Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance

11:00 a.m. – 12:00 p.m., Wednesday, January 26, 2011
Room 2442, Bldg 31, White Oak

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

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

FDA MDUFMA / MDUFA Performance — Actions through December 31, 2010

- Reports on all decision goals for the FY 2003 - 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 — 4th Quarter of FY 2010

- User fee receipts through the 1st Quarter of FY 2011, compared with expectations. *Handout, David Miller, FDA-OFM.*
- Update on Budget Requests and appropriations. *Daniel Montgomery, CDRH-OMO.*

Medical Device Registration and Listing

- Report on medical device registration and Listing statistics. Jennifer Medicus, CDRH-OC.

CDRH Staff Training Update

- Report on CDRH staff training. Laura Stewart, CDRH-OCER

Discussion

- Questions from industry.
- Set date for next meeting, following close of Q2. Target: Week of 4/27/2011.

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Medical Device Guidance Documents
Issued During 1st Quarter FY 2011
Through December 31, 2010

First Quarter (October 2010 – December 2010)

1. Guidance for Industry and Food and Drug Administration Staff - Blood Lancet Labeling
   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm234577.htm (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 Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of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
   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm234868.htm (11-29-10)

3. The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13
   http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM185904.pdf (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)
   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm233275.htm (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
   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm233027.htm (11-10-10)

6. Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System
   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107552.htm (11/5/10)

7. Guidance for Industry: Cellular Therapy for Cardiac Disease
   http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/ucm164265.htm (11-4-10)

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

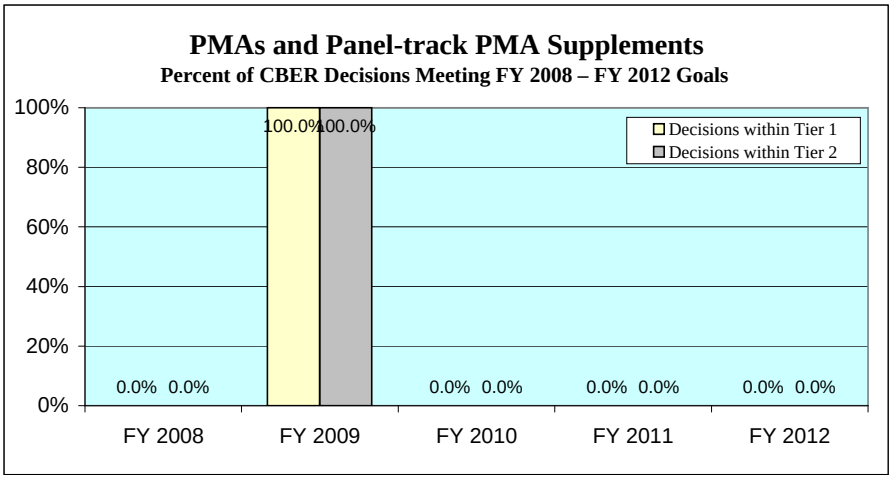
Actions through 31 December 2010

Data on FY 2008 – FY 2012 Cohorts

Actions through 31 December 2010

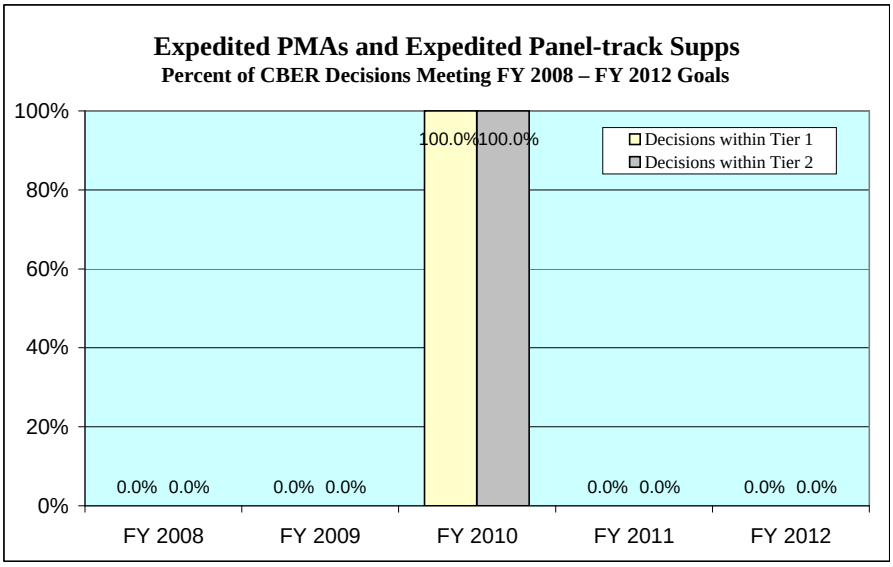
PMAs and Panel-track Supplements

	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	—



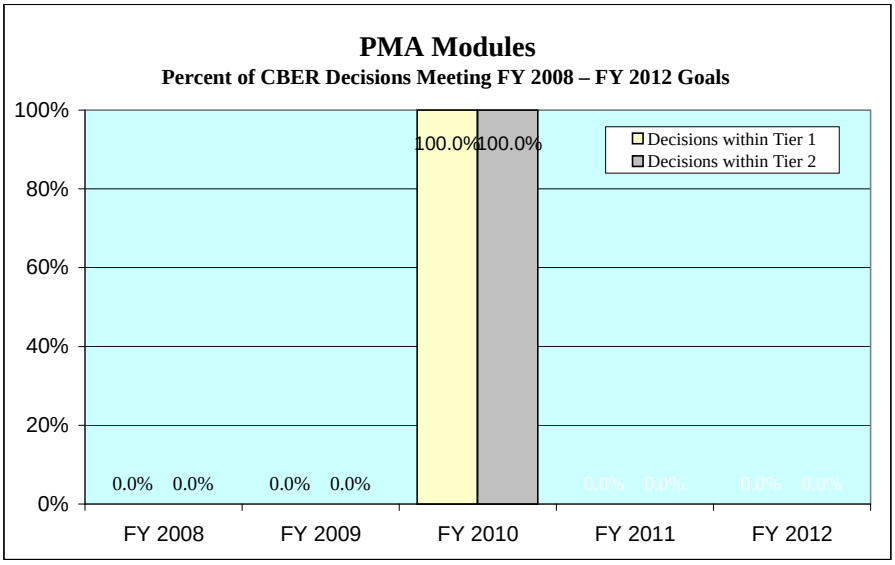
Expedited PMAs and Expedited Panel-track Supplements

