

New Medical Device User Fees Required in the US

Diane Mandell and colleagues discuss the impact of new US legislation.

This article looks at one of the major recent changes affecting the medical device industry in the US resulting from passage of the *Medical Device User Fee and Modernization Act (MDUFMA)* on 26 October 2002. Of all the changes that result from *MDUFMA*, perhaps the greatest impact will result from the collection of user fees for reviewing a variety of regulatory documents concerning medical devices by the Center for Devices and Radiological Health (CDRH). This paper explores the user fee component of the new law, how pharmaceutical user fees provided a model for medical device user fees, the cost to medical device manufacturers, and potential ways for manufacturers to maximise their value (and minimise cost) for the fees that they pay.

User fees have been collected by the Center for Drug Evaluation and Research (CDER) through *PDUFA* (the *Prescription Drug User Fee Act*) since 1992. CDER collects three types of user fees under *PDUFA*: application fees (collected when filing a human drug application), establishment fees (collected for operating an establishment that manufactures prescription drug products), and product fees (when marketing a prescription drug product). For the year 2002, *PDUFA* application fees for drugs ranged from \$156 660 (supplements or applications not requiring clinical data) to \$313 320 (for applications requiring clinical data). At present, CDRH plans to collect application fees but not establishment or product fees. Also in contrast, application fees for medical device applications will be much lower than for drugs, ranging from \$2187 (for a premarket notification or 510(k)) to \$154 000 (for a PMA).

As with prescription drugs, medical device user fees will be collected for the purpose of 'the review of devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met,' and serve to partially restore funds lost because of reductions in government funding. If the *MDUFMA* user fee programme is successful, the end result will be more timely patient access to new, safe and effective medical devices. Specific performance goals of *MDUFMA* have been outlined with respect to cycle goals (i.e. time to issuance of approval or action letters) and decision goals for all categories of medical device submissions¹.

MDUFMA amends the *Federal Food, Drug, and Cosmetic Act (FD&CA)* to assess medical device user fees beginning in fiscal year 2003 (1 October 2002) through fiscal year 2006, and requires reauthorisation by the 'sunset' date of 1 October 2007. On 25 February 2003, the long-awaited *Federal Register* notice on user fee payment procedures was published, announcing the plans for collection, retention and accounting of fees retroactive to applications submitted on or after 1 October 2002².

MDUFMA signed into law

MDUFMA, P.L. 107-250, was signed into law on 26 October 2002 and amends the *Federal Food, Drug and Cosmetic Act*. Medical device user fee authority is found in sections 737 and 738 of the *FD&C Act* (21 U.S.C. 379i and j).

PDUFA as a model

Congress passed *PDUFA* in 1992 in response to slow review times created by staff shortages at the FDA. User fees had the support of not only Congress, but the FDA, industry, and patient groups in general. The new system was designed to supplement congressional appropriations (which appealed to Congress). It provided much-needed additional staff (which was welcomed by the FDA) and quicker review times to bring new medications to market, which was embraced by both manufacturers and consumers. *PDUFA* was not without its detractors, however. Concern was raised that industry funding of product reviews might influence approvals.

As intended, under *PDUFA* the FDA has generally met its objective of reducing review times for drugs and has benefited from greatly increased staff. Total resources for drug review activities increased from \$120 million in 1992 before *PDUFA* to \$325 million in 2002³. Pharmaceutical Research and Manufacturers of America (PhRMA) notes that by the autumn of 2002, the pharmaceutical industry will have paid \$980 million in user fees, enabling FDA to pay the salaries of over 1 000 reviewers and cutting the review time for new drugs almost in half⁴. In addition, because of improved communication with industry, the percentage of approvals for drug applications has increased to 80%, up from 60% before *PDUFA*³. The law was renewed by Congress in five-year increments as *PDUFA II* in 1997 and again as *PDUFA III* in 2002. The hope is that *MDUFMA* will be as successful.

Medical Device User Fee & Modernization Act was passed 26 Oct 2002

MDUFMA requires payment of fees for assessing devices retroactively from 1 Oct 2002

Equivalent prescription drug fees have seen improved FDA approval performance...

