



FDA's Third Annual MDUFMA Stakeholder Meeting

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“The User Fee Structure”

Mark Leahy, Executive Director
Medical Device Manufacturers Association (MDMA)

MDMA

MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today For Better Health Care Tomorrow™



User Fees *before* MDUFSA

- Volatile and unpredictable for the industry
- Fees increased between 55-60% in just two years
 - PMA fee from \$154,000 (FY03) to \$239,237 (FY05)
 - 510(k) fee from \$2,187 (FY03) to \$3,502 (FY05)
- Allowed FDA to collect more \$ per submission if they saw a decline in fee generating submissions
- Increases were unsustainable for 99% of the industry
- Fee generating submissions dropped significantly after the user fee was created



User Fees *after* MDUFSA

- Fees are much more predictable for the industry
- Fees increases capped at 8.5% annually (MDMA recommended inflation)
- Eliminated the workload and compensating adjustments (MDMA recommendation from 2002 & previous two stakeholder meetings)
- Provided greater fee relief for companies under \$100million in annual revenues (MDMA recommendation from 2002)



User Fees - What's Ahead

- Evaluate the value of user fees
- Fees must be reasonable & rational
 - Look at fees and performance together
- Need to ensure that fees do not increase at unsustainable rates
- Understanding that fees are meant to be additive to appropriations and not a substitute
- Determine FDA's actual resource needs related to the premarket review program



User Fees -What's Ahead

- Looking forward to working with the FDA, the Hill and other stakeholders to ensure that patients have timely access to safe and effective medical technologies and that smaller companies continue to have the ability to innovate