Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance
9:00 A.M., Friday, October 21, 2011

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- FDA issued 13 medical device guidance documents during the 4th quarter. *Barbara Zimmerman, CDRH-ODE*; *Kate Cook, CBER; Don St. Pierre, CDRH-OIVD*

FDA MDUFMA / MDUFA Performance — Actions through September 30, 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. *Carol Benson,* CDRH-OIVD.

Qualitative Update on Finances and Use of Resources – 4th Quarter of FY 2011

- User fee receipts through the 4th quarter of FY 2011, compared with expectations. *David Miller, FDA-OFM.*
- Update on budget requests and appropriations. *Noni Buchanan*, CDRH-OMO.

CDRH Registration and Listing

- Report on registration and listing. *Dave Gartner*, CDRH-OC

Discussion

- Questions from industry.
- Set date for next meeting, following close of Q1. Target Date: 1/25/2012.

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Medical Device Guidance Documents
Issued through 4th Quarter FY 2011
Through September 30, 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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Fourth Quarter (July 2011- September 2011)

1. Draft Guidance for Industry and Food and Drug Administration Staff - Postmarket Surveillance Under Section 522 of the Federal Food, Drug and Cosmetic Act, OSB (08/16/11).

2. Draft Guidance for Industry, Clinical Investigators, and Food and Drug Administration Staff - Design Considerations for Pivotal Clinical Investigations for Medical Devices, ODE/OIVD (08/15/11).

3. Draft Guidance for Industry and Food and Drug Administration Staff - Factors to Consider when Making Benefit-Risk Determinations in Medical Device Premarket Review, OCD (08/15/11).

4. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays, OIVD (08/09/11).

5. Guidance for Industry and Food and Drug Administration Staff and Foreign Governments - FY 2012 Medical Device User Fee Small Business Qualification and Certification, OCD (08/01/11).

6. Guidance for Industry and FDA Staff - 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device, ODE/OIVD (07/27/11).

7. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems, ODE (07/26/11).

8. Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Electrocardiograph Electrodes, ODE (07/21/11).

9. Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications, OCD (07/21/11).

10. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use, ODE (07/20/11).

11. Guidance for Industry and FDA Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses, OIVD (07/15/11).

12. Draft Guidance for Industry and Food and Drug Administration Staff - In Vitro Companion Diagnostic Devices, OIVD (7/14/11).

13. Draft Guidance for Industry and Food and Drug Administration Staff - Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices, OIVD (07/12/11).

Third Quarter (March 2011- June 2011)

1. Draft Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems, ODE (6/22/2011).

2. Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design, ODE (6/22/2011).

3. ODE Draft Guidance for Industry and FDA Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of methicillin-resistant Staphylococcus aureus (MRSA) for Culture Based Devices, OIVD (6/15/2011).

4. “Notice to Industry” Letter- SOP for Center process to clarify and more quickly inform stakeholders when CDRH has changed its expectations relating to, or otherwise has new scientific information that could affect, data submitted as part of an Investigational Device Exemption (IDE) or premarket submission that needs to be disseminated in a timely manner, OCD (6/15/11).

5. Draft Guidance for Industry and FDA Staff - Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions, OIVD (6/1/2011).

6. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Bacillus spp. Detection, OIVD (5/18/2011).

7. Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment, OCER (5/17/2011).

8. Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for Chlamydia trachomatis and/or Neisseria gonorrhoea: Screening and Diagnostic Testing, OIVD (5/11/2011).

9. Draft Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, ODE (5/2/2011).

10. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities, ODE (4/25/2011).

11. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use, ODE (4/14/2011).

