Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance

9:30 am, Wednesday, May 4, 2011
Switzer Bldg, Washington, DC

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- FDA issued 7 medical device guidance documents during the second quarter. *Barbara Zimmerman, CDRH-ODE*; *Kate Cook, CBER; Don St. Pierre, CDRH-OIVD*

FDA MDUFMA / MDUFA Performance — Actions through March 31, 2011

- Reports on all decision goals for the FY 2008 - FY 2011 cohorts.
  - CBER: *Kate Cook, CBER.*
  - CDRH: *Barbara Zimmerman, CDRH.*

CLIA Waiver Review Times

- Report on qualitative goals and number of pending waiver requests, Don St. Pierre, CDRH-OIVD.

Qualitative Update on Finances and Use of Resources — 2nd Quarter of FY 2011

- User fee receipts through the 2nd Quarter of FY 2011, compared with expectations. *Handout, David Miller, FDA-OFM.*
- Update on Budget Requests and appropriations. *Daniel Montgomery, CDRH-OMO.*

Discussion

- Questions from industry.
- Set date for next meeting, following close of Q3. Target: Week of 7/27/2011.

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Medical Device Guidance Documents
Issued through 2nd Quarter FY 2011

Through March 31, 2011

A comprehensive list of guidances can be found at the following:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Second Quarter (January 2011- March 2011)

1. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System (3/23/2011)

2. Guidance for Industry and FDA Staff - Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence (3/8/2011)

3. Draft Guidance for Industry and FDA Staff - Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder (2/7/2011)

4. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use (2/7/2011)

5. Electronic Source Documentation in Clinical Investigations (CDER/CBER/CDRH/OCPP) (1/6/2011)

6. Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of Nucleic Acid-Based In vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant Staphylococcus aureus (MRSA) and Staphylococcus aureus (SA) (1/5/11)

7. Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi (1/5/11)

First Quarter (October 2010 – December 2010)

1. Guidance for Industry and Food and Drug Administration Staff - Blood Lancet Labeling (11-29-10)

2. Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Clostridium difficile (11-29-10)

3. The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13 (11-16-10)

4. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT) (11-10-10)

5. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin (11-10-10)

6. Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System (11/5/10)