	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	—



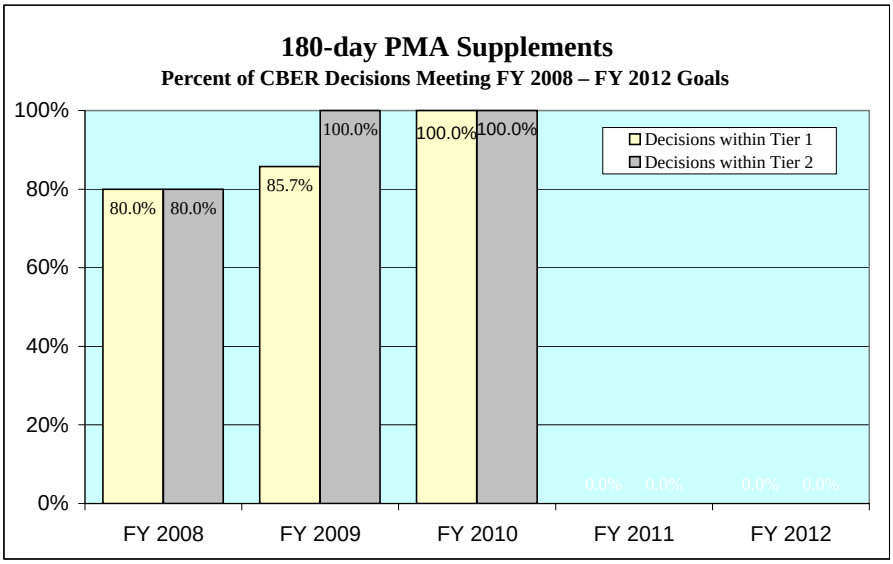
PMA Modules

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	0	—
MDUFMA Cohort	0	0	1	0	—
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	—



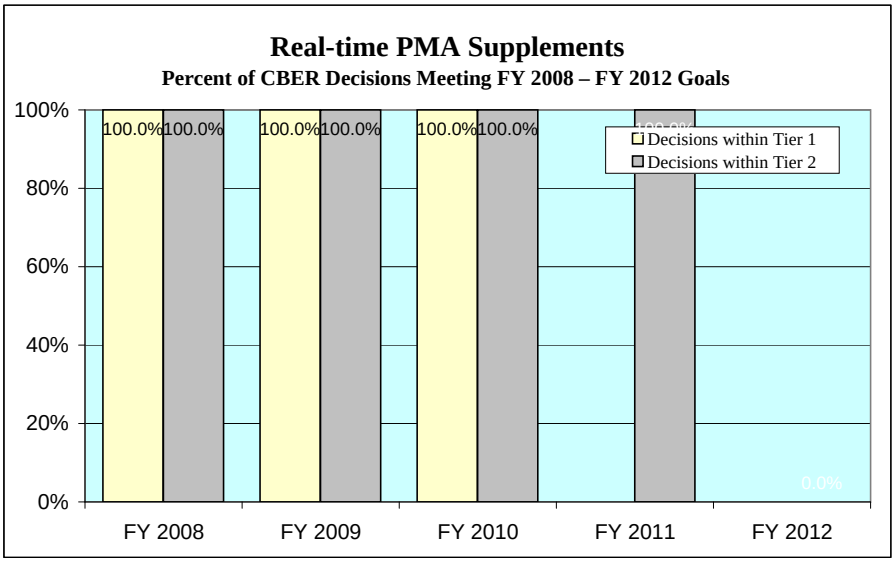
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	2	—
Total FDA Decisions	5	7	5	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*	Open	Open	—



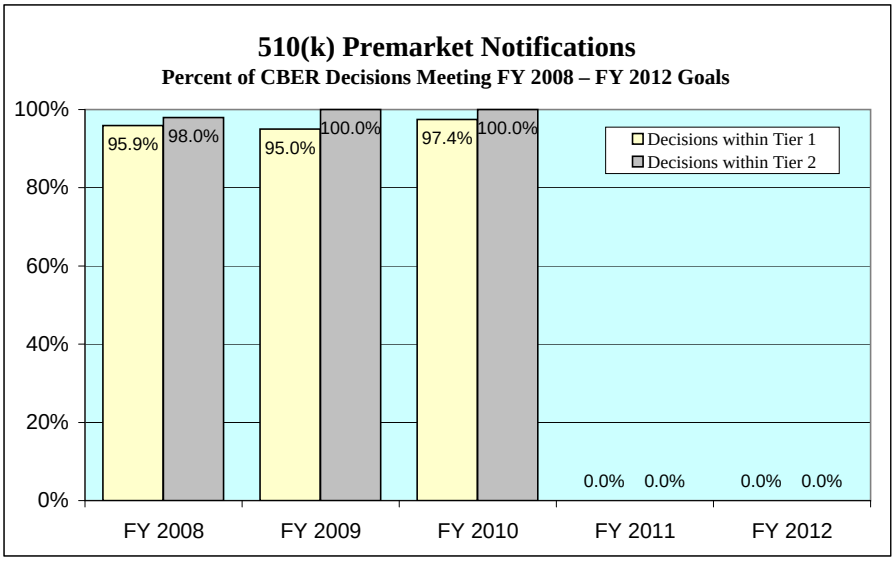
Real-time PMA Supplements

	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	9	—
MDUFMA Cohort	51	42	49	8	—
Total FDA Decisions	49	40	39	0	—
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.4%	--	—
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%	--	—
Tier 2 goal — *Percent within 150 days*	*98%*	*98%*	*98%*	*98%*	*98%*
Cohort status	Open	Open	Open	Open	—