12. Guidance for Industry and FDA Staff - 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes, OC (4/13/2011).

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

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

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 —

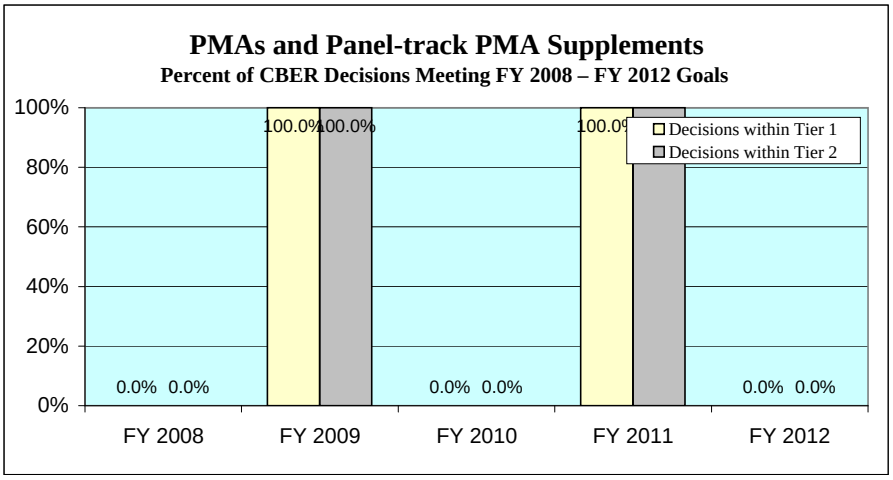
Actions through 30 September 2011

Data on FY 2008 – FY 2012 Cohorts

Actions through 30 September 2011

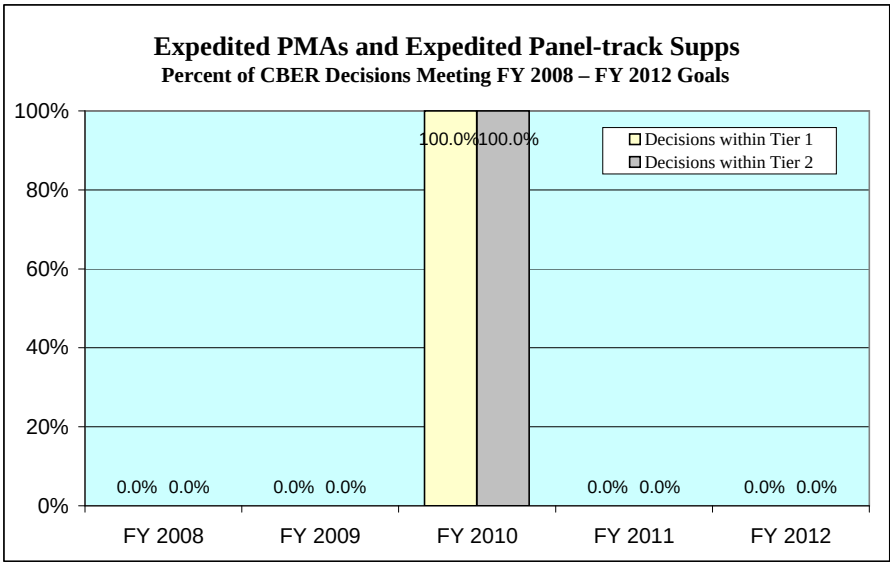
PMAs and Panel-track Supplements

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



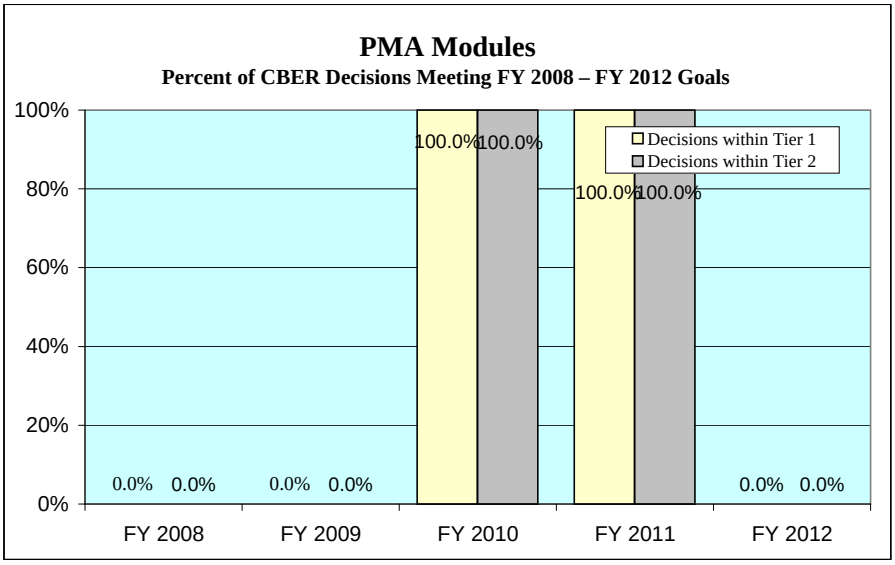
Expedited PMAs and Expedited Panel-track Supplements

