60 days before such lay offs would have to occur.³ However, neither layoffs nor notices were ultimately necessary. FDAAA was signed into law on September 27, 2007 — four days before the user fee collection authorities would have expired.

Numerous topics of debate related to user fees have emerged over time. While many of these are related to the smaller details of the user fee program, three raise overarching policy issues for lawmakers. One concern is that the agency’s reliance on funds collected from the establishments that it regulates could possibly create a conflict of interest. A second is that a reliance on fees could lead appropriators to give the agency less federal funding than they otherwise would.⁴ A third is that the requirement that user fees only be expended on activities related to medical device approval drains resources needed for postmarket activities. Consideration of each of these issues will help to inform readers as they consider the details of the medical device user fee program described in this report.

³ See “Prescription Drugs: FDA Could Issue Layoff Notices Without Prescription Drug User Fee Act Reauthorization,” *Kaiser Daily Health Policy Report* (September 17, 2007), at [http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=47555].

⁴ See CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, by Judith A. Johnson, Donna V. Porter, Susan Thaul, and Erin D. Williams.

The remainder of this report contains the following information. The first section presents background information about FDA's regulation of medical devices. The second section contains details about the medical device user fee acts and related key documents. The third section describes the way in which medical device user fees currently function, and provides relevant background for the various user fee provisions. The final section of the report discusses the various non-user fee topics that have been introduced or addressed in medical device user fee acts.

Background: FDA and Medical Device Regulation

In order to understand the function and impact of medical device user fees, and related policy issues, a basic understanding of the way that FDA reviews and regulates devices is useful. This section presents the definition of a medical device, an overview of the device industry, an introduction to the medical device components at FDA, and a survey of the agency's user-fee relevant requirements for medical device establishments, both before and after products come to market.

Medical Devices and the Device Industry

The first step to understanding FDA's regulation of medical devices is to see how the agency defines the term. According to statute, a medical device is

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.⁵

According to this definition, a medical device can be anything from a tongue depressor to a home pregnancy test to a wheelchair to a pacemaker. Types of medical devices vary widely, as do their respective levels of complexity and risk. Therefore, device manufacturing requirements vary significantly as well.

In part due to the diversity of medical devices themselves, medical device establishments tend to have certain characteristics. These characteristics can be highlighted by comparing the device industry with the pharmaceutical industry. The device industry is more fragmented and smaller than the pharmaceutical industry, with estimated earnings of \$274 billion in 2007 compared with the drug industry's estimated \$712 billion.⁶ It is also dominated by smaller companies. These

⁵ FFDCAs 201(h); 21 U.S.C. 321(h).

⁶ "Industry Profile," *Standard and Poor's Industry Survey Healthcare: Pharmaceuticals* (continued...)

characteristics are important in discussions of user fees, particularly with regard to the way that fee amounts impact individual companies, and the effect that fees have on the development and review of new medical devices.

FDA Device Regulatory Structure

A brief structural overview of FDA provides background for understanding the way that FDA regulates medical devices, and for understanding the activities that require user fees. FDA has five regulatory centers, each focused on a particular type of product. The center within FDA primarily responsible for ensuring the safety and effectiveness of medical devices is the Center for Devices and Radiological Health (CDRH). One other center, the Center for Biologics Evaluation and Research (CBER), regulates some devices — specifically those associated with blood collection and processing procedures, as well as with cellular therapies (e.g., stem cell treatments). Jurisdiction of the centers' medical device review is governed by the FDA Intercenter Agreement between CBER and CDRH (October 31, 1991).⁷

Approval or Clearance of Medical Devices

Different types of applications to FDA trigger different user fees. These application types are highlighted in the following description of the way in which FDA classifies devices, and the mechanisms establishments can use to apply to market their devices.

CDRH categorizes medical devices according to their risk into one of three classes: Class I, II, and III. (See **Table 1**.) The risk a device poses, and the regulatory controls required, increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type in each class. Most Class I devices are exempt from Premarket Notification and require only registration with FDA before marketing; most Class II devices require Premarket Notification (a 510(k)⁸) before marketing; and most Class III devices require Premarket Approval (PMA). Device applications are reviewed by CBER under biological license applications (BLAs). Devices on the market under 510(k)s have been *cleared* by FDA, while those on the market under a PMA or BLA have been *approved* by FDA.

⁶ (...continued)

(April 24, 2008); “Industry Profile,” *Standard and Poor’s Industry Survey on Healthcare: Products and Supplies* (March 13, 2008).

⁷ FDA, “Devices Regulated by CBER” (updated March 15, 2007), at [<http://www.fda.gov/cber/dap/devlst.htm>].

⁸ 510(k), which is short hand for Premarket Notification, refers to the governing section of the FDCA.

Table 1. Medical Device Approval Basics

| Device Classification | Examples | Safety/Effectiveness Controls | Required Submission |
|------------------------------|--|--|---|
| Class I | elastic bandages, examination gloves, and hand-held surgical instruments | General Controls ^a | - <i>Registration only</i> unless 510(k) specifically required |
| Class II | powered wheelchairs, infusion pumps, and surgical drapes | General Controls & Special Controls ^b | - <i>510(k) clearance</i> unless exempt - <i>IDE possible</i> |
| Class III | heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators | General Controls & Premarket Approval | - <i>PMA approval</i> unless 510(k) specifically permitted - <i>IDE probable</i> |

- a. General controls include five elements: (1) establishment registration (use FDA Form 2891) of companies which are required to register under 21 CFR 807.20, such as manufacturers, distributors, repackagers and relabelers, and foreign firms; (2) medical device listing (use FDA Form 2892) with FDA of devices to be marketed; (3) manufacturing devices in accordance with Good Manufacturing Practices (GMPs) specified in 21 CFR 820; (4) labeling devices in accordance with labeling regulations in 21 CFR 801 or 809; and (5) submission of a premarket notification 510(k) before marketing a device. (Most Class I devices are exempt from the premarket notification requirements).
- b. Special controls may include special labeling requirements, mandatory and voluntary performance standards, and postmarket surveillance.

Of all device-related submissions, a PMA (or Panel Track Supplement, which is described below) is the most rigorous and time-consuming application process for manufacturers and review process for the FDA. A 510(k) is significantly less rigorous, and is much more common. Most PMAs and some 510(k)s require clinical trials,⁹ which are conducted with FDA permission via an investigational device exemption (IDE) that allows a device to be used in a clinical trial to gather information on its safety and effectiveness. The majority of medical devices that come to market do so with 510(k) clearance rather than PMA approval. (See **Table 2.**) Applications to FDA for PMAs, BLAs, and 510(k)s all require user fees.

⁹ For more information on the regulation and sharing of results from clinical trials, see CRS Report RL32832, *Clinical Trials Reporting and Publication*, by Erin D. Williams, and CRS Report RL32909, *Federal Protection for Human Research Subjects: An Analysis of the Common Rule and Its Interactions with FDA Regulations and the HIPAA Privacy Rule*, by Erin D. Williams.

Table 2. Premarket Approvals (PMAs), Panel-Track Supplements, and Premarket Notification (510(k)s), FY2003-FY2008 Cohorts

| Fiscal Year | PMAs and Panel-Track Supplements | 510(k)s ^a |
|-------------|----------------------------------|----------------------|
| FY2003 | 50 | 3,795 |
| FY2004 | 48 | 3,383 |
| FY2005 | 58 | 3,401 |
| FY2006 | 56 | 3,491 |
| FY2007 | 37 | 3,036 |
| FY2008 | 10 | 1,821 |

Source: FDA Office of Legislation. Counts include both CDRH and CBER workloads received through March 31, 2008.

- a. The receipt cohort is defined to exclude 510(k)s that were closed for any reason other than a decision to clear or not to clear a product under the 510(k) (e.g., when FDA finds that a 510(k) was not required). For this reason, some 510(k)s currently awaiting a decision may ultimately be excluded from the cohort.