7. Guidance for Industry: Cellular Therapy for Cardiac Disease (11-4-10)

Quarterly Update on
Medical Device Performance Goals
— CBER Performance Data —

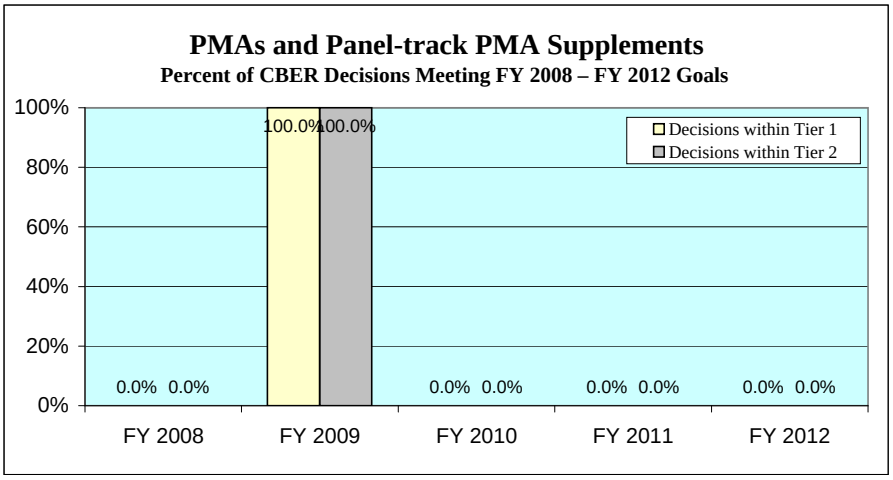
Actions through 31 March 2011

Data on FY 2008 – FY 2012 Cohorts

Actions through 31 March 2011

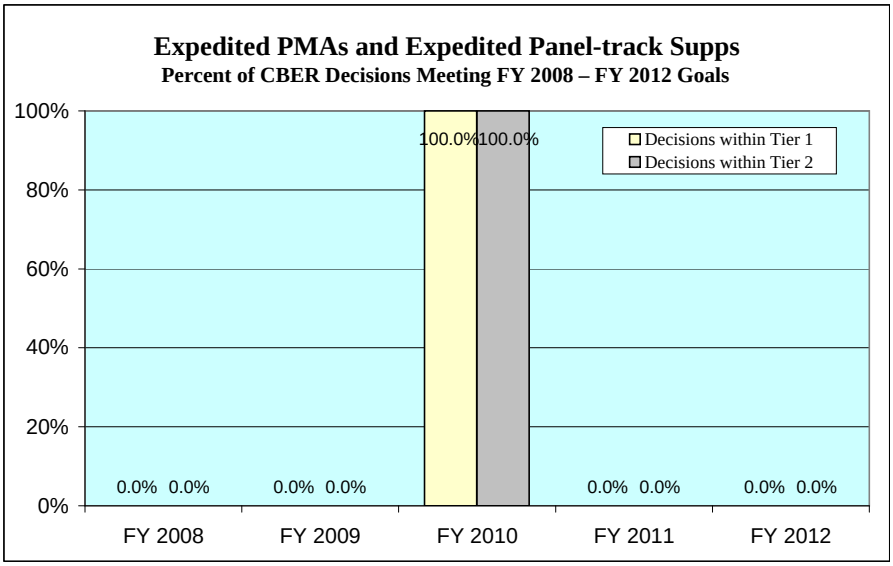
PMAs and Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	2	0	1	—
Total FDA Decisions	0	2	0	0	—
Percent within Tier 1 goal (180 days)	-	100.0%	-	0.0%	—
Tier 1 goal — *Percent within 180 days*	*60%*	*60%*	*60%*	*60%*	*60%*
Percent within Tier 2 goal (295 days)	-	100.0%	-	0.0%	—
Tier 2 goal — *Percent within 295 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	—



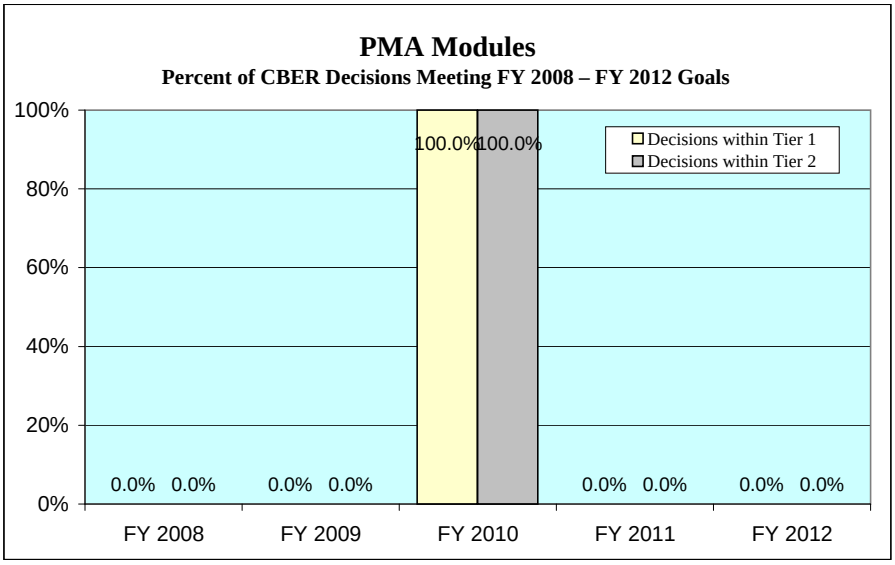
Expedited PMAs and Expedited Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	0	—
Total FDA Decisions	0	0	1	0	—
Percent within Tier 1 goal (180 days)	-	-	100.0%	-	—
Tier 1 goal — *Percent within 180 days*	*50%*	*50%*	*50%*	*50%*	*50%*
Percent within Tier 2 goal (280 days)	-	-	100.0%	-	—
Tier 2 goal — *Percent within 280 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	—