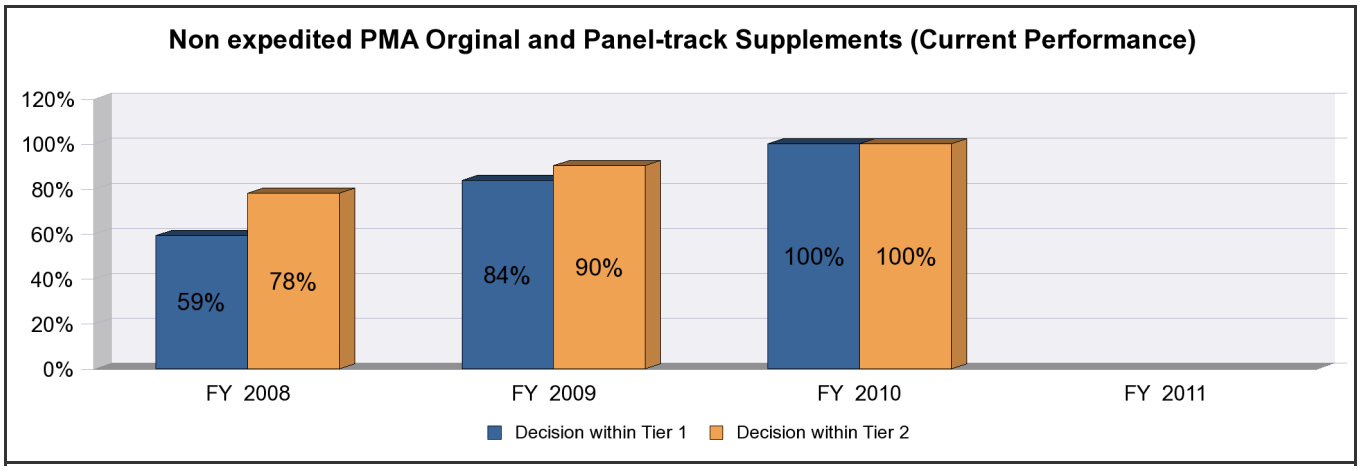
Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----

Action through 31 December 2010

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

For Submissions Filed Between Year 2008 to 2011 as of 12/31/2010 11:59:00 PM

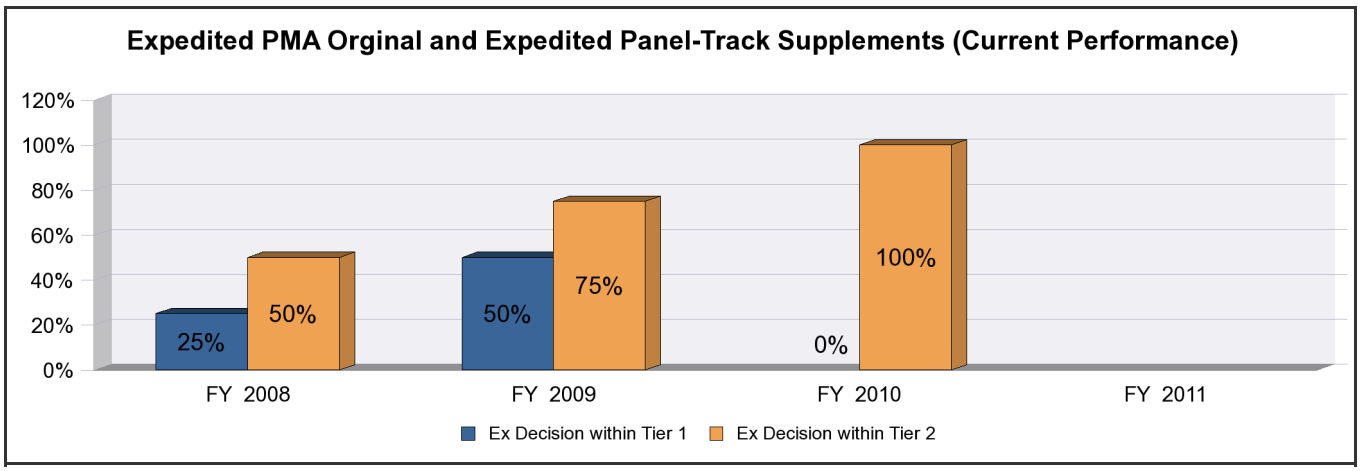
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	33	39	53	8
Total FDA Decision	32	31	8	0
Tier 1 goal -- Percent within 180 Days	*60%*	*60%*	*60%*	*60%*
Goal met(yes/no/unknown)	unknown	yes	unknown	unknown
Pending Performance-Best Case	61%	74%	92%	100%
Pending Performance-Worst Case	58%	67%	15%	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%	87%	100%	100%
Pending Performance-Worst Case	76%	72%	15%	0%
Cohort status	Open	Open	Open	Open



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

For Submissions Filed Between Year 2008 to 2011 as of 12/31/2010 11:59:00 PM

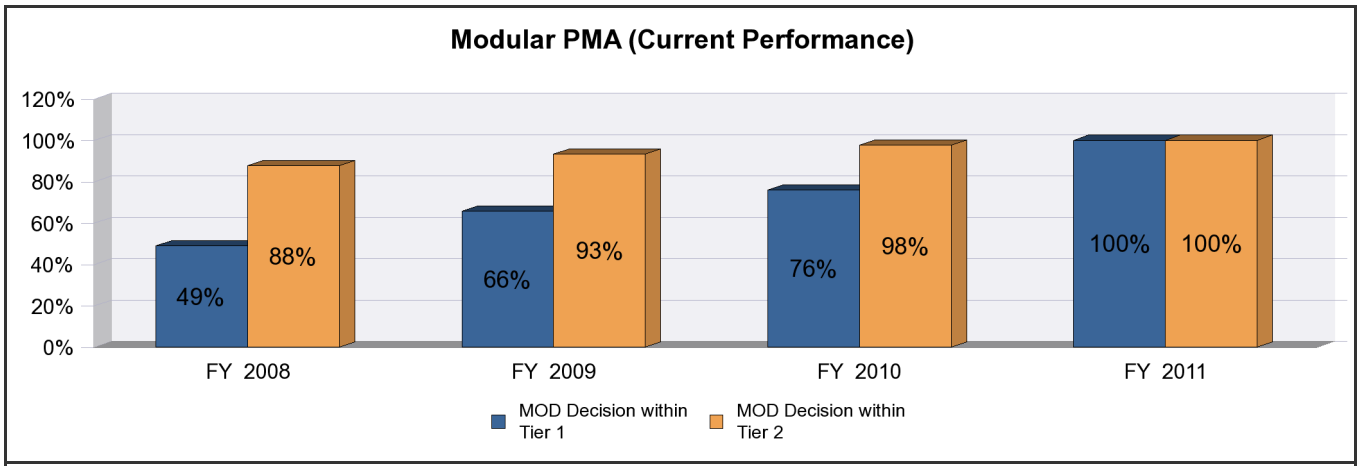
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	4	4	6	1
Total FDA Decision	4	4	1	0
Tier 1 goal -- Percent within 180 Days	*50%*	*50%*	*50%*	*50%*
Goal met(yes/no/unknown)	no	yes	unknown	unknown
Pending Performance-Best Case	25%	50%	67%	100%
Pending Performance-Worst Case	25%	50%	0%	0%
Tier 2 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 12/31/2010 11:59:00 PM