Device user fees are also required with four types of submissions FDA may require to supplement a PMA when there are changes in safety and effectiveness data: Panel Track Supplements, 180-Day Supplements, Real Time Supplements, and 30-Day Notices. Panel Track Supplements are akin to second entire PMAs. They reflect new indications for use or significant changes in device design or performance, and require substantial clinical data. An artificial heart valve approved for use to replace the aortic valve, and proposed for use in the mitral valve, would require the submission of a Panel Track Supplement. 180-Day Supplements are submitted for significant changes to medical device components, materials, designs, specifications, software, labeling, or color additives. A proposed change in a blood glucose monitoring system from wired to wireless telemetry would require this type of submission. Real Time Supplements are submitted when there are minor changes to the design, software, sterilization or labeling of a device. A change in the storage temperature and expiration dating for an injectable gel would require this type of supplement. 30-Day Notices are submitted for modifications to manufacturing processes or methods, such as a change in the sterilization process.

One alternative to a PMA that FDA offers also requires a fee: the Product Development Protocol (PDP). A PDP is based on early consultation between the sponsor and the FDA, leading to a device development and testing plan acceptable to both parties. It aims to minimize the risk that the sponsor will unknowingly pursue — with the associated waste of capital and other resources — the development of a device that FDA will not approve.

One additional type of submission also requires a fee. It is a 513(g) request for classification information, so named because of the section of the FFDCa that

regulates it. 513(g)s enable requesters to obtain information from FDA regarding the regulatory status of their devices or products.

FDA Postmarket Activities

In addition to receiving FDA clearance or approval prior to marketing, device establishments must meet certain requirements once their products are on the market. Many notable examples of this do not have an associated fee. For example, FDA inspects establishments where medical devices that are marketed in the United States are manufactured. Inspections assess compliance with FDA's *quality system requirements* for ensuring *good manufacturing practices* and other applicable specifications.¹⁰ FDA also collects information about adverse events related to medical devices, and may request or require recalls of medical devices in certain circumstances. While no fee is associated with these functions, they are important to consumer protection, because they reflect the agency's efforts to help ensure that devices on the market meet required safety and effectiveness standards. In addition, they help to inform user-fee related policy discussions; the effect that user fees have on the agency's ability to conduct postmarket activities has been debated.

Two postmarket activities required of medical device establishments do have user fees associated with them. One is that establishments must register annually with FDA (*establishment registration*). The other is that establishments of certain class III devices must file periodic reports required by a PMA approval order (*periodic reporting*).

Medical Device User Fee Acts

Congress first authorized FDA to collect user fees from medical device manufacturers with the passage of MDUFMA in 2002. This was 20 years after a parallel authority had been granted for prescription drugs. As had been the case for drugs, the impetus behind authorizing user fees for medical devices was reducing the amount of time it took for FDA to make decisions about manufacturers' applications to market their products. The agency attributed the long review times to a shortage of funds to employ enough staff. The time taken in review affected patients, who waited for new products, and manufacturers, which waited to market the products. Manufacturers thus agreed to pay user fees (and Congress granted FDA the authority to collect them) so that FDA could hire more staff and decrease its review times. This section provides a historical overview of the laws Congress has passed related to medical device user fees: MDUFMA, MDTCA, MDUFSA, and MDUFA 2007. It also introduces two important related documents, the FDA Agreement and the Commitment Letter.

¹⁰ The regulations governing FDA's quality system requirements for ensuring good manufacturing practices can be found at 21 CFR 820.

MDUFMA

In the years prior to MDUFMA's 2002 enactment, FDA's resources for its devices and radiological health program had increased at a lower rate than its costs.¹¹ As stated in the House Report to H.R. 3580 (MDUFMA):

The medical device industry is growing rapidly. The complexity of medical device technology is increasing at an equally rapid pace. Unfortunately, FDA's device review program lacks the resources to keep up with the rapidly growing industry and changing technology. Because prompt approval and clearance of safe and effective medical devices is critical to improving public health, it is the sense of the Committee that adequate funding for the program is essential.¹²

In addition to issues raised by medical device review funding capabilities at FDA, prior to MDUFMA, concerns had also emerged regarding the reprocessing and re-use of medical devices that FDA had cleared or approved as *single use devices* (SUDs). Reprocessing means cleaning and sterilizing a device and verifying that it functions properly. Concerns about SUDs, funding, and the agency's capacity to inspect device establishments as frequently as required by law paved the way for congressional action in 2002.

In preparation for the enactment of MDUFMA, FDA officials met with industry leaders to agree upon mutually acceptable fee types, amounts, exceptions, and performance goals.¹³ The agreement specified that, in return for the additional resources provided by medical device user fees, FDA was expected to meet performance goals defined in a November 14, 2002, letter from the HHS Secretary to the Chairmen and Ranking Minority Members of the Committee on Health, Education, Labor and Pensions of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representatives.¹⁴

¹¹ FDA, "Medical Device User Fee and Modernization Act; Public Meeting," *Federal Register*, vol. 72, no. 74, p. 19528, (April 18, 2007) at [<http://frwebgate6.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=40432151607+2+1+0&WAIAction=retrieve>], (hereinafter, "Public Meeting").

¹² U.S. Congress, "House Committee on Energy and Commerce, Medical Device User Fee and Modernization Act of 2002," H.Rept. 107-728, report to accompany H.R. 3580, 107th Cong., 2nd sess., part 1 (Washington: GPO, 2002), p. 23.

¹³ This process was similar to the one used previously during the enactment and reauthorization of the user fee act for prescription drugs, the Prescription Drug User Fee Act (PDUFA). For further information on PDUFA, see CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): Background and Issues for PDUFA IV Reauthorization*, by Susan Thaul.

¹⁴ This letter is generally referred to as the 2002 "FDA Commitment Letter." See 148 Cong. Rec. S11549-01(2002).

MDUFMA was enacted in order to provide FDA “with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time, and to ensure that reprocessed medical devices are as safe and effective as original devices.”¹⁵ MDUFMA amended the FDCA to enact three significant provisions for medical devices: (1) it established user fees for premarket reviews of devices, (2) it allowed establishment inspections to be conducted by accredited persons (third parties), and (3) it instituted new regulatory requirements for reprocessed single-use devices.

Key MDUFMA Provisions:

- device user fees authorized through FY2007
- establishment inspections by third parties allowed
- reprocessed single-use devices regulated

MDUFMA enabled FDA to collect over \$133 million from medical device companies during the first five years of the program (FY2003-FY2007).

MDTCA

Prior to MDUFA 2007, MDUFMA was amended by two laws. The first of these was the Medical Device Technical Corrections Act (MDTCA, P.L. 108-214). It addressed three areas of MDUFMA.¹⁶ First, it removed certain barriers to the third-party inspection program. Second, it amended an electronic labeling provision to extend the circumstances in which electronic labeling could be used. Third, it delayed the implementation of a provision that required a device to “prominently and conspicuously” bear the name of its manufacturer.

MDUFSA

The second law that amended MDUFMA prior to its reauthorization was the Medical Device User Fee Stabilization Act of 2005 (MDUFSA, P.L. 109-43). It contained five primary measures. First, it lowered *trigger* amounts of direct appropriations required for the agency to be able to collect user fees. Triggers are discussed in more detail below. Second, it changed the method of setting user fee amounts, eliminating the inflation, workload, compensating, and final year adjustments of revenues used for setting fees. Third, it allowed the HHS Secretary to use unobligated carryover balances from fees collected in previous fiscal years. Fourth, it made it easier for companies to qualify as small businesses and pay reduced user fees. Fifth, it deemed as misbranded (and thus subject to FDCA penalties) any reprocessed SUD that did not identify the manufacturer, but allowed such information to be provided by a detachable label intended to be affixed to the medical record of a patient.

¹⁵ Medical Device User Fee and Modernization Act of 2002, H.Rept. 107-728 (October 7, 2002), p. 21.

¹⁶ For further information about MDTCA, see FDA, “Summary of the Medical Devices Technical Corrections Act (MDTCA),” (November 2004), at [<http://www.fda.gov/cdrh/mdufma/mdtcasummary.html>].