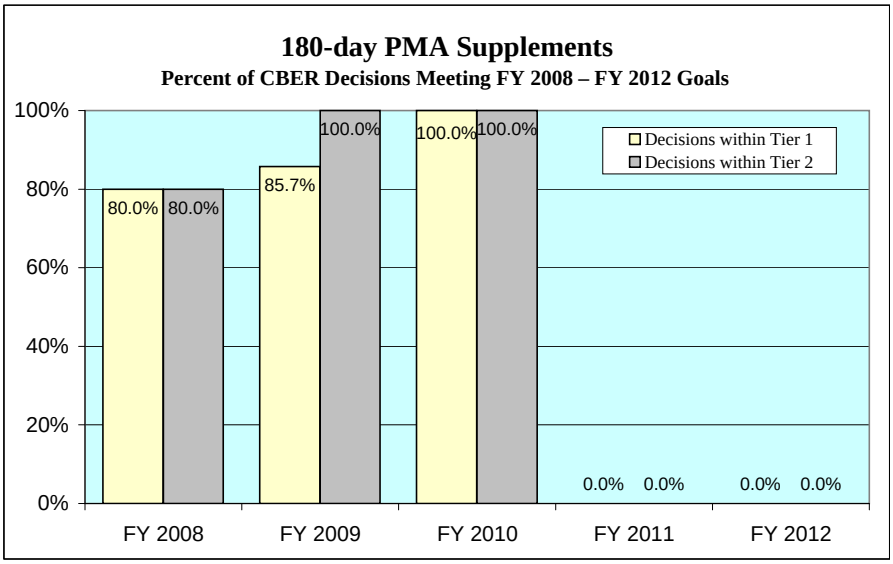
PMA Modules

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	1	—
MDUFMA Cohort	0	0	1	1	—
Total FDA Decisions	0	0	1	0	—
Percent within Tier 1 goal (90 days)	-	-	100.0%	-	—
Tier 1 goal — *Percent within 90 days*	*75%*	*75%*	*75%*	*75%*	*75%*
Percent within Tier 2 goal (120 days)	-	-	100.0%	-	—
Tier 2 goal — *Percent within 120 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	—



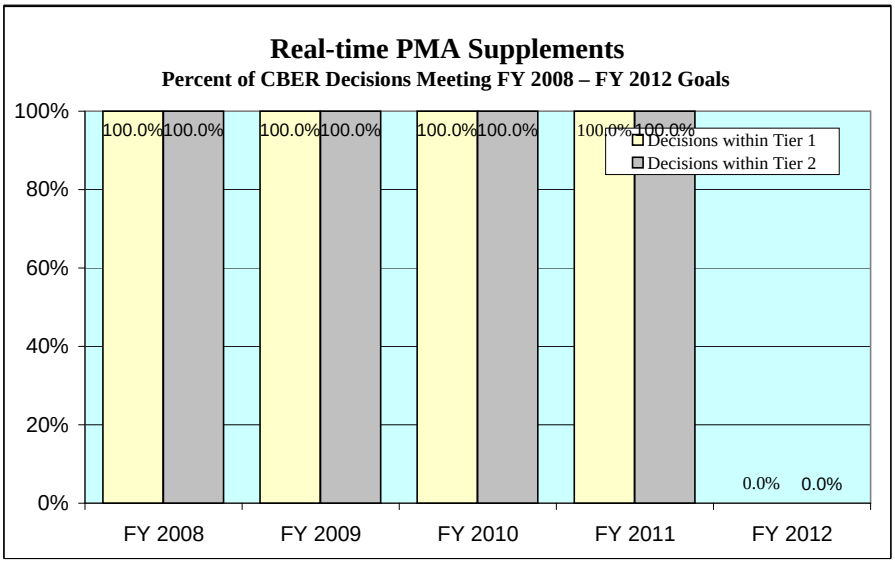
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	3	—
Total FDA Decisions	5	7	7	0	—
Percent within Tier 1 goal (180 days)	80.0%	85.7%	100.0%	-	—
Tier 1 goal — *Percent within 180 days*	*85%*	*85%*	*85%*	*85%*	*85%*
Percent within Tier 2 goal (210 days)	80.0%	100.0%	100.0%	-	—
Tier 2 goal — *Percent within 210 days*	*95%*	*95%*	*95%*	*95%*	*95%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	—