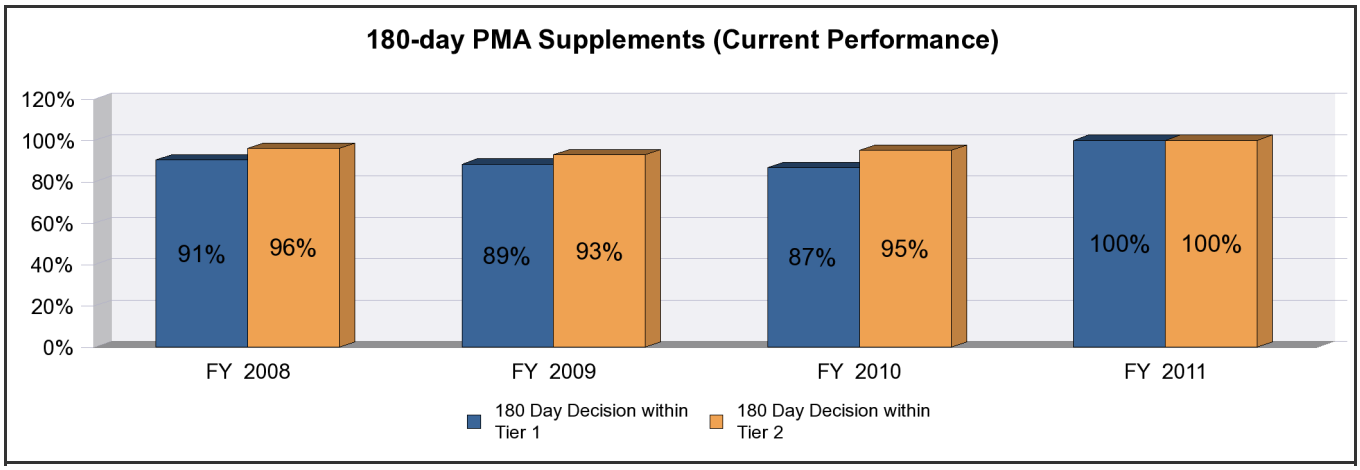
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Cycle Started)	45	68	85	24
Total FDA Decision	49	76	83	3
Tier 1 goal -- Percent within 90 Days	*75%*	*75%*	*75%*	*75%*
Goal met(yes/no/unknown)	no	no	unknown	unknown
Pending Performance-Best Case	49%	66%	76%	100%
Pending Performance-Worst Case	49%	64%	74%	13%
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%	98%	100%
Pending Performance-Worst Case	88%	91%	95%	13%
Cohort status	Complete	Open	Open	Open



MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 12/31/2010 11:59:00 PM

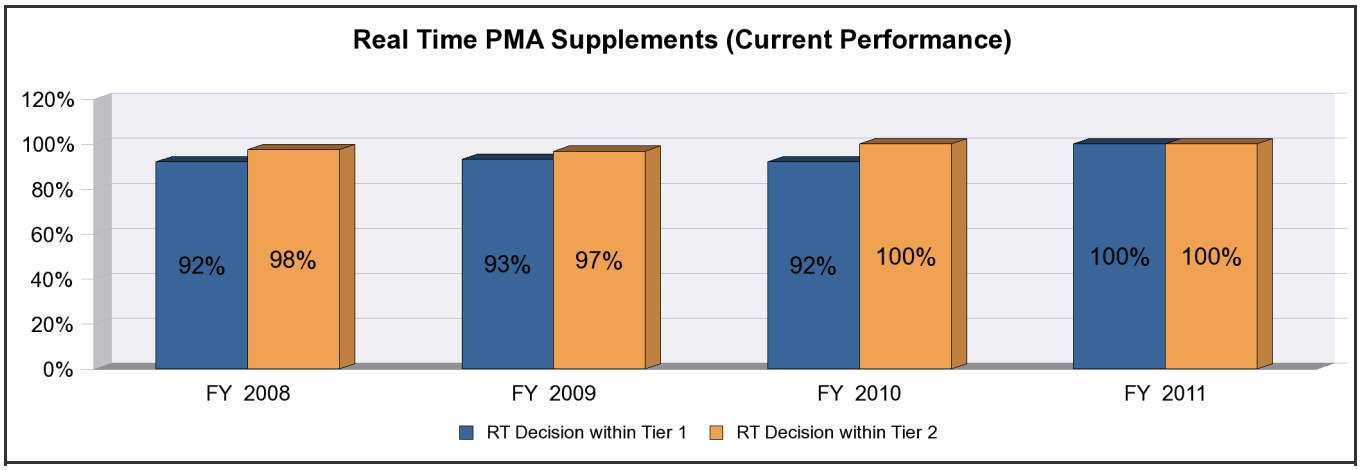
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	170	167	157	32
Total FDA Decision	160	157	84	1
Tier 1 goal -- Percent within 180 Days	*85%*	*85%*	*85%*	*85%*
Goal met(yes/no/unknown)	yes	yes	unknown	unknown
Pending Performance-Best Case	90%	87%	88%	100%
Pending Performance-Worst Case	90%	85%	48%	3%
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%	92%	96%	100%
Pending Performance-Worst Case	95%	89%	53%	3%
Cohort status	Open	Open	Open	Open



MDUFA II Quarterly (Real Time PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 12/31/2010 11:59:00 PM