FDA Agreement

In preparation for MDUFA 2007, FDA and industry representatives met, as they had prior to MDUFMA, and discussed many of the above factors. They negotiated an agreement that they submitted to Congress (“FDA Agreement”).¹⁷ The Agreement contained legislative proposals as well as arguments to support those proposals. Pursuant to MDUFMA (§105), on April 30, 2007, FDA held a public meeting about the FDA Agreement. Attendees expressed general satisfaction with its terms. Congress incorporated most of the recommendations into MDUFA 2007.

MDUFA 2007

Congress addressed many issues in MDUFA 2007. Subtitle A reauthorized and amended FDA’s authority to collect medical device related user fees. Subtitle B amended certain aspects of medical device regulation.

The primary issue addressed in MDUFA 2007 was the reauthorization of FDA’s authority to collect user fees from medical device manufacturers. FDA’s authority to collect these fees would have expired on October 1, 2007, if Congress had not acted.

MDUFA 2007 extended the authority through October 1, 2012. The pending expiration of this authority was one of the primary drivers of MDUFA 2007 and FDAAA.

Key MDUFA 2007 Provisions:

- device user fees authorized through FY2012
- new fee types added
- fee amounts reduced
- qualification as a small business made easier

MDUFA addressed several other issues as well. One was to generate an increased and more stable user fee revenue stream for the agency with the addition of two new types of fees. MDUFMA had only authorized FDA to collect various *application fees*, which were payable upon submission of an application of FDA. According to FDA, there were fluctuations in the number of applications submitted from year to year, and fee revenues repeatedly fell short of expectations.¹⁸ In order to address this issue, MDUFA 2007 added *establishment fees* (paid annually by each device establishment registered with FDA) and *product fees* (paid annually for each class III device for which periodic reporting was required pursuant to the PMA). MDUFA 2007 also added two new application fees and lowered the existing application fee amounts. The law was drafted to increase the total revenue generated by user fees, offsetting the lowered application fee amounts with revenue from the new fees.

Another issue addressed by MDUFA 2007 was that domestic and foreign companies had expressed frustration with the difficulty in qualifying for small business user fee discounts. This led Congress to enact amendments designed to ease that process.

¹⁷ Public Meeting.

¹⁸ Public Meeting.

Commitment Letter

As was the case for MDUFMA, the requirements of MDUFA 2007 are supplemented by a “Commitment Letter” from the HHS Secretary, this one dated September 27, 2007.¹⁹ The contents of the letter are incorporated into the law by reference.²⁰ The requirements of the law, as supplemented by the Commitment Letter, are summarized below.

Medical Device User Fees

FDA has the authority to collect three types of medical device user fees:

- application fees (paid each time an application is submitted),
- establishment fees (paid annually by all non-exempt establishments),
and
- product fees (paid annually for each qualifying Class III device).

The authority to collect these fees will expire on October 1, 2012. This section presents the current law with respect to medical device user fees. Subsections describe the conditions under which FDA may collect user fees (triggers), how user fees relate to the medical device budget, which activities require and are exempt from fees, and the fee collection offset. They also describe the ways that fees may be used by FDA, fee-associated performance goals, required quarterly performance reports, the effect of fees on postmarket activities, and required annual reports to Congress.

This section presents current user fee law for each topic mentioned above. (For information on the history of each of the provisions in law, see **Appendix B**). Relevant citations to sections of MDUFA 2007 and MDUFMA are included parenthetically in the text, while those to the FFDCA and United States Code (USC) are included in footnotes.

Triggers

The authority to collect user fees is subject to two statutory triggers. If either trigger is not satisfied for a given fiscal year, FDA loses the authority to collect user fees. The first trigger places a requirement on Congress. It prohibits FDA from collecting fees if direct congressional appropriations to FDA for salaries and expenses related to devices and radiological health fall below a certain threshold. The trigger requires that, each fiscal year, FDA’s salaries and expenses appropriation line for Devices and Radiological Health, exclusive of user fees, not be more than 1% below \$205,720,000 multiplied by an inflation adjustment factor.²¹ For FY2007, the

¹⁹ “Commitment Letter” from Michael O. Leavitt to Edward M. Kennedy, September 27, 2007, at [<http://www.fda.gov/cdrh/mdufma/commitmentletter.pdf>].

²⁰ FDAAA §201(c).

²¹ FFDCA 738(g); 21 USC 379j(g).

year that user fees were last reauthorized, this translated into a minimum requirement of \$229,334,000.²²

The second trigger places a requirement on the HHS Secretary. It requires that fees only be collected and available to defray increases in the costs of the resources allocated for the process for the review of device applications. This requirement is considered to have been met each fiscal year if the costs funded by appropriations and allocated for the process for the review of device applications do not fall below specified levels.²³

User Fees and the Device Review Budget

The amount of user fees collected has increased each year since collection was first authorized. MDUFMA fees comprised less than 7% of FDA's program level device review budget in FY2003, and over 13% in FY2007. The amounts are projected to continue to increase each year until the authorization expires in FY2012. In addition, almost every year since user fees were first introduced, they have constituted an increasing proportion of FDA's device-related budget. (See **Table 3.**) Over the period of FY2003 to FY2007, the amount of user fees more than doubled, while the amount of direct appropriations increased by about a quarter. In FY2007, device user fees translated into 208 FTEs, or 15.6% of the FTEs in the device review process. (See **Table 4.**)

For FY2008, an increase of 37.6% in user fees is authorized above the FY2007 level. For each subsequent year through FY2012, fee amounts are authorized to increase by 8.5% per year, generating a total of \$287 million for FDA over five years.²⁴

²² FDA Office of Management, "Funding For MDUFMA and ADUFA Triggers," FY2007 Budget Formulation and Presentation, (February 22, 2006), at [<http://www.fda.gov/oc/oms/ofm/budget/2007/HTML/7UserFeeTriggersBCPPOM.htm>].

²³ FFDCA 738(h)(2)(B); 21 USC 379j(h)(2)(B).

²⁴ FFDCA 738(h)(3); 21 USC 379j(h)(3).

Table 3. Medical Device Review Process Funding: Total Program Level and User Fee Funding, FY2003-FY2012
(dollars in thousands)

| Fiscal Year | Total Program Level | Medical Device User Fees | User Fee/ Total |
|-------------------|---------------------|--------------------------|-----------------|
| FY2003 Actual | \$217,285 | \$14,838 | 6.8% |
| FY2004 Actual | \$179,245 | \$23,875 | 13.3% |
| FY2005 Actual | \$244,282 | \$27,161 | 11.1% |
| FY2006 Actual | \$255,041 | \$32,069 | 12.6% |
| FY2007 Actual | \$267,543 | \$35,202 | 13.2% |
| FY2008 Enacted | \$283,777 | \$48,431 | 17.1% |
| FY2009 Estimate | \$290,921 | \$52,547 | 18.1% |
| FY2010 Authorized | not available | \$57,014 | — |
| FY2011 Authorized | not available | \$61,860 | — |
| FY2012 Authorized | not available | \$67,118 | — |

Sources: *FY 2003-FY2009:* Food and Drug Administration tables for FY2005-FY2009, “ALL PURPOSE TABLE — Total Program Level,” at [<http://www.fda.gov/oc/oms/ofm/budget/documentation.htm>]; *FY2010-FY2012:* MDUFA 2007.

Table 4. Full Time Equivalents (FTEs) in the Medical Device Review Process, FY2003-FY2009

| Fiscal Year | Total Device Review FTEs | Device User Fee Funded FTEs | Device User Fee Funded/Total |
|------------------------|--------------------------|-----------------------------|------------------------------|
| FY2003 Actual | 1,485 | 33 | 2.2% |
| FY2004 Actual | 1,061 | 137 | 12.9% |
| FY2005 Actual | 1,516 | 153 | 10.1% |
| FY2006 Actual | 1,498 | 184 | 12.2% |
| FY2007 Actual | 1,544 | 208 | 15.6% |
| FY2008 Enacted | 1,546 | 208 | 15.5% |
| FY2009 Estimate | 1,536 | 208 | 15.7% |

Source: Food and Drug Administration tables for FY2005-FY2009, “ALL PURPOSE TABLE — Total Program Level,” at [<http://www.fda.gov/oc/oms/ofm/budget/documentation.htm>].