	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*	*Complete*	—



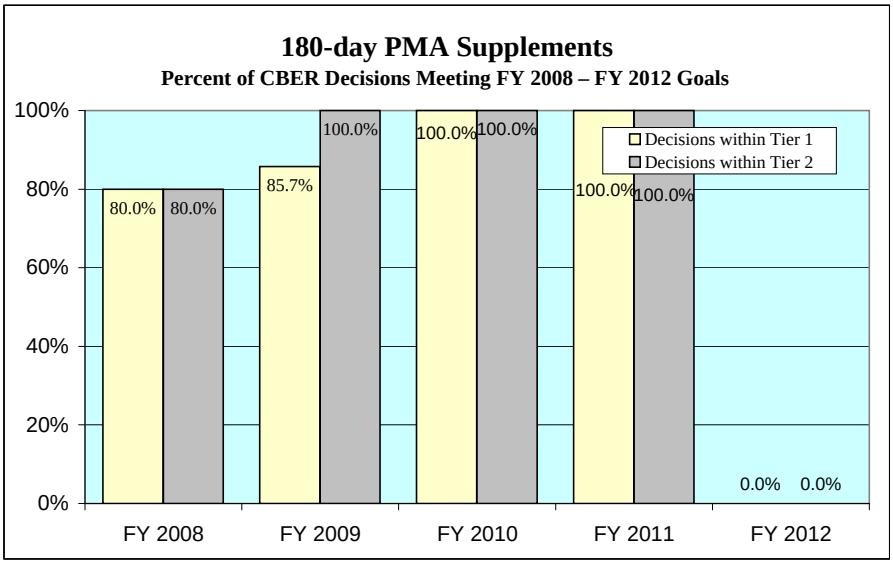
PMA Modules

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	5	—
MDUFMA Cohort	0	0	1	5	—
Total FDA Decisions	0	0	1	2	—
Percent within Tier 1 goal (90 days)	--	--	100.0%	100.0%	—
Tier 1 goal — *Percent within 90 days*	*75%*	*75%*	*75%*	*75%*	*75%*
Percent within Tier 2 goal (120 days)	--	--	100.0%	100.0%	—
Tier 2 goal — *Percent within 120 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	—



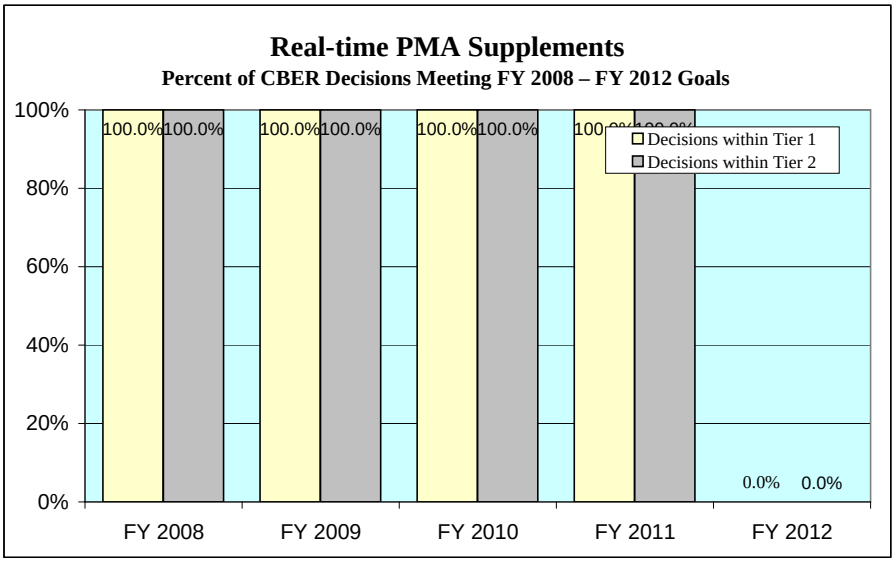
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	9	—
Total FDA Decisions	5	7	7	2	—
Percent within Tier 1 goal (180 days)	80.0%	85.7%	100.0%	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%	100.0%	—
Tier 2 goal — *Percent within 210 days*	*95%*	*95%*	*95%*	*95%*	*95%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	—



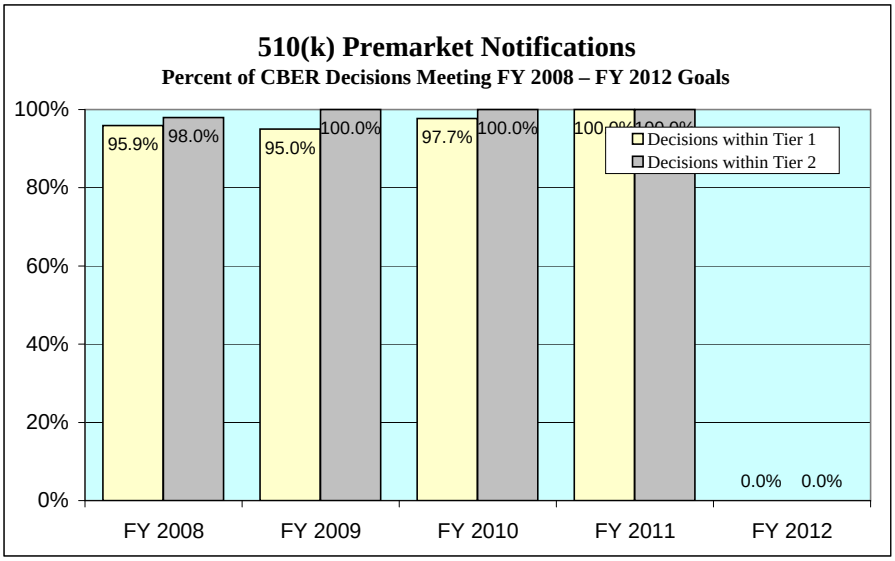
Real-time PMA Supplements

	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*	*Complete*	—



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	53	50	55	44	—
MDUFMA Cohort	49	41	45	42	—
Total FDA Decisions	49	40	43	14	—
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.7%	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	*Complete*	Open	Open	Open	—



