Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance

1:00 – 2:00, Wednesday, July 30, 2008
Room 100D, 9200 Corporate Blvd.

This agenda and all FDA materials distributed during the meeting will be available through our MDUFMA Internet site, www.fda.gov/cdrh/mdufma

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Welcome. *Kate Cook, CDRH-OCD.*

FDA MDUFMA / MDUFA Performance — Actions through June 30, 2008

- Reports on all decision goals for the FY 2003 – FY 2008 cohorts.
    - CBER report: *Leonard Wilson, OD/ADRM*
    - CDRH report: *Donna-Bea Tillman, ODE*

Overview of FDA Medical Device Guidance Issued During Q3 — *Donna-Bea Tillman, CDRH-ODE; Don St. Pierre, CDRH-OIVD.*

- FDA issued 10 medical device guidance documents during the third quarter.

Implementation of Electronic Registration and Listing — *David Racine, CDRH-OC.*

- A sufficient number of establishments have registered and paid the registration fee to surpass the baseline target of 12,750 establishments.
- Database trimmed by approximately 13,700 establishments (status changed to inactive) — 63% of these were domestic establishments, 37% foreign.

Quarterly General Update on Finances

- User fee receipts through June 30, 2008, compared with expectations. *Helio Chaves, FDA-OFM.*

Other Topics

- Publication of ODE/OIVD FY 2006 and FY 2007 report. *Donna-Bea Tillman, CDRH-ODE.*
- FY 2008 user fee rates to be published August 1, 2008. FY 2009 small business qualification and certification guidance to be published on our web site August 1, 2008. *James Norman, CDRH-OCD.*

Discussion

- Questions from industry.
- At the next quarterly meeting, FDA will provide "a qualitative update on how finding is being used for the device review process, including investments in information technology and training" for all FY 2008. We will also provide an update of performance data, reflecting FDA actions through September 30, 2008, including data on total review times (time with FDA plus time with the company) from receipt or filing to final decision for approval, denial, SE, or NSE, and de-identified review performance data for the branch with the shortest average review times and the branch with the longest average review times for 510(k)s, 180-day supplements, and real-time supplements.
- Set date for next meeting. Target: Wednesday, October 22 – Friday, November 7 (*no sooner than* three weeks following close of FY 2008).

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Quarterly Update on Progress Towards Meeting Medical Device Performance Goals

— CBER Performance Data —

Actions through June 30, 2008

Data on FY 2003 – FY 2007 Cohorts

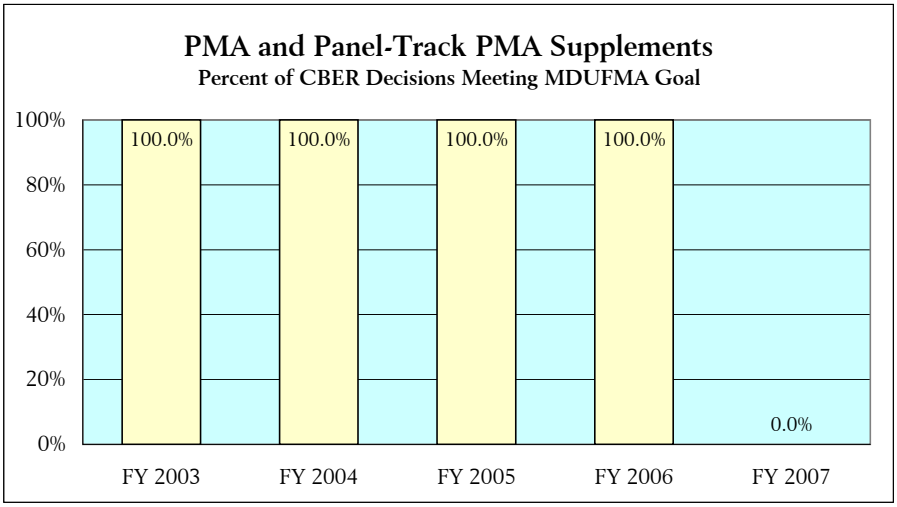
PMAs and Panel-Track Supplements
CBER Actions through June 30, 2008

Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
PMAs	3	1	5	3	0
Panel-Track Supplements	0	0	0	0	0
Total Workload	**3**	**1**	**5**	**3**	**0**

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	3	1	5	3	0
Goal – *Percent within 320 days*	—	—	—	*80%*	*90%*
Percent of decisions within goal	100.0%	100.0%	100.0%	100.0%	--
Applications without a decision	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*
Goal – Percent within 180 days	—	—	—	—	*50%*
Percent of decisions within goal	66.7%	100.0%	20.0%	33.3%	--



- All MDUFMA cohorts are closed.
- All decisions were made within the time specifed by MDUFMA performance goals.

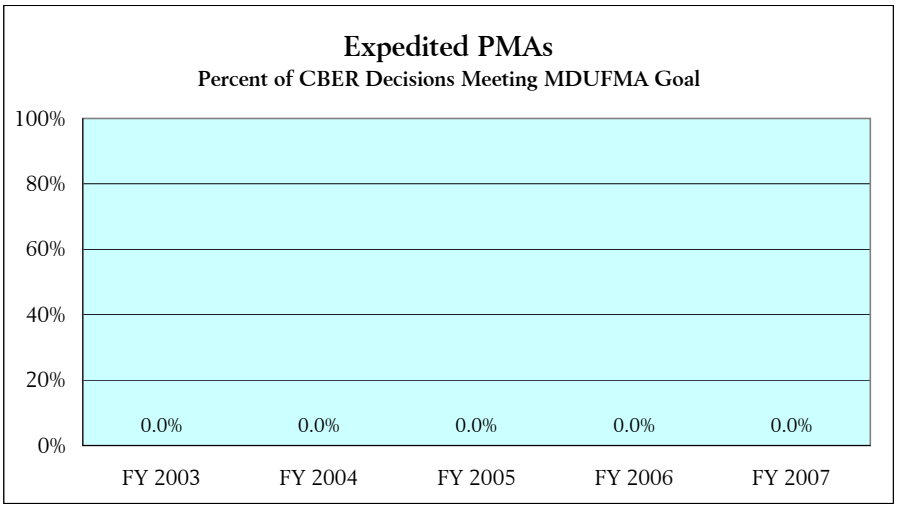
Expedited PMAs
CBER Actions through June 30, 2008

Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Expedited PMAs	0	0	0	0	0

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	0	0	0	0	0
Goal – *Percent within 300 days*	—	—	*70%*	*80%*	*90%*
Percent of decisions within goal	--	--	--	--	--
Applications without a decision	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*



- To date, no CBER PMA has qualified for Expedited status under MDUFMA. All MDUFMA cohorts are closed.

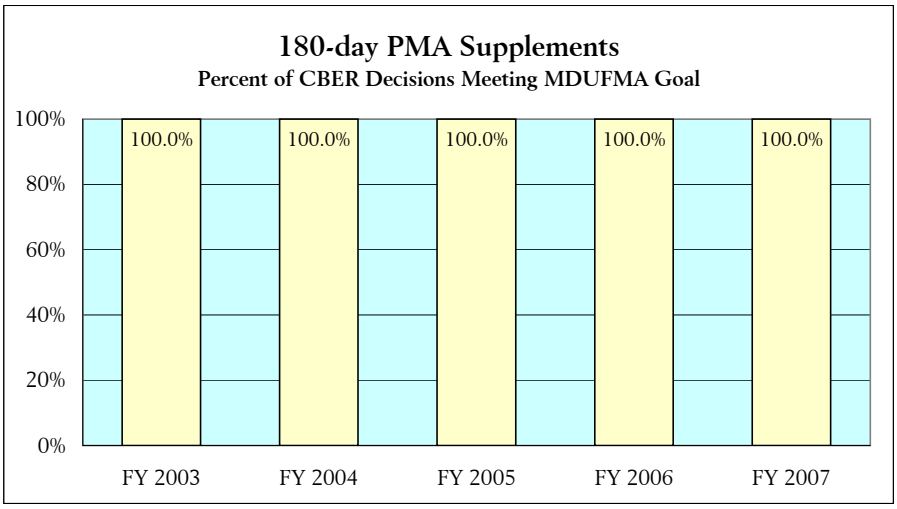
180-day PMA Supplements
CBER Actions through June 30, 2008

Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
180-day PMA Supplements	3	3	2	3	2

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	3	3	2	3	2
Goal – *Percent within 180 days*	—	—	*80%*	*80%*	*90%*
Percent of decisions within goal	100.0%	100.0%	100.0%	100.0%	100.0%
Applications without a decision	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*



- All MDUFMA cohorts are complete.
- All decisions were made within the time specifed by MDUFMA performance goals.

510(k) Premarket Notifications
CBER Actions through June 30, 2008

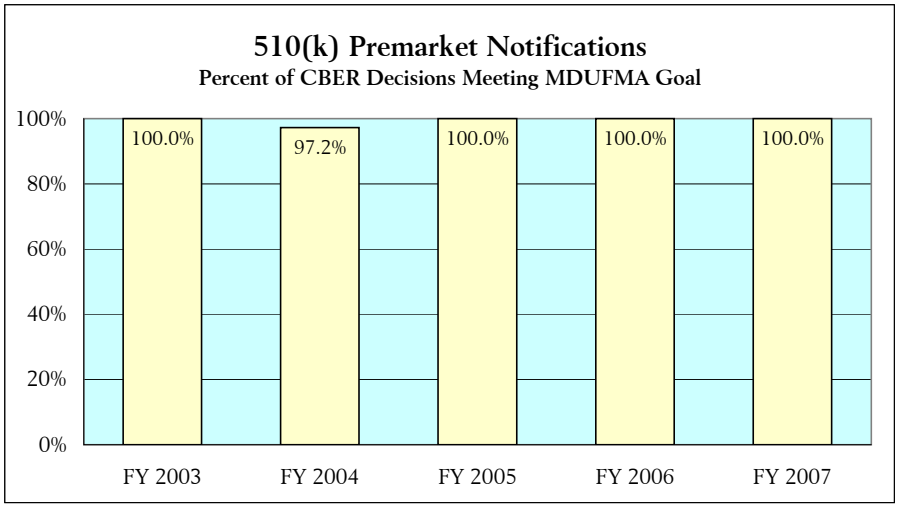
Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Received	65	78	63	60	58
MDUFMA Cohort[1]	54	72	58	55	53

[1] The MDUFMA Cohort excludes 510(k)s that were closed for any reason other than an SE or NSE decision (*e.g.* , when FDA finds that a 510(k) was not required). The number of 510(k)s in the MDUMFA Cohort is subject to change until the cohort is complete.

FDA Decisions (SE and NSE Determinations)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions (SE and NSE)	54	72	57	53	47
Goal – *Percent within 90 days*	—	—	*75%*	*75%*	*80%*
Percent of decisions within goal	100.0%	97.2%	100.0%	100.0%	100.0%
Cohort status	*Complete*	*Complete*	Open	Open	Open



- FY 2003 and FY 2004 cohorts are complete.
- Only one 510(k) from the FY 2005 cohort remains without a decision.