Activities Requiring Fees

Device establishments must pay fees when they submit certain types of applications to FDA for product clearance or approval, and must also pay two types

of annual fees.²⁵ (See **Table 5**.) The annual fees are an establishment registration fee (paid once each year by each manufacturer) and product fees (paid for each Class III device for which the PMA requires periodic reports to be filed). The annual fees are projected to generate about 50% of the total device fee revenue from FY2008-FY2012.²⁶

The amount of each type of user fee, other than the establishment fee, is set as a percentage of the PMA fee,²⁷ also called the *base fee*. The law prescribes both the base fee amount for each fiscal year, and also the percentage of the base fee that constitutes most other fees. For example, a 30-day notice fee is equal to 1.6% of the base fee.

As mentioned under the previous heading, the law raises the base fee (the PMA fee) annually by 8.5% per year from FY2008 to FY2012. (See **Table 5**.) FDA asserts that this annual increase will ensure that fee revenues contribute their expected share to total program costs, and will provide industry with stability and predictability in the fee revenues it would expect to pay.²⁸ During the course of MDUFMA, from FY2003-FY2007, the rate of increase of the base fee (and thus the amounts of the contingent fees) slowed. It increased 34% between FY2003 and FY2004, and 8% between FY2006 and FY2006. (See **Table 10** in **Appendix B** for MDUFMA Base Fee Amounts.)

Unlike the other fees, the amount of the establishment fee (also known as the *establishment registration fee*) is set in its own section of the law.²⁹ Like the other fees, it is authorized to rise 8.5% per year from FY2008-FY2012. (Earlier statistics do not exist, because the fee was first authorized for FY2008). In addition to the base fee increases, in one circumstance, the HHS Secretary has the authority to increase the fee amount of the newly created establishment fee up to an additional 8.5% (over the annual 8.5% increase) in FY2010. The HHS Secretary may do this if fewer than 12,250 establishments pay the fee in FY2009. This measure is designed to ensure that the fees collected from this source total 45% of total fee revenues, ensuring that FDA has a stable funding base from user fees.

²⁵ FFDCA 738(a); 21 USC 279j(a).

²⁶ Public Meeting.

²⁷ A PMA is the most involved type of application that a device manufacturer could make to FDA (FFDCA § 738(a)(2)(A)). For more information, see CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams.

²⁸ Public Meeting.

²⁹ FFDCA 738(a)(3); 21 USC 379j(a)(3).

Table 5. MDUFMA/MDUFA 2007 Fee Schedule, FY2007-FY2012

| Fees Structure | MDUFMA | MDUFA 2007 | | | | |
|---|-----------|------------|-----------|-----------|-----------|-----------|
| | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
| Application Fees | | | | | | |
| PMA/BLA/PDP (i.e., <i>base fee</i>) | \$281,600 | \$185,000 | \$200,725 | \$217,787 | \$236,298 | \$256,384 |
| Small Business ^a | \$107,008 | \$46,250 | \$50,181 | \$54,447 | \$59,075 | \$64,096 |
| Panel Track Supplements | \$281,600 | \$138,750 | \$150,544 | \$163,340 | \$177,224 | \$192,288 |
| Small Business ^a | \$107,008 | \$34,688 | \$37,636 | \$40,835 | \$44,306 | \$48,072 |
| 180-Day Supplements | \$60,544 | \$27,750 | \$30,109 | \$32,668 | \$35,445 | \$38,458 |
| Small Business ^a | \$23,007 | \$6,938 | \$7,527 | \$8,167 | \$8,861 | \$9,614 |
| Real Time Supplements | \$20,275 | \$12,950 | \$14,051 | \$15,245 | \$16,541 | \$17,947 |
| Small Business ^a | \$7,705 | \$3,237 | \$3,512 | \$3,810 | \$4,134 | \$4,485 |
| 510(k) | \$4,158 | \$3,404 | \$3,693 | \$4,007 | \$4,348 | \$4,717 |
| Small Business ^a | \$3,326 | \$1,702 | \$1,847 | \$2,004 | \$2,174 | \$2,359 |
| 30-Day Notice | | \$2,960 | \$3,212 | \$3,485 | \$3,781 | \$4,102 |
| Small Business ^a | | \$1,480 | \$1,606 | \$1,742 | \$1,890 | \$2,051 |
| 513(g) | | \$2,498 | \$2,710 | \$2,940 | \$3,190 | \$3,461 |
| Small Business ^a | | \$1,249 | \$1,355 | \$1,470 | \$1,595 | \$1,731 |
| Product Fee | | | | | | |
| Annual Fee for Periodic Report. | | \$6,475 | \$7,025 | \$7,623 | \$8,270 | \$8,973 |
| Small Business ^a | | \$1,619 | \$1,756 | \$1,906 | \$2,068 | \$2,243 |
| Establishment Fee | | | | | | |
| Establishment Registration | | \$1,706 | \$1,851 | \$2,008 | \$2,179 | \$2,364 |

Source: FDA, "Proposed Industry User Fee Schedule for MDUFA 2007," *Center for Devices and Radiological Health website*, updated April 16, 2007, at [<http://www.fda.gov/cdrh/mdufma/mdufmai-comparison.html>].

- a. Small Business indicates the reduced small business fee associated with whatever item is listed above. (For more on the small business fee reduction, see the small business subsection below.)

Fee-Collection Offset

It is possible that in some years, the amount of fees collected will exceed the amount that FDA is authorized to collect. In that circumstance, for the four-year period of FY2008 through FY2011, FDA may collect fees that exceed the authorized amount. A reduction is to be made in fees in FY2012 only if the total amount collected in the four-year period exceeds the total amount authorized for the same period.³⁰ According to the FDA Agreement, this aggregation over four years will provide for greater financial stability for FDA than treating each year in isolation.

Fee Exceptions, Reductions, Refunds

Certain types of devices, sponsors, and manufacturers are exempt from certain fees, and small businesses pay a reduced rate.³¹ These fee reductions, exemptions, and refunds are explained below.

Humanitarian Use Devices (HUDs). HUD applications are exempt from user fees other than establishment fees.³² An HUD is a device that is intended to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States per year. A device establishment's research and development costs could exceed its market returns for products to address diseases or conditions affecting small patient populations. HUD law provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations. A qualifying manufacturer may submit a humanitarian device exemption (HDE) application, which is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. Once on the market, certain follow-up measures related to effectiveness apply.

Devices Intended for Pediatric Use. In order to encourage the development of devices for use with children, any application for a device intended solely for pediatric use is exempt from fees other than establishment fees. If an applicant obtains an exemption under this provision, and later submits a supplement for adult use, that supplement is subject to the fee then in effect for an original PMA.

Applications from Federal or State Government Entities. Any application from a state or federal government entity is exempt from fees for a premarket application, premarket report, supplement, premarket notification submission, or establishment registration unless the device is to be distributed commercially. Indian tribes are exempted from having to pay establishment registration fees, unless the device is to be distributed commercially.

³⁰ FFDCA 738(h)(4); 21 USC 379j(h)(4).

³¹ Unless otherwise noted with an alternate citation, all exceptions listed in this section can be found at FFDCA 738(a)(2)(B); 21 USC 379j(a)(2)(b).

³² FFDCA 520(m); 21 USC 360j(m).

Further Manufacturing. In order to avoid the charging of multiple fees for a device that has multiple manufactured components, any application for a product licenced exclusively for further manufacturing use, is exempt from fees other than establishment fees.