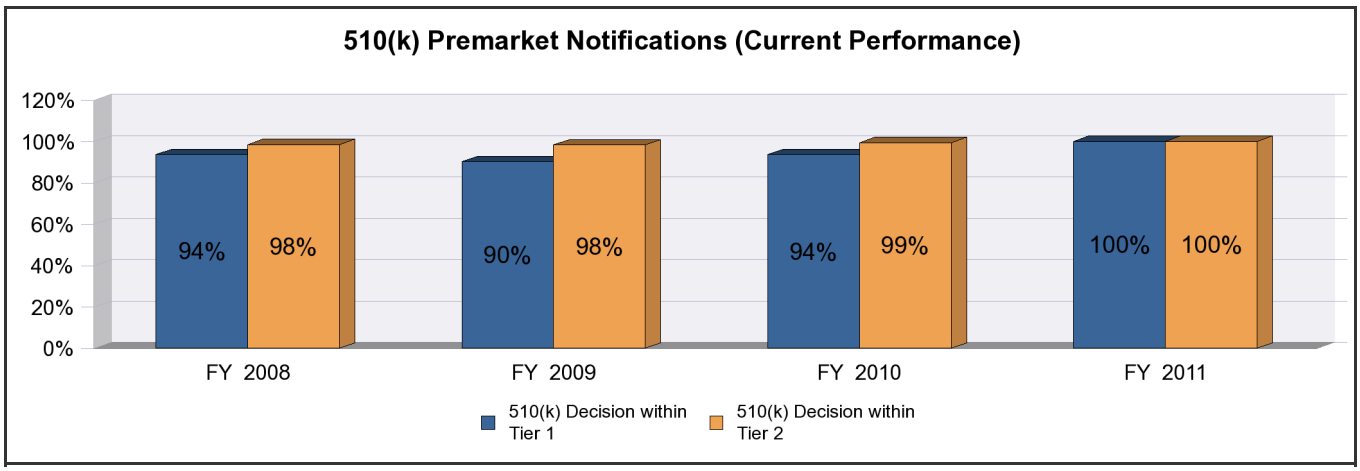
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	249	295	269	49
Total FDA Decision	241	279	256	1
Tier 1 goal -- Percent within 60 Days	*80%*	*80%*	*80%*	*80%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown
Pending Performance-Best Case	92%	93%	91%	86%
Pending Performance-Worst Case	92%	93%	91%	2%
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%	2%
Cohort status	Complete	Complete	Open	Open



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2011 as of 12/31/2010 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Received to Date)	3,848	4,103	3,881	918
MDUFA Cohort	3,262	3,422	3,452	910
Total FDA Decision	3,256	3,365	2,458	118
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%	95%	100%
Pending Performance-Worst Case	94%	89%	67%	13%
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%	100%	100%
Pending Performance-Worst Case	98%	97%	71%	13%
Cohort status	Open	Open	Open	Open



CLIA ***WAIVER BY APPLICATION*** WORKLOAD

CLIA Waiver *Decisions Made During FY2009*				
#	**FDA Decision**	**FDA Days**	**MFG Days**	**Total**
1	APPR – Approved	248	38	286
2	APPR – Approved	248	38	286
3	APPR – Approved	398	0	398
4	APPR – Approved	398	0	398

CLIA Waiver *Decisions Made During FY2010*				
#	**FDA Decision**	**FDA Days**	**MFG Days**	**Total**
1	APPR – Approved	77	0	77
2	APPR – Approved	233	0	233
3	APPR – Approved	204	64	268
4	DENIED	320	424	744
6	DENIED	172	0	172
7	DENIED	285	0	285

CLIA Waiver *Decisions Made During FY2011*				
#	**FDA Decision**	**FDA Days**	**MFG Days**	**Total**
1	DENIED	644	7	751

Number of Waiver Applications not yet completed			
Fiscal Year *(Receipt Cohort)*	**On Hold**	**Under Review**	**Total**
2009	3	1	4
2010	0	2	2
2011	0	0	0

1/19/2011

FY 2011 Medical Device User Fee Collections[2]
As of December 31, 2010

Source	FY 2011	FY 2011 Fee Revenues				FY 2011 Surplus
	Authorized[1]	Receipts	Refunds	Net	% of Authorized	*cf.* Authorized
Establishment Registration Fe	$32,685,000	$28,419,286	$0	$28,419,286	86.9%	-$4,265,714
Application / Reporting Fees	$29,175,009	$9,861,048	$637	$9,860,411	33.8%	-$19,314,599
Total	**$61,860,009**	$38,280,333	$637	**$38,279,696**	**61.9%**	**-$23,580,313**

[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	$26,280,073	$31,680,296	$34,485,288	$27,808,956	$47,771,833	$55,667,167	$62,427,502

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 2011 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.

FY '11 Staff College Internal Training Summary Report

From 10/01/2010 to 12/31/2010

As of: **01/18/2011**

FY 2010 MDUFA-Related Training

FDA continues to invest in internal and external training opportunities supporting the medical devices review process. CDRH's Staff College is a workforce development organization that designs and delivers internal training opportunities to meet the professional needs of FDA staff. As medical device reviews grow increasingly complex, training must keep pace with these advancements. Staff College is committed to leveraging internal and external resources to enhance the training provided to Center staff.

Table X provides a summary of internal training conducted between October 1, 2010 and December 31, 2010. Thirty-eight Staff College training courses and seminars were offered addressing reviewer training, new scientific technologies, law, regulation and guidance updates or leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and activities. The remaining charts illustrate that 472 of the approximately 1300 CDRH staff attended an average of 2 internal Staff College learning events representing 7001 contact hours.