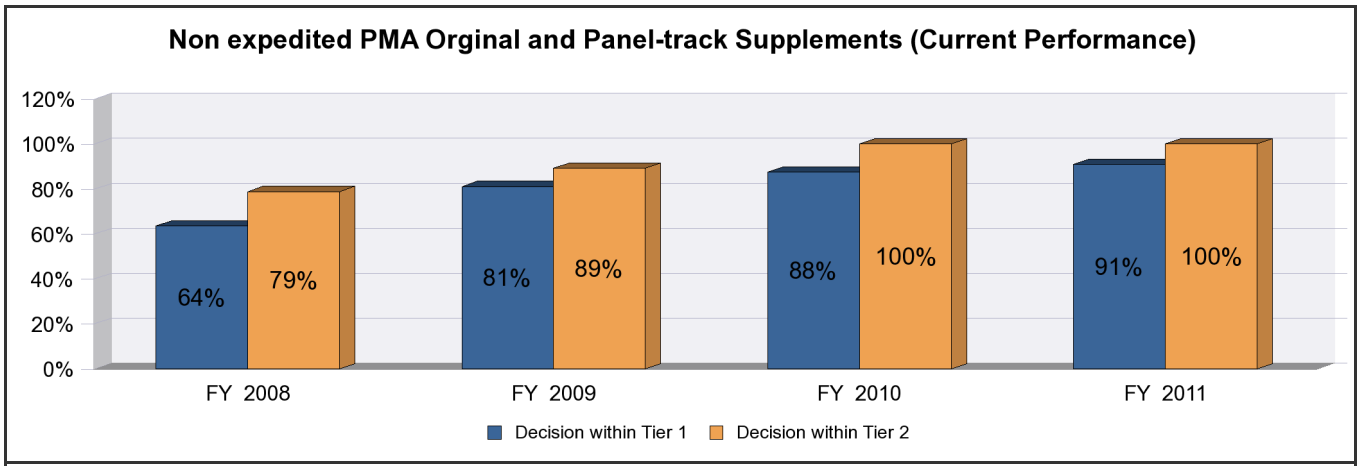
Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----

Action through 30 September 2011

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

For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	33	39	53	43
Total FDA Decision	33	37	40	11
Tier 1 goal -- Percent within 180 Days	*60%*	*60%*	*60%*	*60%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown
Pending Performance-Best Case	64%	77%	79%	91%
Pending Performance-Worst Case	64%	77%	66%	23%
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%	96%	100%
Pending Performance-Worst Case	79%	85%	75%	26%
Cohort status	Complete	Open	Open	Open



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

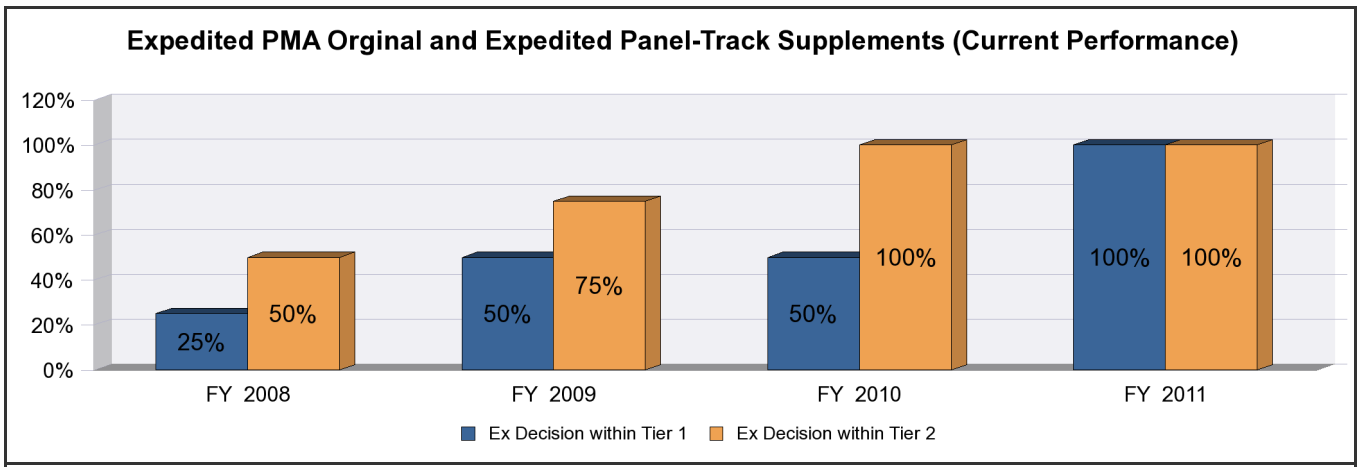
For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	Tier 1											Tier 2						
	Number Submissions	Number with MDUFA	Number with Non MDUFA (OTHER) decision	Goal Met Number 180 Days	Goal Not Met Number 180 Days	Decision within Tier 1	Total Pending Submissions	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %	Goal Met Number 295 Days	Goal Not Met Number 295 Days	Decision within Tier 2	Still Can Meet The Goal	Already Missed The Goal	510_Best Case %	Worst Case %
FY 2008	33	33		21	12	63.64%				63.64%	63.64%	26	7	78.79%			78.79%	78.79%
FY 2009	39	37		30	7	81.08%	2		2	76.92%	76.92%	33	4	89.19%		2	84.62%	84.62%
FY 2010	53	40		35	5	87.50%	13	7	6	79.25%	66.04%	40		100.00%	11	2	96.23%	75.47%
FY 2011	43	11		10	1	90.91%	32	29	3	90.70%	23.26%	11		100.00%	32		100.00%	25.58%