Premarket Notification by Third Parties. Under authority created by FDAMA, FDA accredits third parties, authorizing them to conduct the primary review of 510(k)s for eligible devices.³³ The purpose of the program is to improve the efficiency and timeliness of FDA's 510(k) process, the process by which most medical devices receive marketing clearance in the United States. No FDA fee is assessed for premarket notification (510(k)) submissions reviewed by accredited third parties, although the third parties may themselves charge a fee for their services.

Small Businesses. Small businesses — those with gross receipts below a certain amount — pay reduced user fees and have some fees waived altogether.³⁴ These fee reductions and exemptions are important, because the majority of device establishments are small businesses.³⁵ According to the Government Accountability Office (GAO), the vast majority of companies that paid medical device user fees in 2006 qualified as small businesses:

Of the 697 companies that qualified as small businesses under the MDUFMA user fee program in fiscal year 2006, 656, or about 95%, had revenues at or below \$30 million — the threshold for small business qualification originally set by MDUFMA in 2002. Of the 41 companies that had revenues above \$30 million but at or below the current threshold of \$100 million, 35 had revenues above \$30 million but at or below \$70 million. Of the 697 companies that qualified as small businesses in fiscal year 2006, two-thirds submitted at least one device application subject to user fees during that year. These companies were responsible for about 20% of the approximately 4,500 device applications subject to user fees that were submitted to FDA in fiscal year 2006.³⁶

An establishment is considered to be a small business if it has annual gross sales or receipts of \$30 million or less. Proof of receipts may consist of IRS tax documents or qualifying documentation from a foreign government. Small businesses are exempt from fees for their first PMA, and pay at a rate of 25% of most other user fees, and 50% of premarket notification fees.³⁷ Small businesses must pay the full amount of the establishment fees. (See **Table 5**.)

Modular PMA Refunds. Manufacturers may choose to submit to FDA the large amount of information required in a PMA in sections, over time, in a *modular*

³³ FDCA 523(c); 21 USC 360m(c).

³⁴ FDCA 738(d),(e); 21 USC 379j(d),(e).

³⁵ Public Meeting.

³⁶ Government Accountability Office, "Food and Drug Administration: Revenue Information on Certain Companies Participating in the Medical Device User Fee Program," GAO-07-571R (March 30, 2007), at [<http://www.gao.gov/new.items/d07571r.pdf>].

³⁷ FDCA 738(d); 21 USC 379j(d).

PMA. In the event that a manufacturer chooses to withdraw a modular application before FDA takes its first action on the application or before all of the parts have been submitted, the HHS Secretary may make a partial refund of the filing fee.³⁸

Use of Fees

There are two different provisions that describe how FDA may use the device fees it collects. Both suggest that FDA may expend user fees on premarket approval activities, and not on postmarket surveillance. One provision was created by MDUFMA. It states that fees “shall only be collected and available to defray increases in the costs of the resources allocated for the *process for the review of device applications*.”³⁹ The law specifies the elements of the “*process for the review of device applications*.”⁴⁰ (See **Table 6**.) They focus solely on activities involved in premarket approval. The one partial exception to this rule is the inclusion of the evaluation of postmarket studies that are required as a condition of approval.

MDUFA 2007 did not amend the above provision. However, §201(c) did include the statement in its findings that fees would “be dedicated toward expediting the process for the review of device applications *and for assuring the safety and effectiveness of devices*.”⁴¹ The law specifies that fees are to be used to support FDA in achieving the performance goals identified in the Commitment Letter. While it is conceivable that assuring the safety and effectiveness of devices could be interpreted to encompass postmarket surveillance, the Commitment Letter lists only premarket activities. MDUFMA (§101) contained similar specifications in its findings.

³⁸ FFDCA 738(a)(2)(D); 21 USC 379j(a)(2)(D).

³⁹ Emphasis added. FFDCA 738(h)(2)(A)(ii); 21 USC 379j(h)(2)(A)(ii).

⁴⁰ Emphasis added. FFDCA 737(5); 21 USC 379i(5).

⁴¹ Emphasis added. 21 USC 379i note.

Table 6. The Process for the Review of Device Applications

The USC defines the process for the review of device applications as the following:

- premarket reviews;
 - premarket inspections;
 - monitoring of research relating to premarket reviews;
 - review of *investigational new drug applications* (INDs) and *investigational device exemptions* (IDEs);
 - monitoring of research conducted to develop INDs or IDEs;
 - development of guidance, policy documents, and regulations to improve the process for the review of device applications;
 - development of test methods and standards applicable to premarket reviews;
 - technical assistance to applicants;
 - initial classification or reclassification of a device;
 - actions required to call for PMAs for Class III devices marketed before the Medical Device Amendments of 1976 (P.L. 94-295);
 - evaluation of postmarket studies required as a condition of approval; and
 - compiling, developing, and reviewing information concerning devices subject to premarket review to identify safety and effectiveness issues.
-

Source: 21 USC 379i(5); FFDCA 737(5).

Performance Goals

In addition to enabling the continued collection of user fees, user fee law requires FDA to meet new performance goals, which are articulated in the Commitment Letter.⁴² These performance goals set general timetables for certain types of activities (such as PMA reviews), but allow for some flexibility that may be prudent, given that different types of PMAs and other applications may vary in complexity. Therefore, performance goals generally state that, for a certain percentage of applications, FDA will complete a particular type of activity within a given time period. (See **Table 7**.)

In addition to the specific time-related goals presented in **Table 7**, the Commitment Letter also articulates several other goals. Four of these are related directly to the review process. One states that FDA will, at a minimum, maintain its current performance for processes for which quantitative goals were not identified (such as IDEs and 30-Day notices). Two others state that FDA will continue to incorporate an interactive review process for informal communication between FDA and sponsors to facilitate accurate and timely application reviews, and will make every effort to schedule both informal and formal meetings before and during the review process. In a fourth goal, the agency agrees to apply user fee revenue to support device reviewer training, as resources permit.

⁴² FFDCA 738(g); 21 USC 379j(g).

The Commitment Letter contains several other goals as well. Three relating to guidance documents state that FDA will update, or issue to the extent possible, guidance documents in accordance with the goals stated in the Commitment Letter, and will develop a guidance document regarding imaging devices with contrast agents or radiopharmaceuticals. In another, FDA agrees to facilitate the development of in vitro diagnostic devices (laboratory tests) by exploring ways to clarify the regulatory requirements and reduce the regulatory burden.

Performance Goal-Setting Process

FDA will be required to work with various stakeholders in order to develop performance goals and plans for meeting those goals in preparation for user fee reauthorization in 2012.⁴³ FDA will be required to consult with an array of governmental, professional, and consumer groups; publish its recommendations in the *Federal Register*; provide a public comment period; and hold a public meeting. In addition, the recommendations will have to be revised upon consideration of public comments, and transmitted to Congress not later than January 15, 2012.

Quarterly Performance Reports

The Commitment Letter states that FDA will report quarterly its progress toward meeting the quantitative performance goals. In addition, for all submission types, FDA will track total time (time with FDA plus time with the company) from receipt or filing to final decision (approval, denial, substantial equivalence [SE], or nonsubstantial equivalence [NSE]). FDA will also provide, on an annual basis, de-identified review performance data for the branch (section of reviewers grouped by subject-matter) with the shortest average review times and the branch with the longest average review times for 510(k)s, 180-day supplements, and real-time supplements.

⁴³ FFDCA 738A(b); 21 USC 738A(b).