...but watch-outs are high FDA staff turnover and insufficient resourcing in other areas

Lessons learned from PDUFA

Despite its successes, several issues have arisen since the enactment of *PDUFA*, which can provide lessons for the medical device industry to learn from as well as pitfalls to avoid with *MDUFMA*. First, the FDA has expressed concern about a lack of sufficient appropriations from Congress. Because industry insisted on a provision in *PDUFA* to ensure that user fees pay for new review resources rather than replace appropriations, much of the appropriations must also go to review activities. The FDA has complained that this has left insufficient resources in other drug regulatory areas, such as monitoring of adverse events and advertising review. The FDA has also complained that the strict performance goals enacted by *PDUFA* have resulted in high staff turnover. The Government Accounting Office (GAO) confirmed this finding in a recent report on *PDUFA*⁵.

More recently, the FDA received less money in user fees than expected from *PDUFA*, because of an unanticipated change in the composition of the new application pool. This change relates to fewer new molecular entities and fewer new drug applications (NDAs), applications that usually represent a large proportion of the user fee income⁶. Despite decreases in review times over the years, recent increases have triggered an internal FDA audit. Separately, GAO has found an increase in the rate at which prescription drugs are withdrawn from the market due to adverse events, since *PDUFA* was enacted⁵, prompting concern that decreased review times may indicate less careful reviews. These observations are important to note while CDRH implements *MDUFMA*, as similar effects of implementation of user fees may result. For example, if decreased review times result in lower assurances of medical device safety and effectiveness, CDRH will be faced with a similar increase in medical device withdrawals from the market.

Then came MDUFMA

History of MDUFMA's development

While the *Prescription Drug User Fee Act* enabled a 22% increase in the staffing of full-time equivalents at CDER from 1995-2002, CDRH's full-time equivalents' level actually declined by 8% over that same period⁷. CDRH clearly needed assistance.

MDUFMA began as medical device reform legislation (H.R. 3580) sponsored by Representatives Jim Greenwood (R-Penn.) and Anna Eshoo (D-Calif.) of the U.S. House of Representatives' Energy and Commerce Committee. It included a number of provisions, such as allowing third-party review and inspections for medical devices, but originally did not include a provision for user fees.

Medical device industry organisations lobbied to include these provisions in the reauthorisation of *PDUFA* in 2002 in order to expedite the process of providing for third party review and inspection of medical devices and despite the fact that *PDUFA* pertains to prescription drug legislation. At that time, the efforts to 'tack on' the medical device third party review and inspection provisions to *PDUFA* failed because legislators believed that this change would delay passage of *PDUFA* beyond the reauthorisation deadline⁸. It must be recognised that there have been mixed signals from industry regarding the implementation of fees. Smaller companies have been concerned about the size of the fees, whereas larger companies were more concerned about increasing the speed of product approvals promised by a fee system. The provisions were revised by Energy and Commerce Committee Chair Billy Tauzin (R-La.) as a stand-alone bill, *MDUFMA* (H.R. 5651), which included user fee provisions. Negotiation with industry and the FDA defined the goals of the legislation, which was supported by a bipartisan group of legislators⁹. After several additional modifications, *MDUFMA* was passed and signed into law.

Congress passed *MDUFMA* with the following findings:

- prompt approval and clearance of medical devices is critical to the improvement of the public health;
- public health will be served by making more funds available to augment the FDA's resources devoted to device review; and
- fees authorised will be dedicated to meeting the goals identified in the Congressional Record.

Annual stakeholder meetings are one way of checking MDUFMA delivers on objectives

There are several oversight mechanisms in place to ensure that the user fee provisions outlined in *MDUFMA* meet their intended goals. These include annual stakeholders' meetings, GAO reports to Congress, and annual reports to Congress by the FDA concerning progress in achieving performance goals and implementation of the authority for fees and the use of fee revenue.

Now begins the struggle for implementation of the user fee act. A recent (20 February 2003) guidance document announcing the *Federal Register* notice on user fee payment procedures outlines the mechanism for implementation of the law¹⁰. Congressional appropriations are required to fund the medical device user fee programme; if funding targets are not met, the programme will automatically expire after fiscal year 2005. Industry groups are expected to lobby heavily to ensure that *MDUFMA* survives¹¹.