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

For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	4	4	6	7
Total FDA Decision	4	4	4	1
Tier 1 goal -- Percent within 180 Days	*50%*	*50%*	*50%*	*50%*
Goal met(yes/no/unknown)	no	yes	no	unknown
Pending Performance-Best Case	25%	50%	33%	71%
Pending Performance-Worst Case	25%	50%	33%	14%
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%	67%	14%
Cohort status	Complete	Complete	Open	Open



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

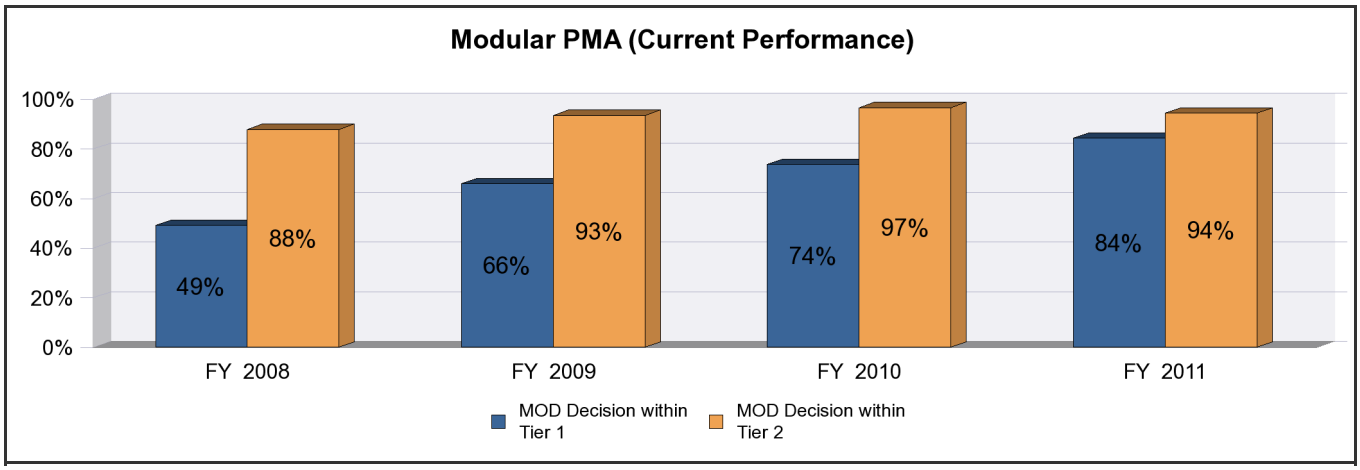
For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	Tier 1											Tier 2						
	Number Submissions	Number with MDUFA	Number with Non MDUFA (OTHER) decision	Goal Met Number 180 Days	Goal Not Met Number 180 Days	Decision within Tier 1	Total Pending Submissions	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %	Goal Not Met Number 280 Days	Goal Not Met Number 280 Days	Decision within Tier 2	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %
FY 2008	4	4		1	3	25.00%				25.00%	25.00%	2	2	50.00%			50.00%	50.00%
FY 2009	4	4		2	2	50.00%				50.00%	50.00%	3	1	75.00%			75.00%	75.00%
FY 2010	6	4		2	2	50.00%	2		2	33.33%	33.33%	4		100.00%	2		100.00%	66.67%
FY 2011	7	1		1		100.00%	6	4	2	71.43%	14.29%	1		100.00%	6		100.00%	14.29%

MDUFA II Quarterly (Modular PMA)

For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Cycle Started)	57	90	104	85
Total FDA Decision	49	76	87	70
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%	86%
Pending Performance-Worst Case	49%	64%	74%	74%
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%	95%
Pending Performance-Worst Case	88%	91%	97%	83%
Cohort status	Complete	Open	Complete	Open



MDUFA II Quarterly (Modular PMA)