Data on FY 2003 – FY 2008 Cohorts

Note: No Commitment Goals After FY 2007

Biologics Licensing Applications

CBER Actions through June 30, 2008

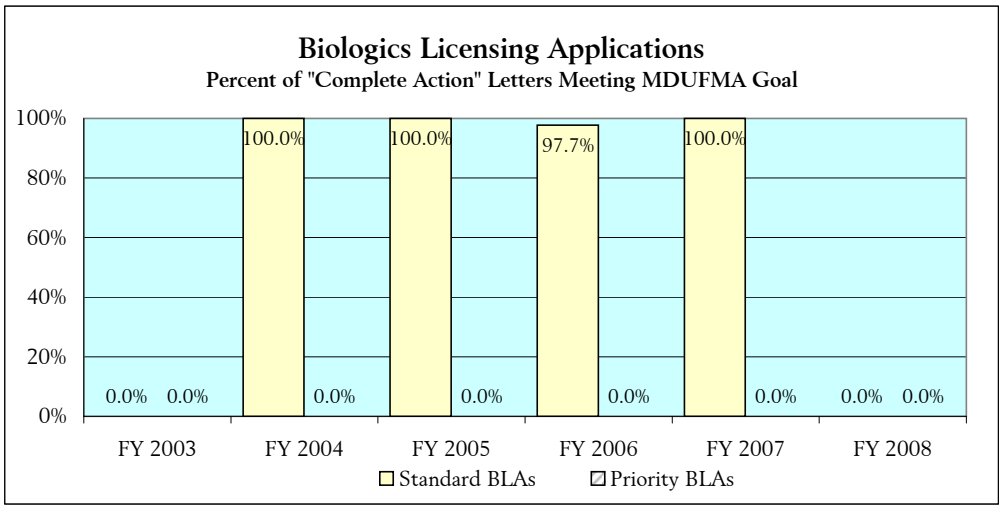
Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Standard BLAs	0	9	15	44	2	0
Priority BLAs	0	0	0	0	0	0
Total Workload	**0**	**9**	**15**	**44**	**2**	**0**

Review and Act on Original BLAs ("Complete Action" Letter)

Standard BLAs —	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
"Complete Action" Letter	0	9	15	44	2	0
Goal – *Percent within 10 months*	—	—	—	*75%*	*90%*	*90%*
Percent of actions within goal	--	100.0%	100.0%	97.7%	100%	0%
Applications without an action	0	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*	Open

Priority BLAs —	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
"Complete Action" Letter	0	0	0	0	0	0
Goal – *Percent within 6 months*	—	—	—	*75%*	*90%*	*90%*
Percent of actions within goal	--	--	--	--	--	0.0%
Applications without an action	0	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*	Open



- All MDUFMA cohorts prior to FY 2008 are closed for both standard and priority BLAs.
- All decisions prior to FY 2008 were made within the time specifed by MDUFMA performance goals.
- CBER is voluntarily continuing to report on goals identified in the MDUFMA commitment letter that were not continued as

BLA Supplements
CBER Actions through June 30, 2008

Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Standard BLA Efficacy Supplements	3	0	0	0	0	0
Priority BLA Efficacy Supplements	0	0	0	0	0	0
BLA Manufacturing Supplements that Require Prior Approval	73	62	25	26	149	0
Total Workload	**76**	**62**	**25**	**26**	**149**	**0**