Table 7. Comparison of Performance Goals in MDUFMA and MDUFA 2007

| MDUFMA | MDUFA 2007 |
|---|---|
| PMA and Panel Track Supplements | |
| 50% of PMAs and panel track PMA supplements in 180 days | 60% of PMAs and panel track PMA supplements in 180 days |
| 90% of PMAs, panel track supplements, premarket reports in 320 days | 90% of PMAs and panel track supplements in 295 days |
| N/A | 50% of expedited PMAs and expedited panel track PMA supplements in 180 days |
| 90% of expedited PMAs in 300 days | 90% of expedited PMAs and expedited panel track PMA supplements in 280 days |
| Modular PMA | |
| N/A | 75% of PMA modules in 90 days |
| N/A | 90% of PMA modules in 120 days |
| 510(k)s | |
| 80% of 510(k)s in 90 days | 90% of 510(k)s in 90 days |
| N/A | 98% of 510(k)s in 150 days |
| 180-Day PMA Supplements | |
| 90% of 180-Day PMA supplements in 180 days | 85% of 180-Day PMA supplements in 180 days |
| | 95% of 180-Day PMA supplements in 210 days |
| Real-Time PMA Supplements | |
| N/A | 80% of Real-Time PMA Supplements in 60 days |
| | 90% of Real-Time PMA Supplements in 90 days |
| Biological License Applications | |
| 90% of BLAs in 10 months | Same as MDUFMA |
| 90% of BLA supplements in 10 months | |
| 90% of BLA resubmissions and BLA supplement resubmissions in two months | |

Source: FDA, "Comparison of Quantitative Decision Goals in MDUFMA I and II," CDRH website, updated April 16, 2007, at [<http://www.fda.gov/cdrh/mdufma/mdufmaii-comparison.html>].

Postmarket Safety

While FDA may not generally use medical device user fees to fund postmarket surveillance or safety activities, MDUFA 2007 (§212(h)) did separately authorize appropriations for postmarket safety information.⁴⁴ (See **Table 8.**)

Table 8. Appropriations Authorized for Postmarket Safety Information, FY2008-FY2012

| FY2008 | FY2009 | FY2010 | FY2011 | FY2012 |
|-------------|-------------|-------------|-------------|-------------|
| \$7,100,000 | \$7,455,000 | \$7,827,750 | \$8,219,138 | \$8,630,094 |

In preparation for MDUFA 2007, questions had been raised about the effect of MDUFMA on postmarket activities. According to FDA, MDUFMA focused on premarket review activities, largely limiting FDA's use of MDUFMA funds to this area, and focusing all performance goals on it as well.

Measuring the impact of user fees on enforcement activities is not a straightforward endeavor, and is beyond the scope of this report. For example, while one set of metrics (the number of CRDH warning letters issued each year since FY2000) shows that a decrease in the number of letters coincides with the start of MDUFMA, coincidence in time does not necessarily prove cause and effect. As is shown in **Table 9**, some of the recent decline in warning letters is due to a change in policy related to the Mammography Quality Standards Act (MQSA, P.L. 102-539).⁴⁵

Table 9. CDRH Warning Letters Issued in Total and Under the MQSA, FY2000-FY2008

| Fiscal Year | Non-MQSA | MQSA | Total |
|---------------------|----------|------|-------|
| FY2000 | 191 | 337 | 528 |
| FY2001 | 105 | 393 | 498 |
| FY2002 | 75 | 206 | 285 |
| FY2003 | 121 | 84 | 205 |
| FY2004 | 193 | 5 | 198 |
| FY2005 | 177 | 5 | 182 |
| FY2006 | 149 | 5 | 154 |
| FY2007 | 146 | 10 | 158 |
| FY2008 ^a | 62 | 1 | 63 |

Source: FDA Office of Legislation.

a. Partial year, through March 31, 2008.

⁴⁴ FFDCA 738(h)(3); 21 USC 379j(h)(3).

⁴⁵ For more information about CDRH enforcement statistics, see the CDRH Charts in FDA Office of Enforcement, Office of Regulatory Affairs, "The Enforcement Story," (FY2006), at [http://www.fda.gov/ora/about/enf_story/ch2/cdrh_charts.pdf].

Annual Reports to Congress

MDUFA 2007 (§213) requires the Secretary to submit annual fiscal and performance reports for FY2008 through FY2012 to the Senate Committee on Health, Education, Labor and Pensions, and the House Committee on Energy and Commerce.⁴⁶

Fiscal reports are to address the implementation of FDA's authority to collect medical device user fees, as well as FDA's use of the fees. Performance reports are to address FDA's progress toward and future plans for achieving the fee-related performance goals identified in the Commitment Letter. Performance reports are to include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications, supplements, and premarket notifications in the cohort.

Non-User Fee Provisions Regarding the Regulation of Medical Devices Established in User Fee Acts

In addition to reauthorizing the collection of user fees, MDUFMA and MDUFA 2007 each amended various aspects of the regulation of medical devices. Some topics were addressed by both acts. Others were addressed only in one. This section provides information about the non-user fee topics addressed in MDUFA 2007, and a listing of such topics addressed only in MDUFMA.

Non-user Fee Topics in MDUFA 2007

The non-user fee related topics in MDUFA 2007 were included in its Subtitle B. Some of these were also addressed in MDUFMA. Topics include third-party review of premarket notification, required registration and filings, a unique device identification system, reporting for devices linked to serious injuries or death, inspections by accredited persons, and several reports required from government agencies. The current state of the law with respect to each of these items is summarized below, highlighting the amendments made by MDUFA 2007.

Third-Party Review of Premarket Notification. Under the initial authority of FDAMA, the HHS Secretary has been authorized to accredit non-FDA employees to review applications for Class I and certain Class II devices.⁴⁷ This authority, as reauthorized in MDUFA 2007 (§221), is set to expire at the end of FY2012. According to FDA, the purpose of the accredited third-party (ATP) program is to improve the efficiency and timeliness of FDA's 510(k) process, the process by which most medical devices receive marketing clearance in the United States.

⁴⁶ FFDCA 738A; 21 USC 379j-1.

⁴⁷ FFDCA 523 (c); 21 USC 360m(c).

Under the program, persons may elect to submit a 510(k) to an ATP rather than directly to FDA. The ATP then conducts the primary review of the 510(k), and forwards its review, recommendation, and the 510(k) to FDA. By law, FDA must issue a final determination within 30 days after receiving the recommendation of an ATP. Submissions reviewed by ATPs are not subject to FDA user fees, though the ATP may charge its own fee. For 510(k)s submitted during FY2005, 510(k)s reviewed by Accredited Third Parties (ATPs) received FDA marketing clearance in an average of 81 days after initial receipt by the ATP — 14% faster than comparable 510(k)s reviewed entirely by FDA (94 days).⁴⁸

Required Registrations and Filings. In addition to registering annually with FDA, medical device establishments are required to provide the HHS Secretary a list of devices on which they perform specific functions (such as marketing or manufacturing).⁴⁹ MDUFA 2007 (§§222-223) restricts the list and establishment registration periods from October 1 to December 31 of each year, and reduces the list requirement from twice to once per year. MDUFA 2007 (§224) requires these registrations and listings to be submitted electronically, unless the HHS Secretary grants a waiver.⁵⁰

Unique Device Identification System. The HHS Secretary is required by MDUFA 2007 (§226) to promulgate regulations establishing a unique identification system for medical devices.⁵¹ The law contains no associated deadline. Such a system for medical devices might be used to help reduce medical errors, facilitate recalls, identify incompatibility with other devices or potential allergic reactions, improve inventory control, improve reimbursement, and reduce product counterfeiting.⁵² Since 2004, FDA has required bar code labeling for drugs.

Prior to the passage of MDUFA 2007, the medical device identification encompassed four disparate elements.⁵³ One was the use of the universal product number (UPN), devised by the Department of Defense to streamline purchasing operations. A second was the use of a product data utility (PDU) to maintain accurate product data for electronic data interchange. A third was the use of auto-identification technologies, such as bar coding, that allow distributors and purchasers to electronically read UPNs or other identification information. And a fourth was the use of identification systems in some hospitals that can read UPNs and capture data or link UPNs to a PDU database. These types of medical device identification were quite disparate and had penetrated the market to widely varying

⁴⁸ FDA Office of Legislation. Numbers are the most recent available as of publication.

⁴⁹ FFDCA 510(b), (i)(1), (j)(2); 21 USC 360(b), (i)(1), (j)(2).

⁵⁰ FFDCA 510(p); 21 USC 360(p).

⁵¹ FFDCA 519(f); 21 USC 360i(f).