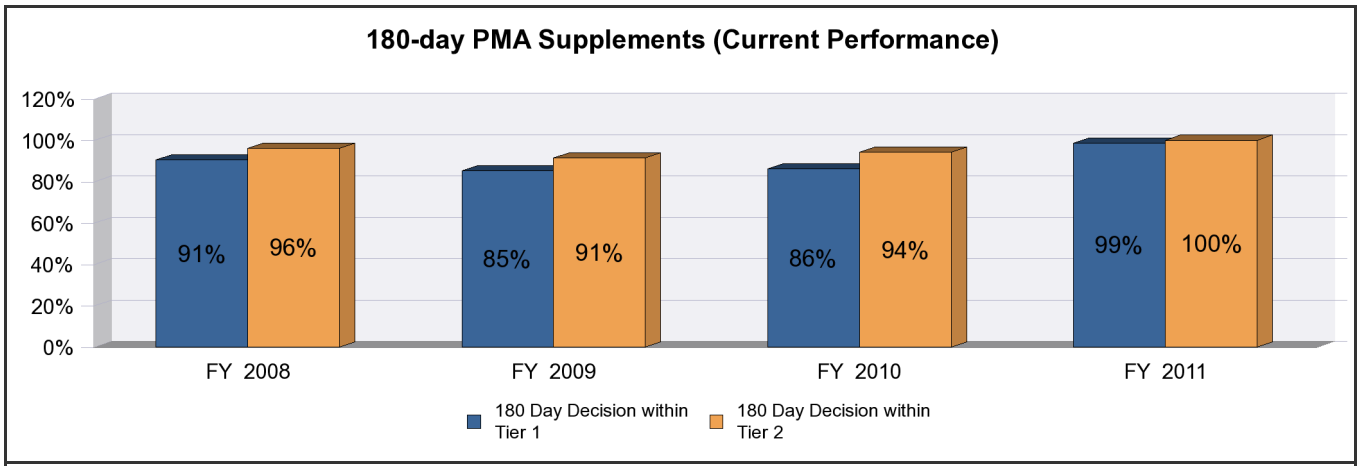
For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	Tier 1												Tier 2						
	Number Submissions	Cycles started	Number with MDUFA	Number with Non MDUFA (OTHER) decision	Goal Met Number 90 Days	Goal Not Met Number 90 Days	Decision within Tier 1	Total Pending Submissions	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %	Goal Met Number 120 Days	Goal Not Met Number 120 Days	Decision within Tier 2	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %
FY 2008	45	57	49	8	24	25	48.98%				48.98%	48.98%	43	6	87.76%			87.76%	87.76%
FY 2009	68	90	76	12	50	26	65.79%	2		2	65.79%	64.10%	71	5	93.42%		2	93.42%	91.03%
FY 2010	86	104	87	17	64	23	73.56%				73.56%	73.56%	84	3	96.55%			96.55%	96.55%
FY 2011	73	85	70	5	59	11	84.29%	10	8	2	85.90%	73.75%	66	4	94.29%	9	1	94.94%	82.50%

MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	170	166	157	145
Total FDA Decision	160	162	138	77
Tier 1 goal -- Percent within 180 Days	*85%*	*85%*	*85%*	*85%*
Goal met(yes/no/unknown)	yes	yes	unknown	unknown
Pending Performance-Best Case	90%	85%	85%	99%
Pending Performance-Worst Case	90%	85%	79%	52%
Tier 2 goal -- Percent within 210 days	*95%*	*95%*	*95%*	*95%*
Goal met(yes/no/unknown)	yes	no	no	unknown
Pending Performance-Best Case	95%	91%	92%	99%
Pending Performance-Worst Case	95%	91%	86%	53%
Cohort status	Open	Open	Open	Open



MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	Tier 1											Tier 2						
	Number Submissions	Number with MDUFA	Number with Non MDUFA (OTHER) decision	Goal Met Number 180 Days	Goal Not Met Number 180 Days	Decision within Tier 1	Total Pending Submissions	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %	Goal Met Number 210 Days	Goal Not Met Number 210 Days	Decision within Tier 2	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %
FY 2008	170	160	8	145	15	90.63%	2		2	89.51%	89.51%	154	6	96.25%		2	95.06%	95.06%
FY 2009	166	162	3	138	24	85.19%	1	1		85.28%	84.66%	148	14	91.36%	1		91.41%	90.80%
FY 2010	157	138	6	119	19	86.23%	13	9	4	84.77%	78.81%	130	8	94.20%	9	4	92.05%	86.09%
FY 2011	145	77		76	1	98.70%	68	67	1	98.62%	52.41%	77		100.00%	67	1	99.31%	53.10%