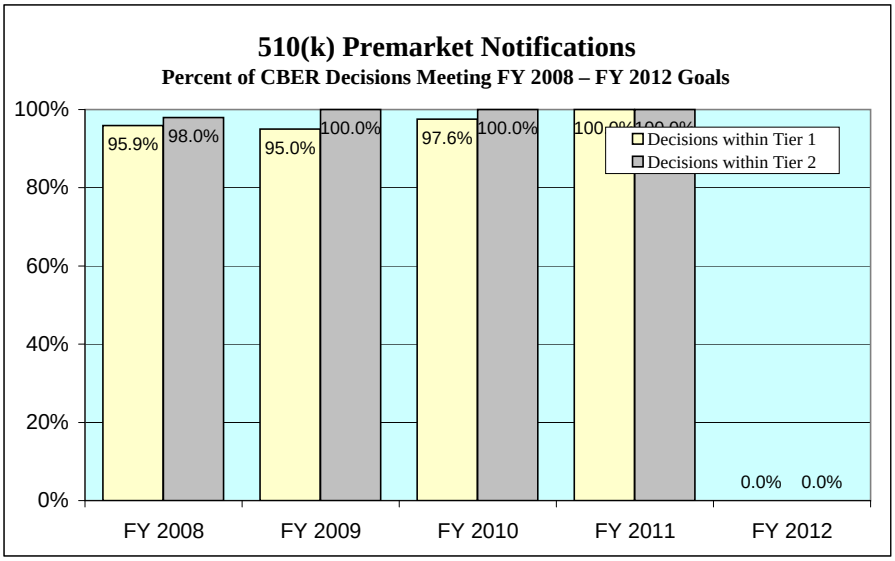
Real-time PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	2	4	2	1	—
Total FDA Decisions	2	4	2	1	—
Percent within Tier 1 goal (60 days)	100.0%	100.0%	100.0%	100.0%	—
Tier 1 goal — *Percent within 60 days*	*80%*	*80%*	*80%*	*80%*	*80%*
Percent within Tier 2 goal (90 days)	100.0%	100.0%	100.0%	100.0%	—
Tier 2 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	—



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	53	50	55	13	—
MDUFMA Cohort	51	42	48	12	—
Total FDA Decisions	49	40	41	3	—
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.6%	100.0%	—
Tier 1 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Percent within Tier 2 goal (150 days)	98.0%	100.0%	100.0%	100.0%	—
Tier 2 goal — *Percent within 150 days*	*98%*	*98%*	*98%*	*98%*	*98%*
Cohort status	Open	Open	Open	Open	—



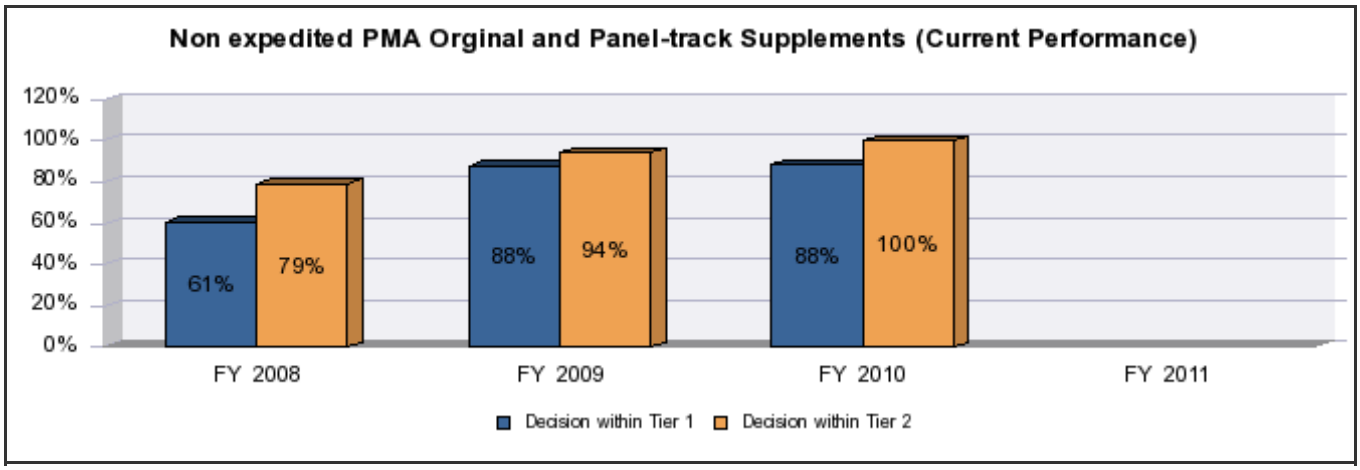
Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----

Action through 31 March 2011

MDUFA II Quarterly (Non expedited PMA Orginal and Panel-track Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 3/31/2011 11:59:00 PM