Review and Act on BLA Supplements

Standard BLA Efficacy Supplements

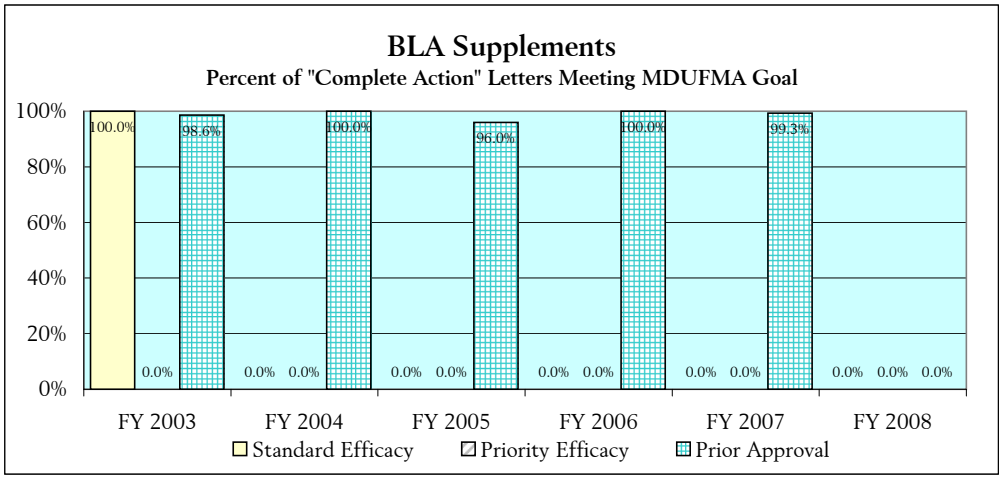
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
"Complete Action" Letter	3	0	0	0	0	0
Goal – *Percent within 10 months*	—	—	—	*75%*	*90%*	*90%*
Percent of actions within goal	100.0%	--	--	--	--	0.0%
Applications without an action	0	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*	Open

Priority BLA Efficacy Supplements

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
"Complete Action" Letter	0	0	0	0	0	0
Goal – *Percent within 6 months*	—	—	—	*75%*	*90%*	*90%*
Percent of actions within goal	--	--	--	--	--	0.0%
Applications without an action	0	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*	Open

Prior Approval Manufacturing Supplements

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
"Complete Action" Letter	73	62	25	26	149	0
Goal – *Percent within 4 months*	—	—	—	*75%*	*90%*	*90%*
Percent of actions within goal	98.6%	100.0%	96.0%	100.0%	99.3%	0.0%
Applications without an action	0	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*	Open



- All cohorts prior to FY 2008 are complete.
- FY 2007 saw a significant, unexpected surge of BLA Manufacturing Supplements that require prior approval.

Resubmissions of BLAs and BLA Supplements
CBER Actions through June 30, 2008

Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Class 1 resubmission of an original BLA or BLA efficacy supplement	0	0	5	0	29	0
Class 2 resubmission of an original BLA or BLA efficacy supplement	2	5	9	5	13	0
Total Workload	**2**	**5**	**14**	**5**	**42**	**0**

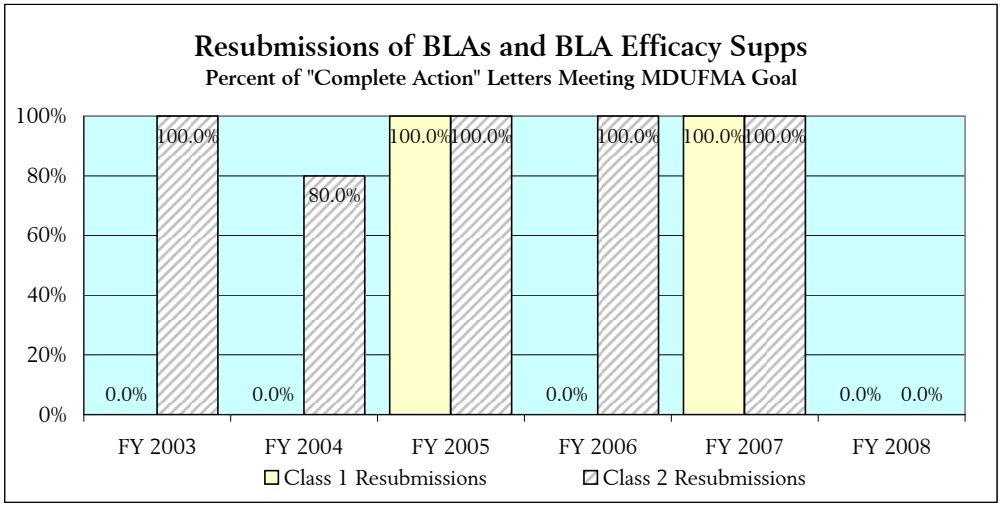
Review and Act on Resubmissions

Class 1 Resubmissions —

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
"Complete Action" Letter	0	0	5	0	29	0
Goal – *Percent within 2 months*	—	—	*75%*	*80%*	*90%*	*90%*
Percent of actions within goal	--	--	100.0%	--	100.0%	0.0%
Applications without an action	0	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*	Open