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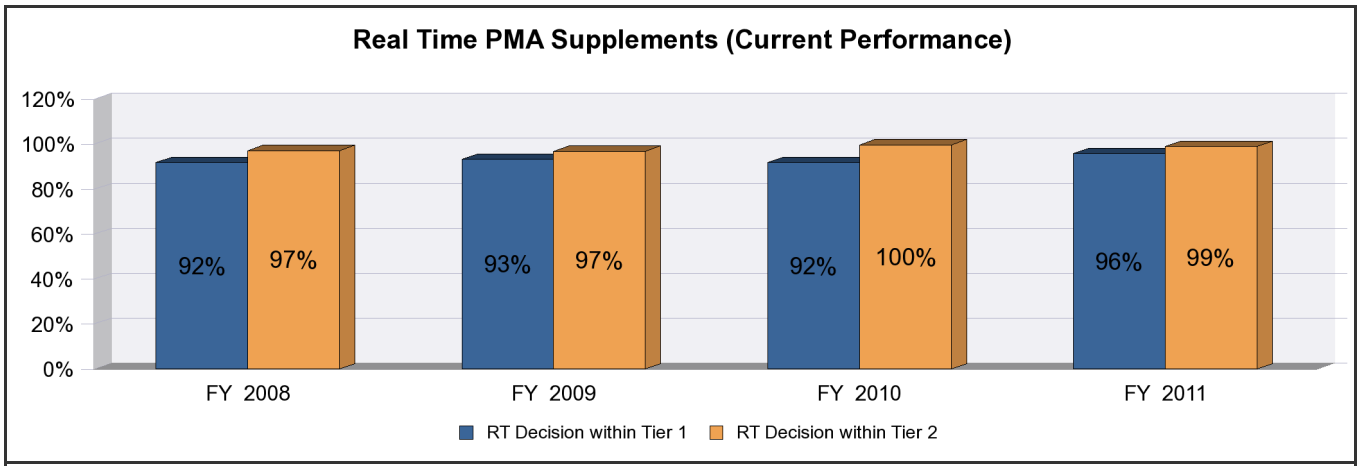
MDUFA II Quarterly (Real Time PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	249	296	269	244
Total FDA Decision	241	280	258	186
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%	92%	96%
Pending Performance-Worst Case	92%	93%	92%	75%
Tier 2 goal -- Percent within 90 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown
Pending Performance-Best Case	97%	97%	100%	99%
Pending Performance-Worst Case	97%	97%	100%	78%
Cohort status	Complete	Complete	Complete	Open



MDUFA II Quarterly (Real Time PMA Supplements)

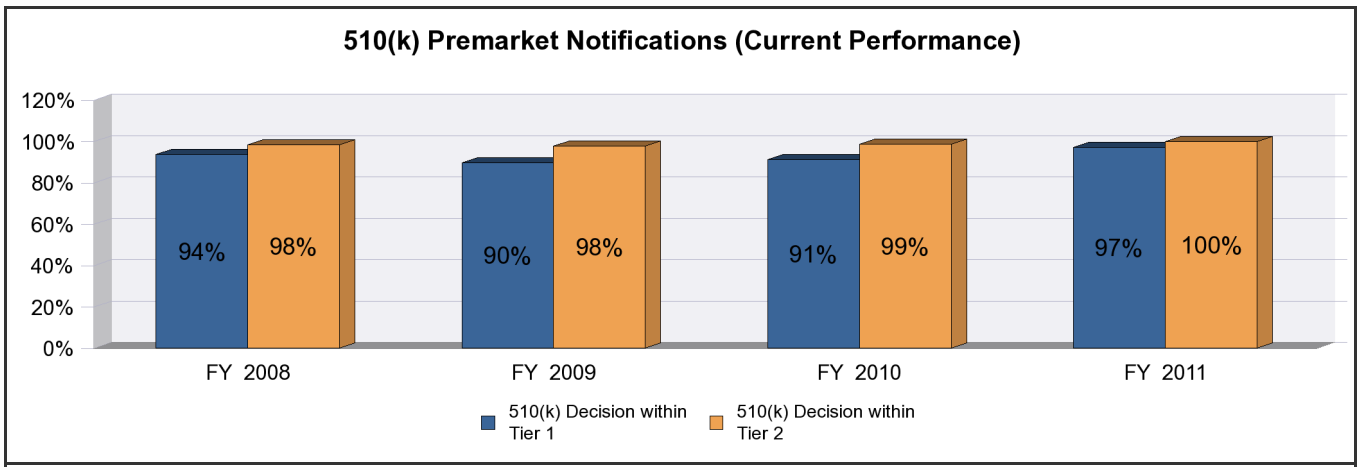
For Submissions Filed Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	Tier 1											Tier 2						
	Number Submissions	Number with MDUFA	Number with Non MDUFA (OTHER)decision	Goal Met Number 60 Days	Goal Not Met Number 60 Days	Decision within Tier 1	Total Pending Submissions	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %	Goal Met Number 90 Days	Goal Not Met Number 90 Days	Decision within Tier 2	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %
FY 2008	249	241	8	221	20	91.70%		0		91.70%	91.70%	234	7	97.10%	0	0	97.10%	97.10%
FY 2009	296	280	16	261	19	93.21%		0		93.21%	93.21%	271	9	96.79%	0	0	96.79%	96.79%
FY 2010	269	258	11	237	21	91.86%		0		91.86%	91.86%	257	1	99.61%	0	0	99.61%	99.61%
FY 2011	244	186	7	178	8	95.70%	51	50	1	96.20%	75.11%	184	2	98.92%	51	0	99.16%	77.64%

MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Received to Date)	3,848	4,103	3,880	3,833
MDUFA Cohort	3,260	3,403	3,178	3,618
Total FDA Decision	3,258	3,398	3,080	1,904
Tier 1 goal -- Percent within 90 Days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	unknown	unknown
Pending Performance-Best Case	94%	90%	91%	98%
Pending Performance-Worst Case	94%	90%	88%	51%
Tier 2 goal -- Percent within 150 Days	*98%*	*98%*	*98%*	*98%*
Goal met(yes/no/unknown)	yes	yes	unknown	unknown
Pending Performance-Best Case	98%	98%	99%	100%
Pending Performance-Worst Case	98%	98%	96%	53%
Cohort status	Open	Open	Open	Open