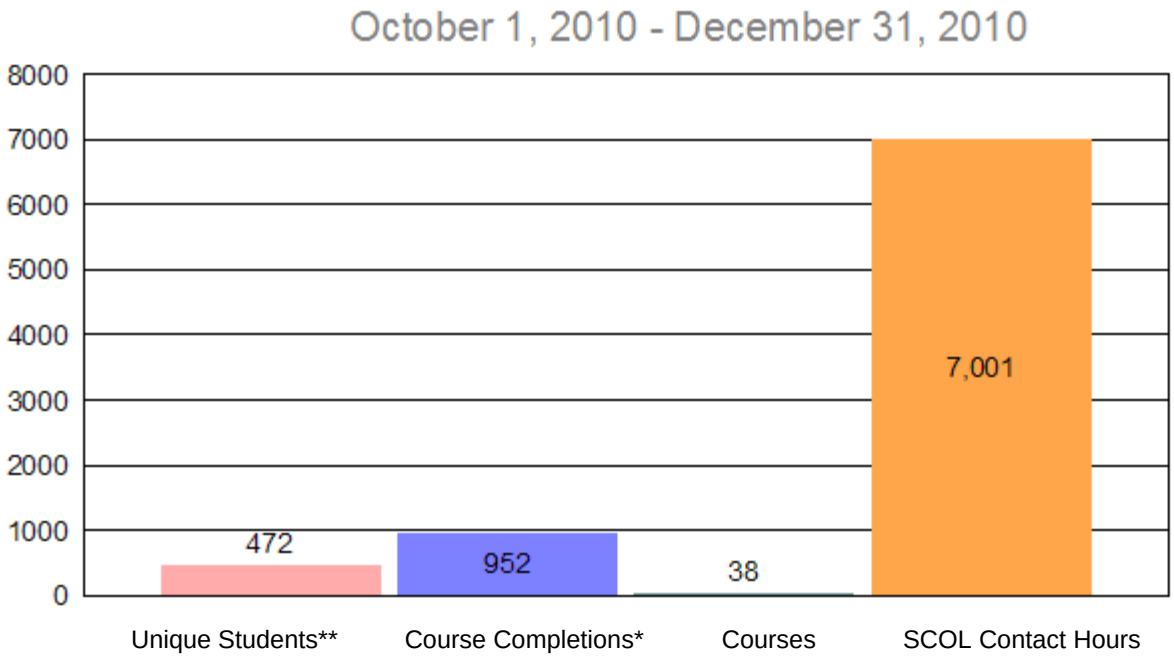
CDRH staff also had opportunities to attend other learning events with a focus on science and application review. Examples of these opportunities include:

- Office Specific Training
    - Office of Device Evaluation Vendor Days
    - Office of Compliance Internal Training
    - Office of Surveillance and Biometrics Internal Training

Table X: MDUFA FY11 CDRH Staff College Internal Training

Topical Area	*# of Learning Events*	*Total # of Participants*	*Examples of Training Conducted/Attended Between 10/1/10 - 12/31/10*
Regulatory and Law (LAW)	**7**	**249**	• Basic Food and Drug Law • Medical Device Law • How to Write Effective Consulting Reviews • How to Write Clear and Concise 510(k) Reviews • Deficiency Writing 4-Part Harmony in Practice • Unique Device Identification
Science (SCI)	**14**	**385**	• Statistics for Diagnostic Devices • Current 510(k) Sterility Review Practices • Regenerative Medicine Series • Basic Respiratory Drug Delivery: Technologies and Frontiers • OC Journal Club – Review of Court Case Involving Medical Device Firms
Leadership Education and Development (LED)	**11**	**223**	• Negotiation and Influencing • Effective Presentations • Project Management • Leadership Forum: Introduction to Situational Leadership
Professional Development (PRO)	**6**	**95**	• Teamwork and Collaboration • Effective Communication Skills for Scientific and Technical Professionals • CDRH New Employee Orientation
TOTAL	**472**	Unique participants	*This total represents the number of unique students overall. Unique students equate to an individual being counted only once within the reporting time period.

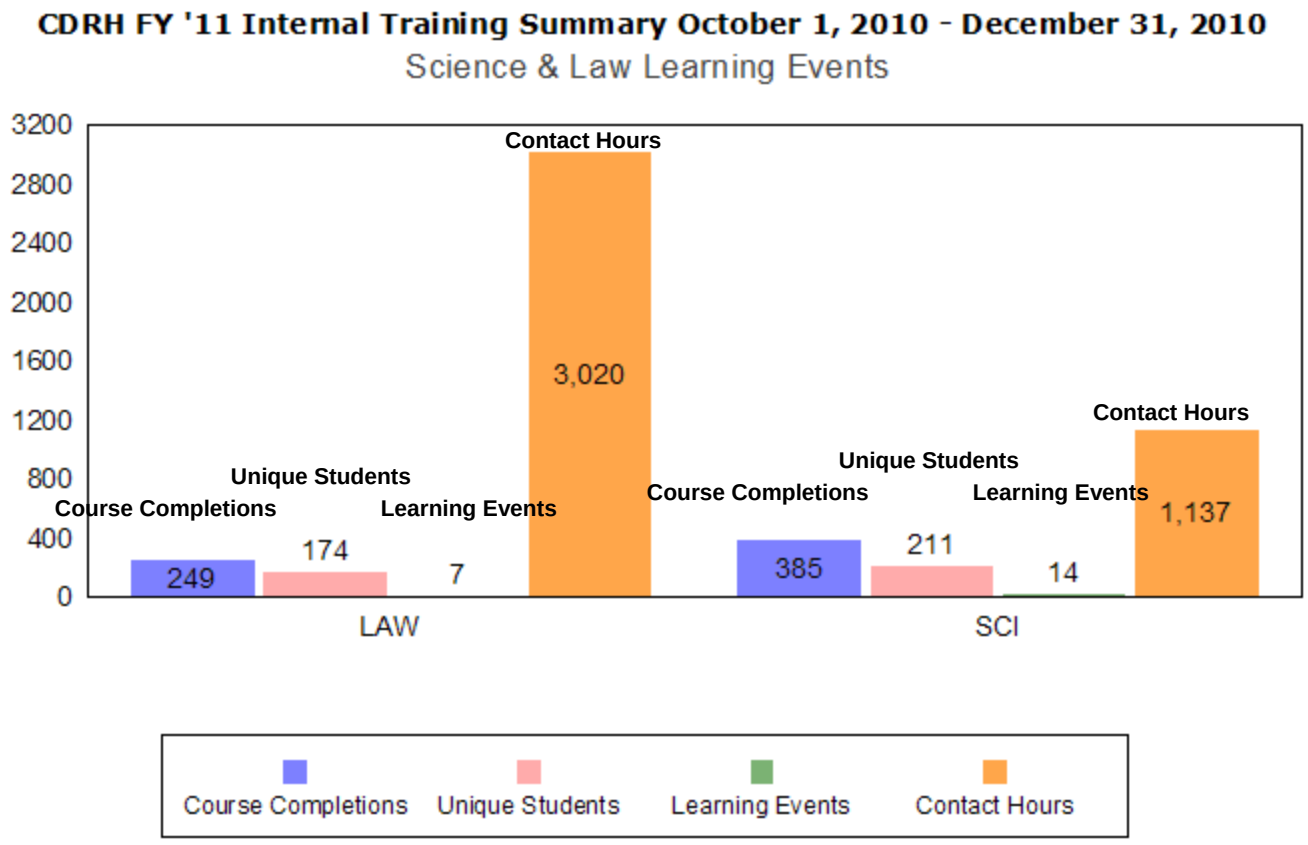
FY '11 Completion Summary Data for CDRH Staff College Internal Learning Events