⁵² *ERG Final Report: Unique Identification for Medical Devices*, prepared for FDA by Eastern Research Group, Inc., March 22, 2006, at [<http://www.fda.gov/cdrh/ocd/udi/erg-report.html>].

⁵³ *Id.*

degrees. Only a few hospitals were making use of identification systems in their operations.

Reporting for Devices Linked to Serious Injuries or Death. When MDUFA 2007 was passed, the law required the HHS Secretary to promulgate regulations requiring establishments to report to the Secretary if they became aware of information reasonably suggesting that their marketed device had or might have caused a serious injury or death.⁵⁴ MDUFA 2007 (§227) specifies the reporting requirements for such devices that have malfunctioned.

Accredited Third-Party Inspections. Accredited third-party inspections were introduced in MDUFMA (as amended by MDTCA) with the goal of reducing the burden on FDA inspectors by enabling FDA-accredited persons (third parties) to conduct certain inspections on FDA's behalf. Inspections play an important role at FDA. According to GAO:

During quality system inspections, FDA investigators examine manufacturing controls, processes, and records. These inspections are FDA's primary means of assuring that the safety and effectiveness of medical devices are not jeopardized by poor manufacturing practices.⁵⁵

MDUFA 2007 (§228) amended the accredited third-party inspection requirements, as described further below. According to the FDA Agreement, the amendments are aimed at increasing the quantity of useful information FDA has about the compliance status of medical devices marketed in the United States, and permitting FDA to focus its resources on inspecting those firms and products posing the greatest risk to public health.

FDA is required, by statute, to inspect certain domestic establishments where medical devices are manufactured at least once every two years.⁵⁶ According to a 2007 GAO report, FDA has not been meeting this requirement.⁵⁷ Instead, five or six years sometimes pass between FDA inspections at any one establishment.

FDA accredited the first third-party on March 11, 2004. As of May 31, 2008, 23 organizations had applied to conduct independent third-party inspections of establishments, of which 16 had received FDA accreditation. Since that time, 43 inspections of domestic establishments and one inspection of a foreign establishment have been conducted by accredited organizations jointly with FDA officials as part of training that FDA requires of accredited organizations. During this same period, 14 auditors from eight of these organizations completed the necessary training and

⁵⁴ FFDCA 519(a)(1); 21 USC 360i.

⁵⁵ Government Accountability Office, "Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations," Report to Congress, GAO-07-157 (January 2007).

⁵⁶ FFDCA 510(h); 21USC 360(h).

⁵⁷ Government Accountability Office, "Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations," Report to Congress, GAO-07-157 (January 2007).

were cleared to conduct independent inspections. As of May 31, 2008, these auditors had conducted 11 independent inspections — 4 of domestic establishments and 7 of foreign establishments.⁵⁸

GAO reports that several factors may influence manufacturers' interest in voluntarily requesting an inspection by an accredited organization:

Potential incentives [to request inspection by an accredited organization] include the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements and to control the scheduling of the inspection. Potential disincentives include bearing the cost for the inspection and uncertainty about the potential consequences of making a commitment to having an inspection to assess compliance with FDA requirements in the near future.⁵⁹

MDUFA 2007 changed the third-party accredited person inspection program in three major ways. First, it streamlined administrative burdens associated with qualifying for the program. For example, for clearance to use a third party, the law now requires that firms provide FDA with 30 days prior notice of their intent to use a third party listed on FDA's website. Previously, a firm was required to petition FDA for such clearance.

Second, it made amendments designed to expand participation in the program. For example, the law now permits firms to use third parties for an unlimited number of consecutive inspections without seeking a waiver, with certain exceptions. Previously, the third-party program restricted qualified manufacturers of Class II and Class III medical devices to two consecutive third-party inspections, after which FDA was required to conduct the next inspection, unless the manufacturer petitioned and received a waiver from FDA.

The third change has to do with FDA's process for setting its inspection priorities. To do this, the agency uses a risk-based approach. To inform the risk-based approach, MDUFA 2007 requires FDA to accept certain reports that are voluntarily submitted by establishments. Establishments may submit reports by third parties that assess conformance with an appropriate international quality systems standard, such as those set by the International Standards Organization.⁶⁰ Previously, FDA did not accept such submissions.

Reports. MDUFA 2007 requires two reports by GAO and one by FDA to be delivered to Congress by September 27, 2008. One report is to present the results of a GAO study on the appropriate use of 510(k) clearance as a part of the device classification process to determine whether a new device is as safe and effective as

⁵⁸ FDA Office of Legislation.

⁵⁹ Government Accountability Office, "Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations," Report to Congress, *GAO-07-157* (January 2007).

⁶⁰ The International Standards Organization (ISO) is the world's largest developer and publisher of international standards. ISO is a non-governmental organization that forms a bridge between the public and private sectors. See [<http://www.iso.org/iso/about.htm>].

a classified device. (§225) The second is to present the results of a GAO study on the number of *nosocomial infections* attributable to new and reused medical devices and the causes of such infections. (§229) MDUFA 2007 defines a nosocomial infection as an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital. The third report requires FDA to conduct consumer testing and determine whether labeling requirements for indoor tanning devices provide sufficient information to consumers regarding the risk of damage to eyes and skin. (§230)

Non-user Fee Topics Only in MDUFMA

The following issues were addressed in MDUFMA, but not in MDUFA 2007:

- The review of combination products (products that combine elements of devices, drugs, or biologics) was to be coordinated by a new office in the Office of the Commissioner.
- Electronic labeling was authorized for prescription devices intended to be used in health care facilities.
- The sunset provision applicable to intended use based on labeling (§513(i)(1)(E)) was revoked.
- MDUFMA explicitly provided for modular review of PMAs.
- New provisions were added concerning devices intended for pediatric use.
- GAO and the National Institutes of Health (NIH) were directed to prepare reports concerning breast implants.
- The manufacturer of a device was required to be identified on the device itself, with certain exceptions.

Appendix A. Acronyms Used in This Report

| | |
|---------------|--|
| 510(k) | Premarket Notification |
| 513(g) | Request for Information About Device Classification |
| ADUFA | Animal Drug User Fee Act |
| BLA | Biological License Application |
| CBER | Center for Biologics Evaluation and Research |
| CDRH | Center for Devices and Radiological Health |
| CLIA | Clinical Laboratory Improvement Amendments (42 U.S.C. 263a) |
| FDA | United States Food and Drug Administration |
| FFDCA | Federal Food, Drug, and Cosmetic Act (21 U.S.C. Chapter 9) |
| FTE | Full Time Equivalent Employee |
| GAO | Government Accountability Office (formerly General Accounting Office) |
| GMP | Good Manufacturing Practice |
| HHS | United States Department of Health and Human Services |
| HUD | Humanitarian Use Device |
| IDE | Investigational Device Exemption |
| IND | Investigational New Drug Application |
| IVD | In Vitro Diagnostic Device (laboratory diagnostic test) |
| MDTCA | Medical Device Technical Corrections Act (P.L. 108-214) |
| MDUFMA | Medical Device User Fee and Modernization Act (P.L. 107-250) |
| MDUFA 2007 | Medical Device User Fee Amendments of 2007 (P.L. 110-85, Title II). |
| MQSA | Mammography Quality Standards Act (P.L. 102-539) |
| MDUFSA | Medical Device User Fee Stabilization Act of 2005 (P.L. 109-43) |
| NSE | Non-Substantial Equivalence |
| OIVD | Office of In Vitro Diagnostic Device |
| PDP | Product Development Protocol |
| PDUFA | Prescription Drug User Fee Act |
| PL | Public Law |
| PMA | Premarket Approval |
| SE | Substantial Equivalence |
| SUD | Single-Use Device |
| USC | United States Code |

Appendix B. History of MDUFA Provisions

This section contains a history of each of the user fee provisions. It presents topics in the same order and format used in the Medical Device User Fees section of this report, with one exception. The history of *Use of Fees* is presented in the main text with the explanation of the provision, not in this appendix, because the evolution of the provisions is relevant to their interpretation.