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2011 as of 09/30/2011 11:59:00 PM

	Tier 1											Tier 2						
	Number Submissions	Number with MDUFA	Number with Non MDUFA (OTHER)decision	Goal Met Number 90 Days	Goal Not Met Number 90 Days	Decision within Tier 1	Total Pending Submissions	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %	Goal Met Number 150 Days	Goal Not Met Number 150 Days	Decision within Tier 2	Still Can Meet The Goal	Already Missed The Goal	Best Case %	Worst Case %
FY 2008	3,848	3,258	588	3,052	206	93.68%	2	2		93.68%	93.62%	3,206	52	98.40%	2		98.40%	98.34%
FY 2009	4,103	3,398	700	3,048	350	89.70%	5		5	89.70%	89.57%	3,320	78	97.70%		5	97.70%	97.56%
FY 2010	3,880	3,080	702	2,807	273	91.14%	98	69	29	91.33%	88.33%	3,035	45	98.54%	87	11	98.58%	95.50%
FY 2011	3,833	1,904	215	1,847	57	97.01%	1,714	1,667	47	98.40%	51.05%	1,900	4	99.79%	1,710	4	99.89%	52.52%

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
		399		399
	DENY - Denied	102		102
		129		129
		189		189
		199		199
		287		287
		320	424	744
	TH - Telephone Hold	136	1219	1355
2008 Total	12			
2009	APPR - Approved	204	64	268
		233		233
	DENY - Denied	285		285
		644	7	651
		740		740
	TH - Telephone Hold	33	944	977
		259	629	888
		518	167	685
2009 Total	8			
2010	APPR - Approved	77		77
	DENY - Denied	105	106	211
		172		172
		248		248
		266		266
	Under Review	518		518
		543		543
2010 Total	7			
2011	AI - Request For Additional Information	84	40	124
		165	32	197
	APPR - Approved	27		27
	Under Review	15		15
		15		15
		243		243
2011 Total	6			
Grand Total	33			

As of 10/04/11

October 2011
MDUFA Stakeholder Meeting
Appropriations Update

FY 2011 Appropriations Update

CDRH received $6.8 million in funding increases in FY 2011 for the National Medical Device Registry, an interagency nanotechnology initiative, pediatric device safety, and other vital medical device safety efforts.

The unpredictability of final funding created by a series of long-term continuing resolutions (CR) posed budget and hiring challenges.

- Final funding levels were not provided until half of the fiscal year had lapsed.
- To be prudent, the Center delayed spending money during the first half of the year to prepare for potential cuts.
- Once the final CR was approved, the Center moved quickly to spend additional resources in a short period of time. By April, when the final funds were released, contracting deadlines were rapidly approaching and planning decisions were made immediately.

FY 2012 Appropriations Update

House:

The FY 2012 Agriculture, Rural Development, FDA, and Related Agencies Appropriations bill (H.R. 2112), passed by the House, would:

- Cut the President's proposed budget authority for FDA by $572 million.
- Provide $270.3 million in budget authority for the Device Program including the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs.
- Meet the FY 2012 budget authority (BA) trigger for MDUFA user fees enabling the Device Program to utilize these funds.

Senate:

The FY 2012 Agriculture, Rural Development, FDA, and Related Agencies Appropriations bill, approved by the Senate Appropriations Committee, would:

- Cut the President's proposed budget authority for FDA by $238 million.

- Provide $322.4 million in budget authority for the Devices Program.
- The Senate bill matches the revised MDUFA user fee revenue target published in the Federal Register on August 1, 2011.
- The budget authority increase includes $19 million for an interagency Medical Countermeasures Initiative. The Devices Program would receive a portion of these funds.

FY 2012 Continuing Resolution (CR)

- Since the House and Senate were unable to complete the appropriations process by the end of the fiscal year, FDA – and many other Departments and Agencies -- are now operating under the second of two continuing resolutions. The current CR will fund the Agency's operations through November 18.

Establishments by Establishment Type - As of 9/30/2011

The hierachy is based on the ranking in the left-most column. For example, if an establishment is both a manufacturer and a contract manufacturer, it will be counted only as a manufacturer.

		Domestic	Foreign	Total
1	Manufacturer*	5,131	7,364	12,495
2	Contract Manufacturer*	305	662	967
3	Contract Sterilizer*	19	41	60
4	Specification Developer*	1,538	322	1,860
5	Reprocessor of Single Use Devices*	14		14
6	U.S. Manufacturer of Export Only Devices*	115		115
7	Repackager/Relabeler	1,729	413	2,142
8	Remanufacturer	56	83	139
9	Foreign Exporter		1,177	1,177
10	Initial Distributor/Importer	4,972		4,972
	Unknown	2		2
	Total:	**13,881**	**10,062**	**23,943**

*Establishment types marked with an asterisk are required to pay the annual registration user fee.