FDA notification of industry regarding enactment of user fees

CDRH is making a concerted effort to keep industry informed about MDUFMA. Fee rates for fiscal year 2003 were announced in a *Federal Register* notice on 21 November 2002¹², and a correction notice was posted clarifying the fee for 510(k)s. The agency announced in the *Federal Register* on 4 February 2003 that it had established a public docket to obtain input on implementation of MDUFMA for submission of comments^{2,13}. In addition, CDRH created a web page dedicated to MDUFMA with information about the law, recent developments and frequently asked questions. Finally, a 20 February 2003 guidance document and a 25 February 2003 *Federal Register* notice outline the details of user fee collection^{2,10}.

The seven MDUFMA Implementation Teams created by CDRH will also look into targeting and communicating with outside audiences on particular issues, hosting workshops and video conferences, and maintaining and updating the web site¹⁴.

AdvaMed opinion of MDUFMA

AdvaMed (the Advanced Medical Technology Association), whose members produce nearly 90% of medical technology products sold in the US, strongly supports MDUFMA¹⁵.

While they recognised the significant shortage of resources devoted to device reviews in CDRH, AdvaMed had previously been opposed to user fees and had lobbied Congress to pass different types of reforms. However, although certain reforms had passed, congressional funding for medical device programmes was smaller in 2002 than it was 10 years before (after adjusting for inflation)¹⁶. In addition, in recent months it became clear that with increasing amounts of congressional funding for the FDA being directed towards bioterrorism and other matters of national defence, it was highly unlikely that the device review programme would receive adequate money for device reviews in the near future¹⁷.

The bleak funding picture, along with increasing numbers of applications for complex novel medical technologies and pressure from senior lawmakers and Bush Administration officials, caused AdvaMed to reverse its position on user fees. AdvaMed worked with Congress and the FDA to promote its goals of reasonable fees, strong performance standards for the FDA, and protection for small companies. AdvaMed states that it hopes MDUFMA will prompt quicker, more predictable device reviews 'in an era of rapidly advancing medical technology'. In addition, AdvaMed will be able to work with Congress through activities such as oversight hearings to ensure that the FDA meets performance goals (which include a goal for 'total FDA days to a review decision,' a provision that the FDA did not accept for PDUFA)¹⁶. The legislation also ensures that user fee money will be directed towards its intended purpose, training and hiring of review personnel and contracting with outside experts.

In addition, AdvaMed lobbied to protect the interests of small, start-up companies and argues that decreased review times will benefit small companies more in the long run than will the initial fee cause harm. (It had initially been proposed that small companies be defined as those firms generating less than \$100 million in yearly revenue. Currently, a small business is defined by the agency as eligible for a small business reduction if it has \$30 million or less of annual revenue in the most recent income tax return).

AdvaMed continues to work with the FDA and Congress toward the rapid implementation of MDUFMA¹⁸. It has been pushing for the active use of outside experts by the agency for the review of breakthrough medical technologies, rather than simply hiring reviewers⁷.

MDMA, the Medical Device Manufacturers Association, which traditionally represents smaller, entrepreneurial medical devices companies, also supports MDUFMA and plans to closely monitor its effect on small companies¹⁹.

User fee structure

User fees are assessed on the basis of the complexity of the application and the anticipated FDA review time. The law states that a fee must be paid for each type of filing listed in Table 1, unless the applicant is eligible for a waiver or exemption.

In late February it was announced that the collection of fees by the FDA will begin on 1 April 2003. As of this date, manufacturers are expected to include the appropriate payment in accompaniment with any eligible submission. All submissions without proper payment 'shall be considered incomplete and shall not be accepted for filing' until the payment has been made in full². Manufacturers submitting applications between 1 October 2002 and 31 March 2003 will be invoiced by the agency, and these manufacturers will be responsible for paying the full user fee within 30 days of receiving an invoice. Those who submit applications before 31 March 2003 have the option of either submitting the user fee at the time of application or waiting for the FDA to send an invoice.