Triggers

The direct congressional appropriations trigger is lower than the one initially set in 2002. MDUFMA had required an appropriation equal to or greater than \$205,720,000 multiplied by an inflation adjustment factor. (Current law requires 1% less than this amount). In 2005, legislation was required to enable the continuation of the MDUFMA user fee program because congressional appropriations had been lower than required for FY2003 and FY2004. MDUFSA (the 2005 legislation) lowered the MDUFMA triggers retroactively for FY2003 and FY2004, and prospectively for FY2005-FY2007, to the level required by current law. MDUFA 2007 perpetuated the MDUFSA trigger, including the adjustment factor, indefinitely.

The second trigger, for the HHS Secretary, was created by MDUFMA (§102) in 2002 and has not been amended.

User Fees and the Device Review Budget

MDUFMA (§102) first authorized the collection of fees in FY2003. MDUFA 2007 (§212(h)(1)) authorized an increase for each year between FY2007 and FY2012. The base fee amounts for FY2003-FY2007 are presented in **Table 10**.

Table 10. MDUFMA Base Fees (PMA), FY2003-FY2007

| FY2003 | FY2004 | FY2005 | FY2006 | FY2007 |
|-----------|-----------|-----------|-----------|-----------|
| \$154,000 | \$206,811 | \$239,237 | \$259,600 | \$281,600 |

Source: “Fees” section, MDUFMA website of FDA’s Center for Biologics Evaluation and Research, updated August 2, 2006, at [<http://www.fda.gov/cber/mdufma/mdufma.htm>].

Activities Requiring Fees

All of the application fees except for the 30-Day Notice and 513(g) were authorized by MDUFMA (§102). As mentioned in the main text, in the lead up to MDUFA 2007, FDA claimed there had been fluctuations in the number of applications submitted from year to year, causing fee revenues to repeatedly fall short of expectations.⁶¹ MDUFA 2007 (§212 (a)(1), (5)) authorized establishment and product fees, as well as two new types of application fees (for 30-Day Notices and

⁶¹ Public Meeting.

513(g)s) to help establish a more consistent and predictable user fee revenue stream for FDA.

MDUFA 2007 also changed the percentage of the base fee assigned to various types of activities, but the basic method of setting the fees is the same as it was under MDUFMA. The one exception to this is the way that the premarket notification fee (for 510(k) submissions) is set. Under MDUFMA, the premarket notification fee had been calculated annually, so that the total of all such fees, in aggregate, comprised a target amount. MDUFA 2007 provided that these fees are to be set like the others — as a percentage of the base fee.

MDUFA 2007 lowered the base fee by \$96,600 in FY2008 from its FY2007 level. However, as noted previously, FDA projects that it will still have more fee revenue in FY2008 than FY2007 because the addition of revenue from the new types of fees should more than compensate for the money lost in fee reductions. The net effect should be an increase in fee revenue for FDA.

Fee-Collection Offset

The authority to consider excess funds in aggregate over several years was added by MDUFA 2007 (§212(h)(2)). Under MDUFMA, FDA was required to reduce fees in any year for which collections in the preceding year exceeded the amount authorized.

Fee Exceptions, Reductions, Refunds

The following is a history of the various device user fee exceptions, reductions and refunds.

Humanitarian Use Devices (HUDs). MDUFMA (§102) created the HUD user fee exemption. MDUFA 2007 did not amend the HUD provisions. However, another FDAAA title, the Pediatric Medical Device Safety and Improvement Act of 2007 (Title III, §303), allowed that certain pediatric device manufacturers may also be able submit an HUD application.⁶² The HUD fee waiver is not significant for manufacturers of pediatric medical devices. This is because under MDUFMA these manufacturers had already qualified for user fee exemptions as described in the next paragraph. The HUD fee waiver does not apply to the establishment registration fee created by MDUFA 2007 (§212(a)(5)).

Devices Intended for Pediatric Use. MDUFMA (§102) created the pediatric use exemption. It was not amended by MDUFA 2007, but the exemption does not apply to the new law's annual establishment fee (§212(a)(5)).

⁶² For more information about the Pediatric Medical Device Safety and Improvement Act of 2007, see CRS Report RL34465, *The FDA Amendments Act of 2007 (P.L. 110-85)*, by Erin D. Williams and Susan Thaul, and CRS Report RL33986, *FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective*, by Susan Thaul.

Applications from Federal or State Government Entities. This exemption was created by MDUFMA (§102). Unlike the other exemptions, MDUFA 2007 (§212(a)(5)) applied this one to establishment registration fees.

Further Manufacturing. MDUFMA (§102) created this exemption. MDUFA 2007 (§212(a)(5)) does not apply it to the newly created establishment registration fee.

Premarket Notification by Third Parties. MDUFMA (§102) created this exemption. MDUFA 2007 does not change the exemption, but Subtitle B (§221) extends third-party review authority from 2007 to 2012.

Small Businesses. MDUFMA (§102) authorized fee reductions for small businesses. MDUFA 2007 (§212(d), (e)) changed the details of the small business rules established under MDUFMA in two ways. First, it lowered the fee percentage that small businesses must pay. For example, as stated above, MDUFA 2007 requires a small business to pay 50% of the standard 510(k) fee and 25% of the standard PMA fee, whereas MDUFMA had required small businesses to pay 80% and 38%, respectively. (See **Table 5**.)

Second, MDUFA 2007 made it easier for entities to qualify as small businesses with two amendments. The first removed MDUFMA's requirement that FDA consider the assets of partners and parent firms in the small business qualification calculation. The second broadened the types of acceptable gross receipt documentation beyond IRS filings, making it possible for foreign establishments to qualify as small businesses.

Modular PMA Refunds. This refund provision was added by MDUFA 2007 (§212(4)).

Performance Goals

MDUFMA (§102) and MDUFA 2007 (§212(g)) each incorporated the contents of a commitment letter into law by reference. According to the FDA Agreement, the MDUFA 2007 goals are fewer and more rigorous than those in MDUFMA. They build on the progress made in MDUFMA. In making these proposals, FDA considered efficiencies gained and expected by means of additional scientific, regulatory, and leadership training; additional staff, including those with expertise demanded by increasingly complex device reviews; expanded use of outside experts; and information technology improvements that allow FDA to better track and manage the device review process. Like MDUFA 2007, MDUFMA had created performance goals, which were articulated in the 2002 Commitment Letter. (See **Table 7**.) According to the FDA Agreement, FDA was on track to meet nearly all of the MDUFMA performance goals, which expired on October 1, 2007.

Performance Goal-Setting Process

A performance goal-setting process was conducted in preparation for MDUFMA. A second one, required by MDUFMA (§105), was created in

preparation for MDUFA 2007. MDUFA 2007 (§213) sets forth requirements for the third such process. The three processes and their requirements were similar, except that MDUFA 2007 added the requirements that the recommendations be revised upon consideration of public comments, and that the recommendations be transmitted to Congress not later than January 15, 2012. MDUFA 2007 also wrote all of the relevant consultation requirements into the FDCA.

Quarterly Performance Reports

These reports were required according to the commitment letters issues pursuant to both MDUFMA and MDUFA 2007. Each letter specified a unique set of factors to be included in the reports.

Postmarket Safety

MDUFMA authorized additional appropriations for postmarket surveillance in the amounts of \$3 million for FY2003, \$6 million for FY2004, and “such sums as may be necessary” for FY2005 through FY2007. However, these sums were not appropriated. MDUFMA also required the HHS Secretary to conduct a study of the postmarket review impact of the medical device user-fee program. MDUFA 2007 changed both the amounts and wording of the purpose of the authorization for post-market safety appropriations.

Annual Reports to Congress

Annual reports were initially required by MDUFMA from the time that FDA was first granted the authority to collect medical device user fees through FY2007. However, MDUFA 2007 changed the law by requiring that the reports be made available to the public, by writing the report requirements into the FDCA, and by expanding substantive requirements of the performance report.