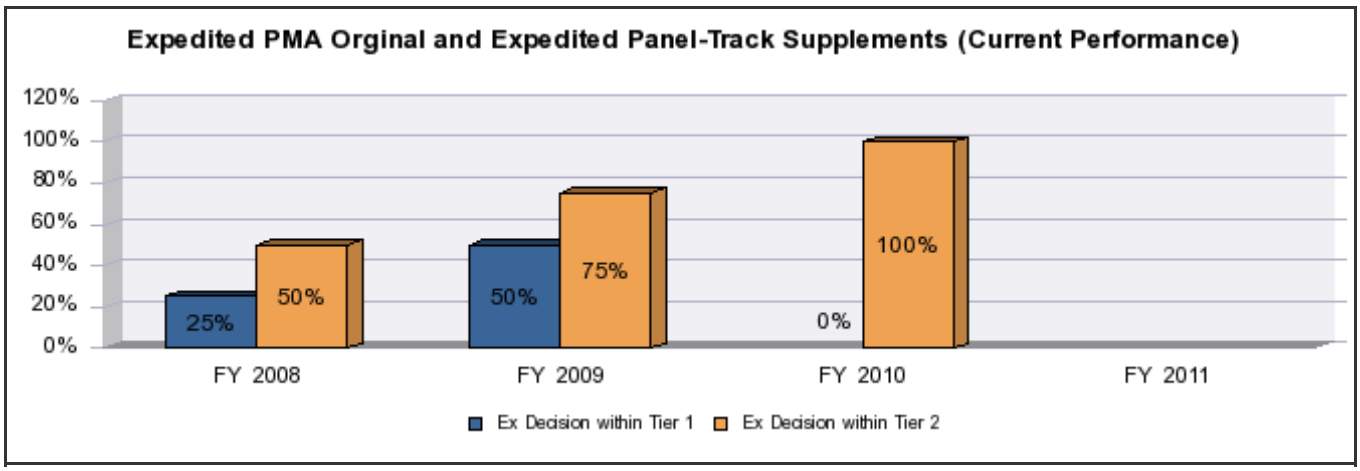
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	33	39	53	21
Total FDA Decision	33	33	25	0
Tier 1 goal -- Percent within 180 Days	*60%*	*60%*	*60%*	*60%*
Goal met(yes/no/unknown)	yes	yes	unknown	unknown
Pending Performance-Best Case	61%	77%	87%	95%
Pending Performance-Worst Case	61%	74%	42%	0%
Tier 2 goal -- Percent within 295 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	unknown	unknown
Pending Performance-Best Case	79%	85%	98%	100%
Pending Performance-Worst Case	79%	79%	47%	0%
Cohort status	Complete	Open	Open	Open



MDUFA II Quarterly (Expedited PMA Orginal and Expedited Panel-Track Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 3/31/2011 11:59:00 PM

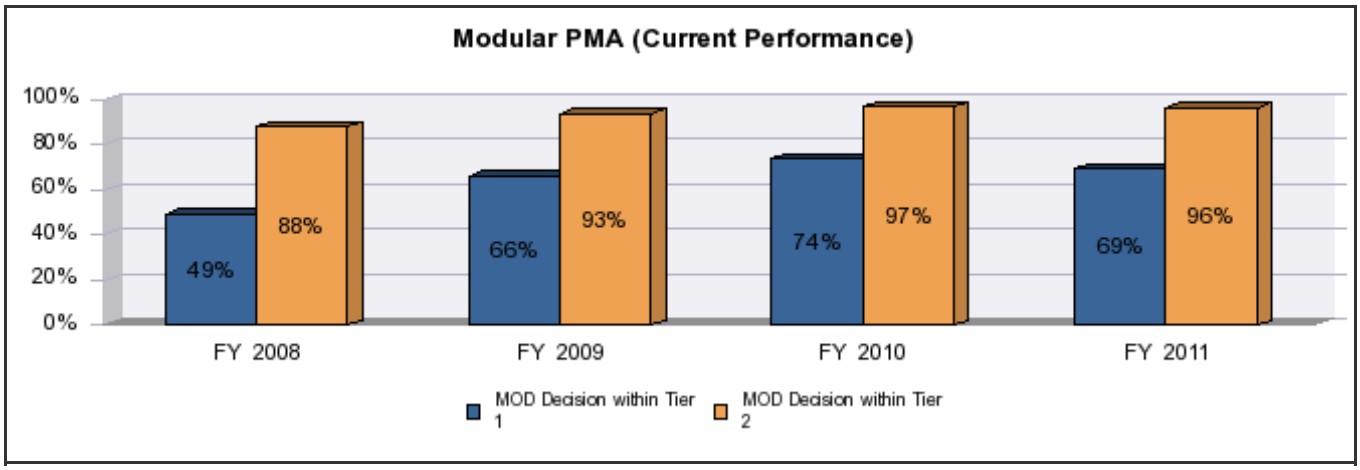
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	4	4	6	2
Total FDA Decision	4	4	1	0
Tier 1 goal -- Percent within 180 Days	*50%*	*50%*	*50%*	*50%*
Goal met(yes/no/unknown)	no	yes	unknown	unknown
Pending Performance-Best Case	25%	50%	67%	100%
Pending Performance-Worst Case	25%	50%	0%	0%
Tier 2 goal -- Percent within 280 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	unknown	unknown
Pending Performance-Best Case	50%	75%	100%	100%
Pending Performance-Worst Case	50%	75%	17%	0%
Cohort status	Complete	Complete	Open	Open