Class 2 Resubmissions —

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
"Complete Action" Letter	2	5	9	5	13	0
Goal – *Percent within 6 months*	—	—	*75%*	*80%*	*90%*	*90%*
Percent of actions within goal	100.0%	80.0%	100.0%	100.0%	100.0%	0.0%
Applications without an action	0	0	0	0	0	0
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*	Open

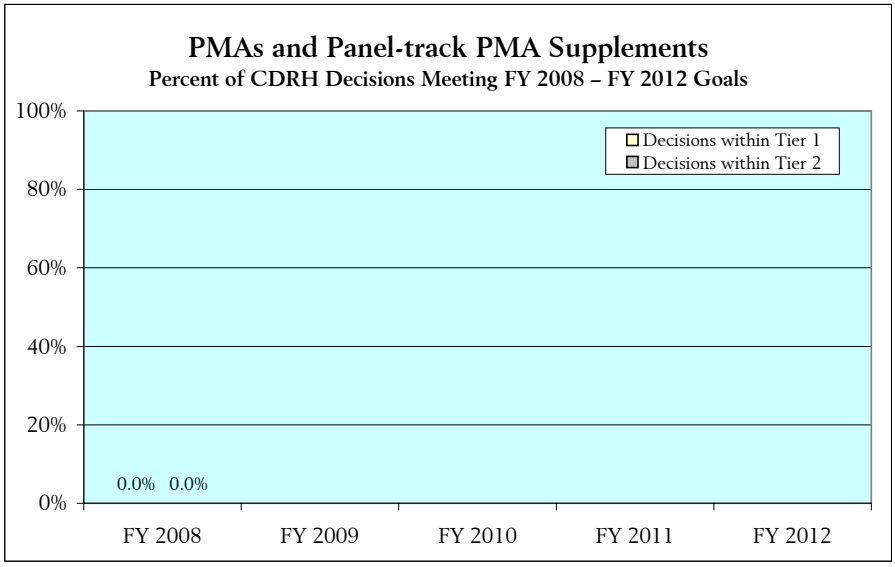


- All MDUFMA cohorts prior to FY 2008 are closed for both class 1 and class 2 resubmissions.