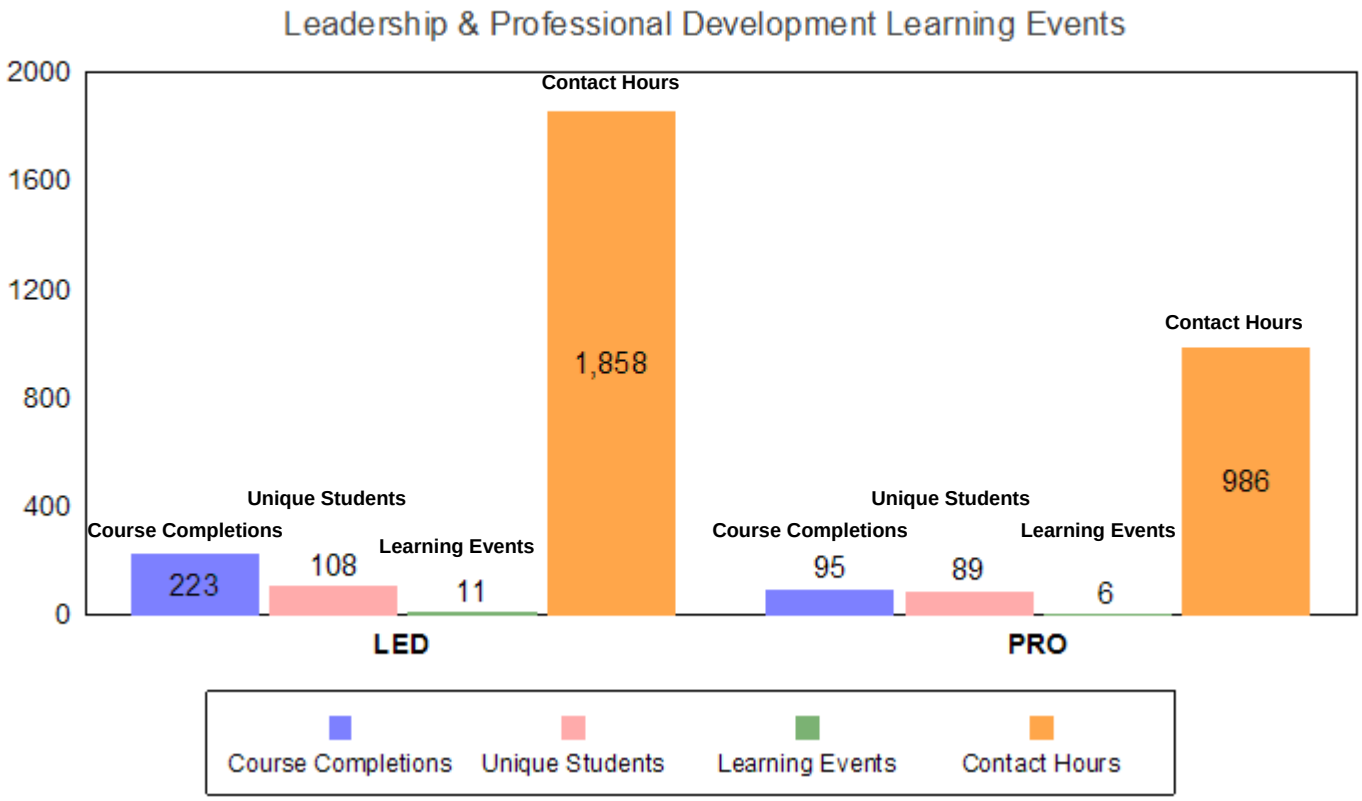
*Course Completions = Successful attendance in a Learning Event

**Unique Students = Number of distinct students

Data date 1/18/2011


CDRH FY '11 Internal Training Summary October 1, 2010 - December 31, 2010
Science & Law Learning Events
3200
2800
2400
2000
1600
1200
800
400
0
Course Completions
Unique Students
Learning Events
Contact Hours
249
174
7
3,020
385
211
14
1,137
LAW
SCI
Course Completions
Unique Students
Learning Events
Contact Hours

CDRH FY '11 Internal Training Summary October 1, 2010 - December 31, 2010



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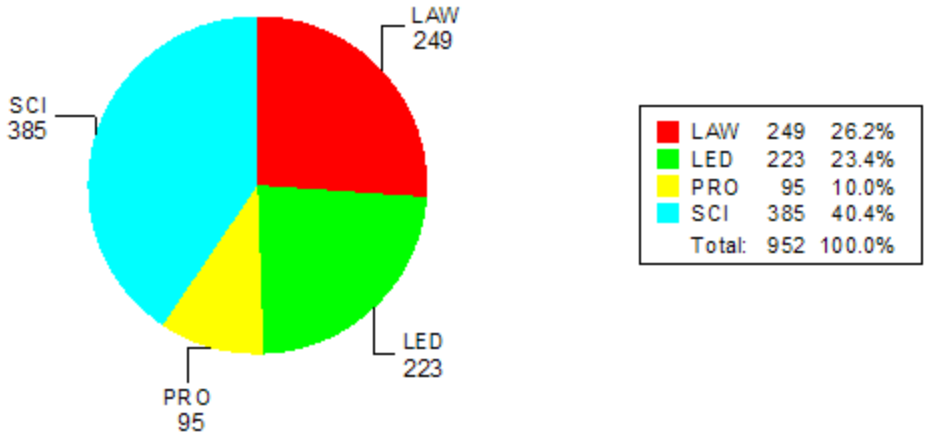
CDRH Total Distribution FY 11 October 1, 2010 - December 31, 2010