MDUFA II Quarterly (Modular PMA)

For Submissions Filed Between Year 2008 to 2011 as of 3/31/2011 11:59:00 PM

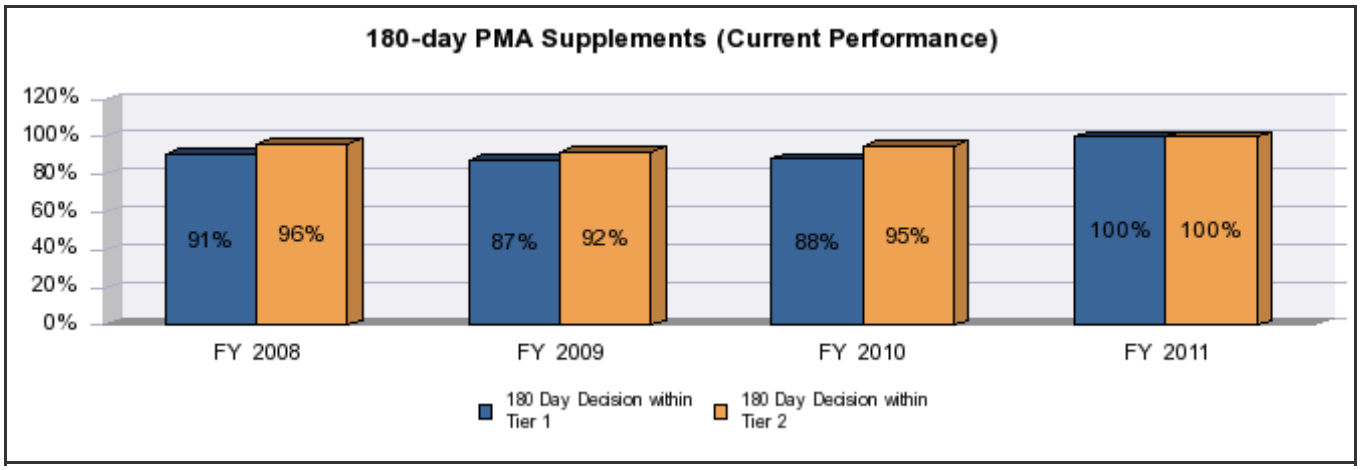
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Cycle Started)	45	68	86	48
Total FDA Decision	49	76	87	26
Tier 1 goal -- Percent within 90 Days	*75%*	*75%*	*75%*	*75%*
Goal met(yes/no/unknown)	no	no	no	unknown
Pending Performance-Best Case	49%	66%	74%	79%
Pending Performance-Worst Case	49%	64%	74%	37%
Tier 2 goal -- Percent within 120 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	yes	yes	unknown
Pending Performance-Best Case	88%	93%	97%	98%
Pending Performance-Worst Case	88%	91%	97%	51%
Cohort status	Complete	Open	Complete	Open



MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 3/31/2011 11:59:00 PM

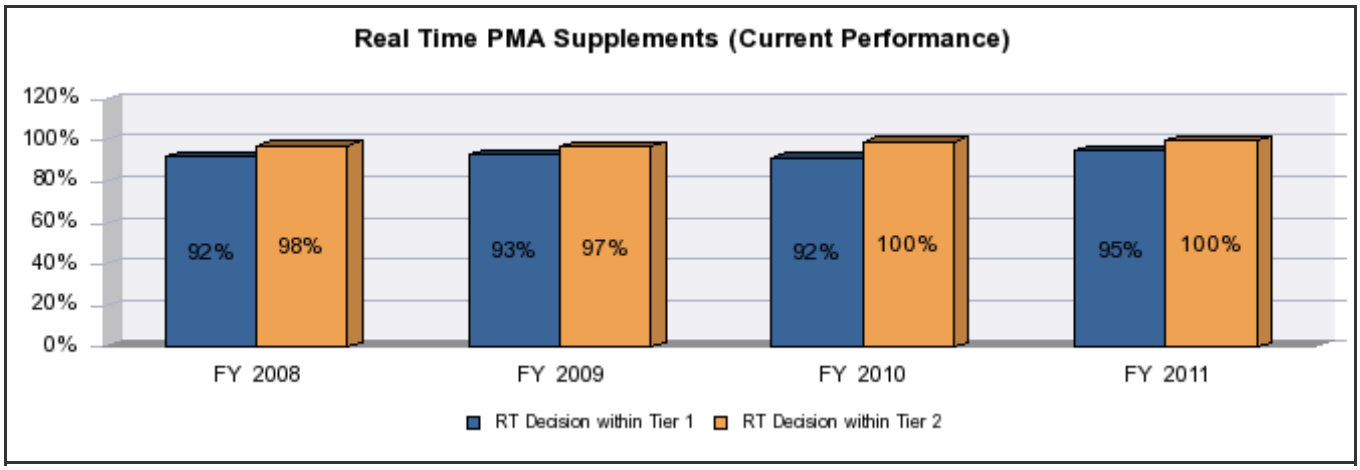
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	170	166	157	73
Total FDA Decision	160	159	109	6
Tier 1 goal -- Percent within 180 Days	*85%*	*85%*	*85%*	*85%*
Goal met(yes/no/unknown)	yes	yes	no	unknown
Pending Performance-Best Case	90%	87%	84%	100%
Pending Performance-Worst Case	90%	85%	63%	8%
Tier 2 goal -- Percent within 210 days	*95%*	*95%*	*95%*	*95%*
Goal met(yes/no/unknown)	yes	no	unknown	unknown
Pending Performance-Best Case	95%	91%	95%	100%
Pending Performance-Worst Case	95%	90%	68%	8%
Cohort status	Open	Open	Open	Open



MDUFA II Quarterly (Real Time PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 3/31/2011 11:59:00 PM

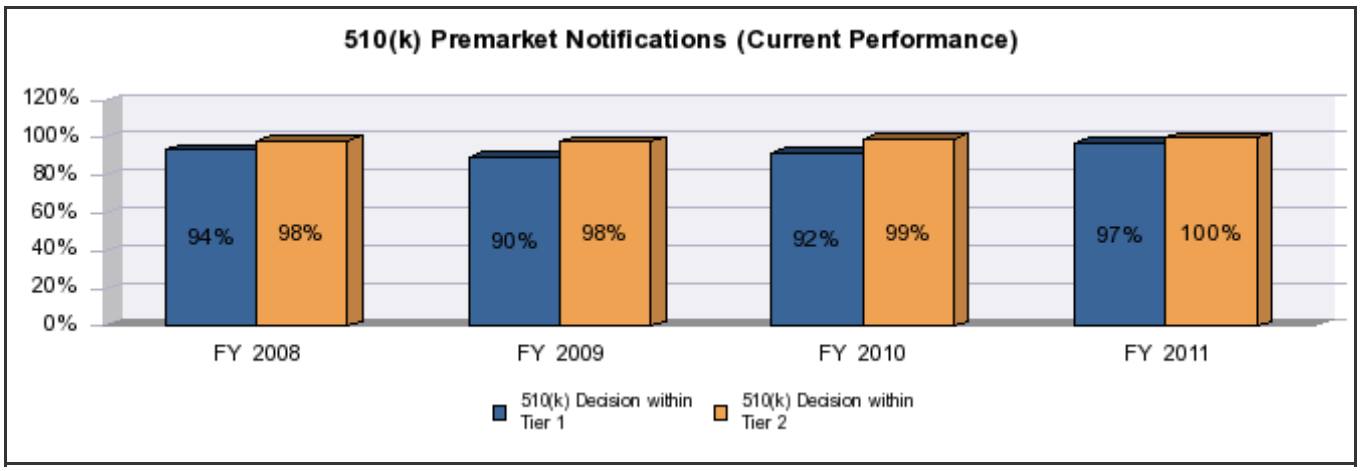
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	249	296	269	105
Total FDA Decision	241	280	257	59
Tier 1 goal -- Percent within 60 Days	*80%*	*80%*	*80%*	*80%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown
Pending Performance-Best Case	92%	93%	91%	97%
Pending Performance-Worst Case	92%	93%	91%	57%
Tier 2 goal -- Percent within 90 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown
Pending Performance-Best Case	98%	97%	99%	100%
Pending Performance-Worst Case	98%	97%	99%	60%
Cohort status	Complete	Complete	Open	Open