CDRH has established public docket for comments on implementation of MDUFMA

Industry has not always supported user fees

Actual fee collection commences 1 April 2003

Fees are based on application complexity and anticipated FDA review time

Table 1. Fiscal year 2003 fee structure, US FDA²⁰

| Type of submission | Percent of baseline fee | Standard fee | Small business (\$30 million threshold) | |
|--|-------------------------|--------------|---|----------------------|
| | | | Percent of standard fee | Small business fee |
| Premarket Application (PMA, BLA, PDP) | 100% | \$154 000 | 38% | \$58 520 |
| Premarket Report (premarket approval application for a reprocessed device) | | | | |
| Panel-Track Supplement | | | | |
| Efficacy Supplement | | | | |
| 180-Day Supplement | 21.5% | \$33 110 | | \$12 582 |
| Real-Time Supplement | 7.2% | \$11 088 | | \$4 213 |
| 510(k) | 1.42% | \$2 187 | 100% | \$2 187 ^a |

Notes

^a In 2003, small business fee reductions do not apply. Small business fees for premarket notifications [510(k)s] will apply beginning in 2004 and will be assessed as 80% of a full application fee; you must be considered a small business for 60 days prior to your first submission in order to qualify for these reduced fees.

^b The term 'baseline fee' refers to the standard fee for submission of a PMA, currently \$154 000.

Abbreviations

- BLA Biological Licensing Applications
- PDP Product Development Plan
- PMA Premarket approval application
- 510(k) 510(k) Premarket Notification application

Refunding of fees is possible under a number of different scenarios

The agency has established several scenarios for reimbursement of user fees, should a submission be withdrawn by the sponsor or denied filing by the FDA. Written requests for reimbursement can be made within 180 days after a fee was due [FD&CA §738(j)] if an applicant decides to withdraw a submission prior to an FDA filing decision, or the FDA refuses the filing for other reasons. Following such a request, the agency has agreed to refund 75% of the fee.

Reimbursement is also possible in cases where a sponsor withdraws a premarket application, premarket report, or supplement after filing, but before any 'first action'. The FDA explains that a 'first action' can include any one of the following rulings: approvable, not approvable, major deficiency, approvable pending GMP inspection, or denial. The agency has complete discretion when reimbursing any portion of the original fee after filing but before a first action. In such cases, determination of the amount of any refund will be based on the level of effort already expended by the FDA, and their decision cannot be reviewed [FD&CA §738(a)(1)(d)(iii)].

Small business qualifications

The FDA has accounted for the onus placed on small businesses by reducing its submission fees to 38% of the standard fee charged to larger companies. 510(k) submissions for FY 2003 will remain the same for both large and small businesses (\$2 187) with an anticipated reduction to 80% of the standard fee charged in FY 2004.

To qualify as a small business for the fiscal year 2003, a company must have less than \$30 million in gross sales or receipts which include those sales and receipts of all affiliates, partners and parent firms. Firms meeting these criteria must apply for the reduced fees by submitting to the agency their Federal income tax forms, and those for any affiliates, partners and parent firms indicating net sales of less than \$30 million. Small businesses must qualify at least 60 days in advance of their first submission in any fiscal year in which they wish to pay the reduced fee²¹. Again, it is at the discretion of the FDA to ultimately decide who is eligible for the reduced fees, and their decision is irrefutable.

Small business may pay just 38% of standard fee

Exemptions and waivers

Under the new law, certain submission types will require no user fee, shown in Table 2.

Devices solely for paediatric use are exempt from fees

| Category | Exemption or waiver |
|---|--|
| Humanitarian Device Exemption | Exempt from any fee [FD&CA §738(a)(1)(B)(i)] |
| BLA for a product licensed for further manufacturing use only | Exempt from any fee [FD&CA §738(a)(1)(B)(ii)] |
| First PMA, PDP, BLA, or premarket report from a small business | One-time waiver of the fee that would otherwise apply [FD&CA §738(d)(1)] |
| First premarket report submitted by a sponsor who, prior to 1 October 2002, submitted a premarket application for the same reprocessed device | One-time waiver of the fee that would otherwise apply (<i>see</i> Section 102(b) of MDUFMA). This provision is intended to avoid penalizing companies that previously submitted a PMA for a reprocessed device, but must submit a new application to satisfy the requirements added by the new law. |
| Third-party 510(k) | Exempt from any FDA fee; however, the third-party may charge a fee for its review [FD&CA §738(a)(1)(b)(iv)] |
| Any application for a device intended solely for paediatric use | Exempt from any fee. 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 premarket application [FD&CA §738(a)(1)(b)(v)] |
| Any application from a State or Federal Government entity | Exempt from any fee unless the device is to be distributed commercially [FD&CA §738(a)(1)(b)(iii)] |

In addition, the new law offers reduced fees to those companies who qualify as a small business (*see* previous page).