Data on FY 2008 – FY 2012 Cohorts

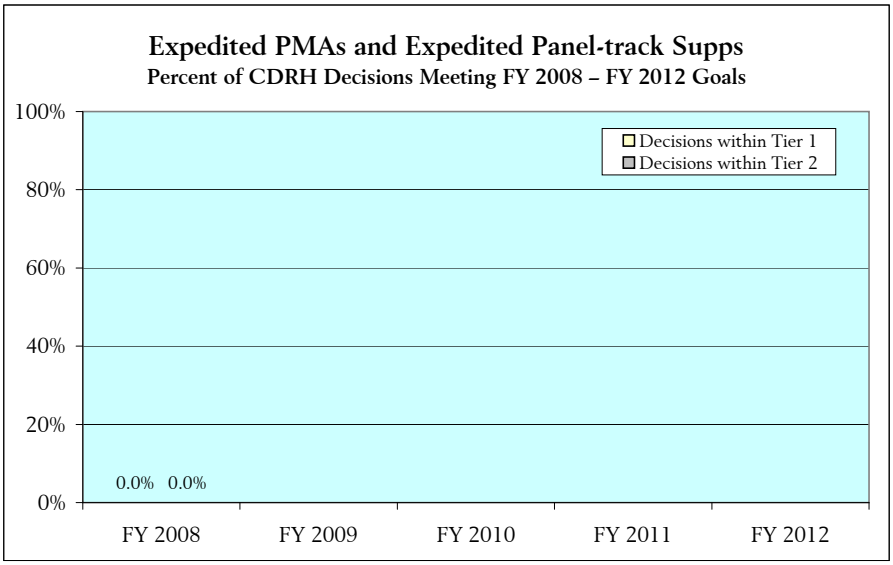
PMAs and Panel-track Supplements

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



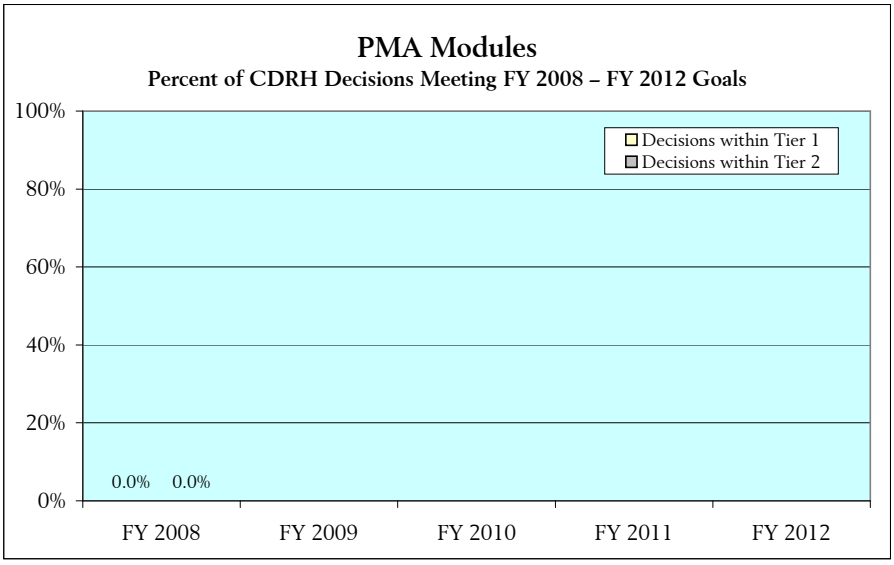
Expedited PMAs and Expedited Panel-track Supplements