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2011 as of 3/31/2011 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Received to Date)	3,848	4,103	3,880	1,839
MDUFA Cohort	3,262	3,410	3,302	1,794
Total FDA Decision	3,258	3,383	2,817	573
Tier 1 goal -- Percent within 90 Days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	unknown	unknown	unknown
Pending Performance-Best Case	94%	90%	93%	99%
Pending Performance-Worst Case	94%	89%	79%	31%
Tier 2 goal -- Percent within 150 Days	*98%*	*98%*	*98%*	*98%*
Goal met(yes/no/unknown)	yes	unknown	unknown	unknown
Pending Performance-Best Case	98%	98%	99%	100%
Pending Performance-Worst Case	98%	97%	85%	32%
Cohort status	Open	Open	Open	Open



CLIA ***WAIVER BY APPLICATION*** WORKLOAD

FISCAL YR RECIEVED	RECOMMENDATION	TOTAL_FDA_DAYS	TOTAL MFR DAYS	TOTAL DAYS
2008	APPR - Approved	61		61
		248	38	286
		248	38	286
		398		398
		398		398
	DENY - Denied	102		102
		129		129
		189		189
		199		199
		287		287
		320	424	744
	TH - Telephone Hold	136	1,058	1,194
2008 Total	12			
2009	APPR - Approved	204	64	268
		233		233
	DENY - Denied	285		285
		644	7	651
		655		655
	NORE - No Response Necessary	776		776
	TH - Telephone Hold	33	783	816
		259	468	727
		518	6	524
2009 Total	9			
2010	APPR - Approved	77		77
	DENY - Denied	105	106	211
		172		172
		243		243
		248		248
	Under Review	357		357
		382		382
2010 Total	7			
2011	NORE - No Response Necessary	82		82
	Under Review	36		36
2011 Total	2			
Grand Total	30			

4/27/11

FY 2011 Medical Device User Fee Collections[2]
As of March 31, 2011

Source	FY 2011 Authorized[1]	FY 2011 Fee Revenues				FY 2011 Surplus
		Receipts	Refunds	Net	% of Authorized	*cf.* Authorized
Establishment Registration Fe	$32,685,000	$32,177,289.76	$395,547.00	$31,781,743	97.2%	-$903,257
Application / Reporting Fees	$29,175,000	$19,147,464.14	$204,675.00	$18,942,789	64.9%	-$10,232,211
Total	**$ 61,860,000**	$ 51,324,754	$ 600,222	**$ 50,724,532**	**82.0%**	**-$11,135,468**

[3]Comparison:
Medical Device User Fee Collection in Prior Years
Excludes Unearned Fees, Includes Refunds

FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
$21,620,549	$25,309,853	$31,801,091	$35,059,601	$28,726,239	$47,586,387	$53,337,680	$61,924,548

Notes:

1. The Authorized revenues shown for Establishment Registration fees assume 15,000 establishments will register and pay the fee of $2,179. The Authorized revenues shown for Application / Reporting Fees represents the difference between the Total authorized fee revenues and the amount shown for authorized Establishment Registration revenues. Total FY 2010 authorized fee revenues are specified in section 738(h)(3) of the FD&C Act.
2. Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 11.
3. Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

May 2011
MDUFA Stakeholder Meeting
Budget Requests and Appropriations Updates

FY 2011 Appropriations Update

Full-Year FY 2011 Continuing Appropriation passed under HR 1473. According to the bill's language:

- "$359,781,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs"
  - *Note: This total is before adding fees from the MQSA indefinite UF program.*
- "$61,860,000 shall be derived from medical device user fees authorized by section 738 of such Act (21 U.S.C. 379j)".

Please note the following:

- The FY 2011 MDUFA collection level amount is a +$4,846,000 increase from the FY 2010 MDUFA collection level and covers the entire Device Process (CDRH, CBER, ORA, OC).
- The BA portion of the Appropriation is subject to an across the board -0.2% rescission for discretionary agencies.
- The Agency is finalizing the rescission and other details that will be publically released at a later date.

CDRH's FY 2011 budget authority increase includes funding for the following activities:

- Science and Innovation Leadership: recruitment of next generation scientists in areas of emerging science.
- Nanotechnology: Nanotechnology laboratory and product testing capacity building, scientific staff development and training, and collaborative and interdisciplinary research to address product characterization and safety.
- Pediatric Safety: Integrate available internal and external data on the pediatric population to strengthen FDA's postmarket science base.
- National Medical Device Registry: Develop and implement a national strategy for the best public health use of health-related electronic data that incorporates unique device identifiers (UDIs) and leverages existing procedure and device registries. The initiative would also support investigating and piloting surveillance and observational methods to understand real world device safety and effectiveness.
- Medical Device Safety: Hire and train staff to effectively review and use third party International Organization for Standardization (ISO) audits of foreign device manufacturer facilities for compliance.