Modular review

In concert with the FDA's efforts to reduce premarket review time, section 515(c) of the *Federal Food, Drug, and Cosmetic Act* was amended under MDUFMA to include additional policy on the submission of modular PMAs. The provision now requires the FDA to accept and review portions of a PMA submission that are ready for review. Many companies in the past have had this arrangement with the agency in which sections of their PMA were reviewed before other sections had been completed.

Entire user fee to be paid upon submission of first module

The new legislation now requires modular submissions from applicants and also requires that the entire fee for a PMA be paid upon the first modular submission. The FDA will not be permitted to re-review any portions of a PMA it deems acceptable, except in rare cases of safety or efficacy concerns. Furthermore if a section of the submission is found unacceptable, the agency is required to identify in writing any deficiencies and describe in detail how the sections can be made acceptable (§ 515(c)(3)(c)).

In addition, sponsors participating in a modular PMA review before 1 October 2002 are required to pay the 2003 fiscal fee if the final module is submitted after that date. The FDA has reserved the right to suspend the modular PMA programme if its authority to collect user fees is revoked.

Ways for manufacturers to reduce user fees

There are several ways for manufacturers to reduce user fees. One mechanism for reducing fees is the 'bundling' of closely related medical device submissions into a single application, paying one fee for the bundled submission. The second mechanism will be to use third-party review for the medical device application, which will result in a third-party review fee that could be lower than the MDUFMA fee.

Bundling of device applications into a single application

The FDA has stated that a bundling policy will be implemented as part of MDUFMA¹. In the past, the FDA has permitted the submission of one application for devices that are related and will be reviewed by the same review team, or whose scientific issues overlap significantly, enabling simultaneous review. Bundling of these devices not only preserves FDA review resources and provides consistent review of related products, but under MDUFMA could result in financial

Closely related device submissions bundled together attract a single fee

A guideline document on bundling is expected

savings to manufacturers. The agency plans to outline bundling procedures for products with multiple related submissions in a guidance document, or it will publish a notice explaining why such a bundled submission is inappropriate.

On 22 January 2003, AdvaMed submitted comments to the agency on the bundling of medical device applications²². In its comments, AdvaMed proposes the following general principles for future FDA policy with regard to bundling:

- the FDA should continue to allow bundling for new medical device applications and for changes to existing devices, and the presence of user fees should not alter this review practice (i.e. one user fee should be assessed for the bundled devices);
- when the FDA performs a single review for a PMA or BLA product, even if the data are cross-referenced in several other products, only a single user fee should be assessed (e.g. a packaging change that may impact on several different approved devices and that will be reviewed by a single FDA reviewer);
- devices to be used on the same platform may be bundled (e.g. an *in vitro* diagnostic laboratory test system which measures a number of analytes on a single platform); and
- multiple assays based on the same technologies relating to the same disease or with the same intended uses (e.g. multiple catheters with variations in specifications).

Bundling concerns are that 510(k) reviews will lengthen, and so attract higher fees

These suggestions have been submitted to the agency for its consideration while further guidance documents are under development. 'Guiding principles' have been presented for bundling of devices in the 20 February 2003 guidance document which will be updated as further developments occur¹⁰. MDMA has observed that if a lenient approach to bundling is adopted, it will lengthen the review process time and may result in increased fees for 510(k) reviews. It is likely, however, that the agency will not alter bundling policy from current accepted practices.

Third-party review

As of 1 August 1996, manufacturers who have certain 510(k) premarket notification applications that are eligible for third-party review can use a paid third-party reviewer to review their application²³. The third-party review programme was designed to expedite reviews of lower-risk devices and enable the FDA to use its reviewers for higher risk devices. This programme, however, could also potentially reduce fees associated with MDUFMA if indeed the third-party reviewer cost is lower than \$2 187 (since user fees will not be charged by the FDA for 510(k)s that have been reviewed by a third-party).

Conclusions

Reduced medical device review times are anticipated

It is the goal of the agency that user fees resulting from MDUFMA could serve to help CDRH meet its objectives of reducing medical device regulatory review times, with the ultimate goal of more efficient clearance (or approval) of safe and effective, novel medical devices in the US. Previous experience with user fees for prescription drugs should enable successful implementation of such a programme, along with the persistence and openness of both the agency and manufacturers to accomplish this goal.

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