Student Course Completions by Category*



*Course Completions = Successful attendance in a Learning Event

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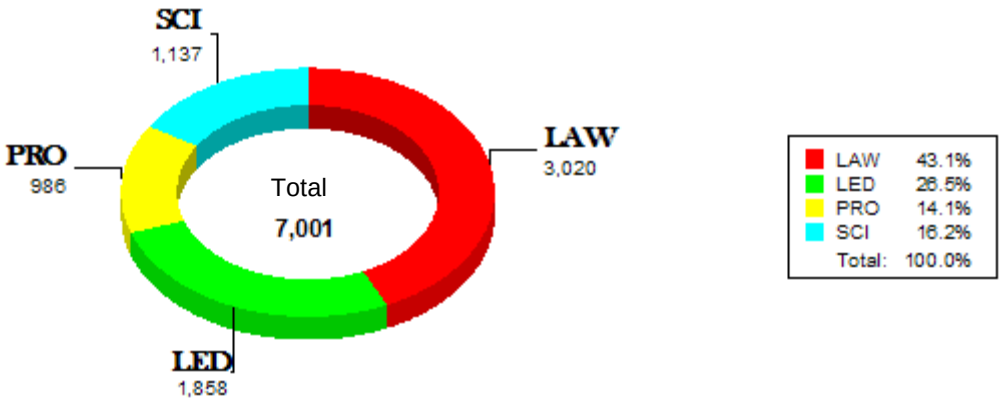
CDRH Total Distribution FY 11 October 1, 2010 - December 31, 2010

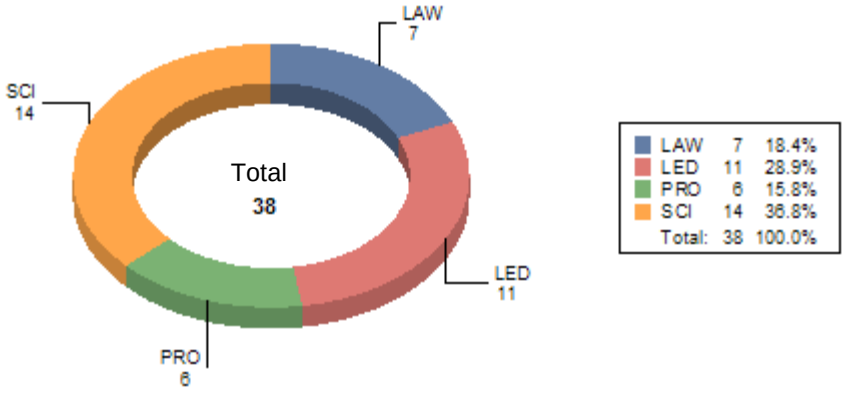
Contact Hours by Category



Key: LAW = Law & Policy, LED = Leadership,
PRO = Professional Development, SCI = Science

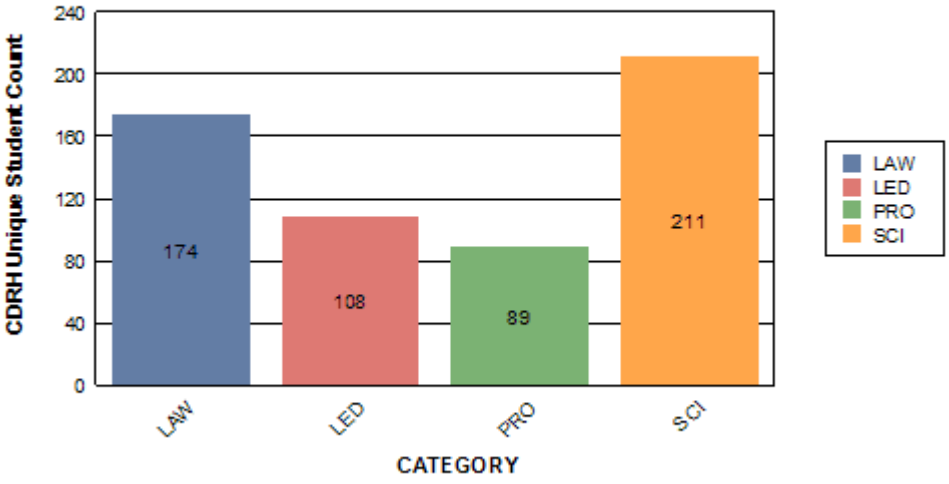
CDRH Total Distribution FY 11 October 1, 2010 - December 31, 2010

Staff College Learning Events by Category



CDRH Total Distribution FY 11 October 1, 2010 - December 31, 2010

Unique Student Count by Category*



*Unique Students = Number of distinct students

Key: LAW = Law & Policy, LED = Leadership,
PRO = Professional Development, SCI = Science

1-26-2011
MDUFA Stakeholder Meeting
Budget Requests and Appropriations Updates

FY 2011 Appropriations Update

Continuing Resolution (CR)

- FDA is operating under a Continuing Resolution (CR) through March 4 unless Congress passes an FY 2011 budget appropriation bill before then.
  - Current CR freezes the pay of Federal civilian employees but not Commissioned Corps pay.
  - FDA will collect user fees at the legislatively mandated FY 2011 level; however, FDA will not spend past FY 2010 authorized levels – until Congress passes a new appropriation authorizing the Agency to do so.
  - The authorized FY 2010 spending level is $57,014,000, the legislatively mandated FY 2011 collections level is $61,860,000, and the difference between FY 2010 and FY 2011 is $4,846,000.
  - FDA may use MDUFA reserve funds to supplement 2010 level spending and prevent decreases in performance resulting from underfunding.
  - There is no guarantee that Congress will pass an appropriation bill by March 4.

FY 2012 Appropriations Update

  - FDA's portion of the FY 2012 President's Budget request will publish next month.

MEDICAL DEVICE REGISTRATION AND LISTING STATS, 1/21/11

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.

RANK	ESTABLISHMENT_TYPE	DOMESTIC	FOREIGN	TOTAL
1	Manufacturer	5055	7117	12,172
2	Contract Manufacturer	318	668	986
3	Contract Sterilizer	16	42	58
4	Specification Developer	1510	311	1,821
5	Reprocessor of Single Use Devices	19	3	22
6	U.S. Manufacturer of Export Only	102	0	102
7	Repackager/Relabeler	1563	384	1,947
8	Remanufacturer	53	75	128
9	Foreign Exporter	0	1068	1,068
10	Initial Distributor/Importer	4,604	0	4,604
--	Unknown	160	73	233
	Total:	13,400	9,741	23,141