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



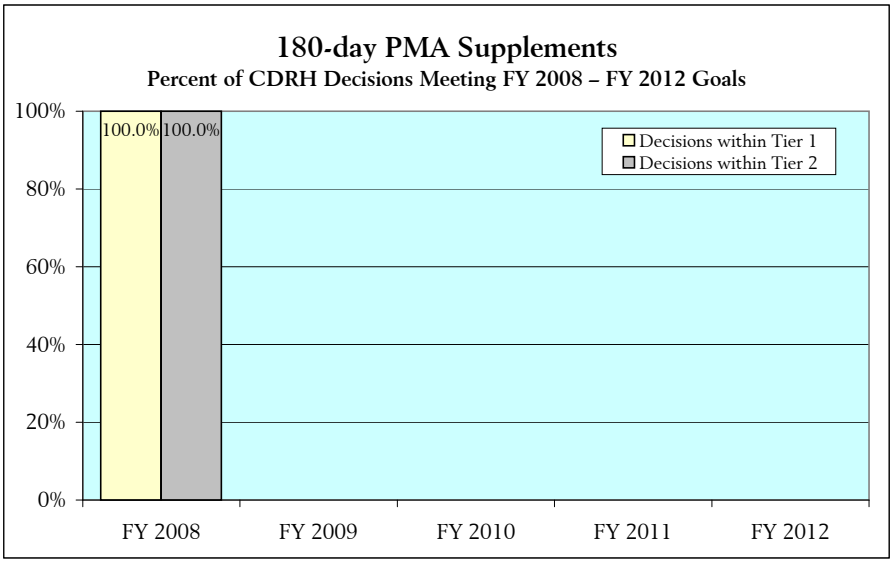
PMA Modules

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



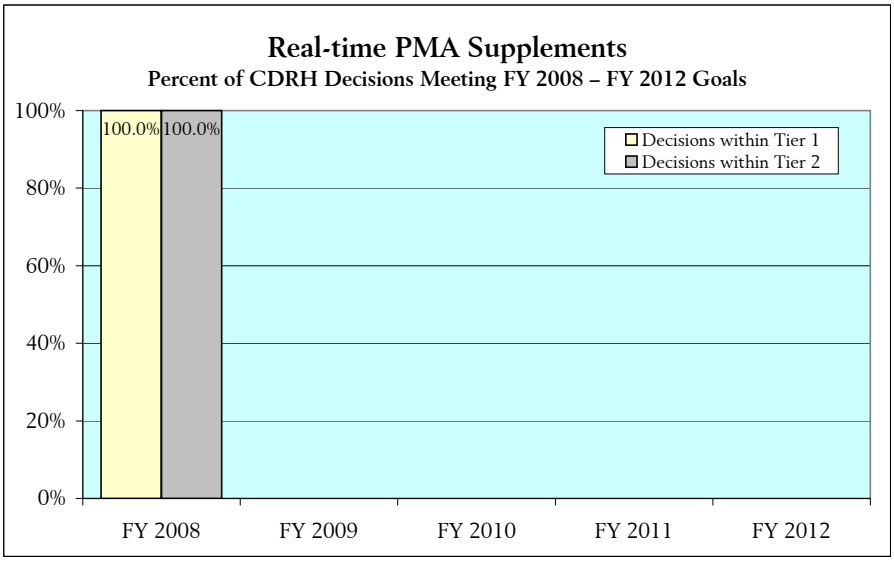
180-day PMA Supplements

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



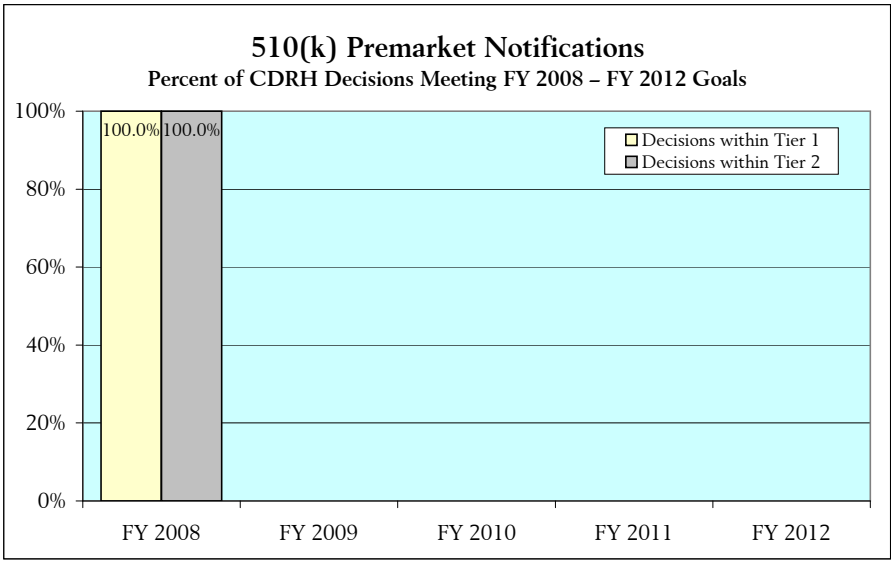
Real-time PMA Supplements

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



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	33	—	—	—	—
MDUFMA Cohort	32	—	—	—	—
Total FDA Decisions	1	—	—	—	—
Percent within Tier 1 goal (90 days)	100.0%	—	—	—	—
Tier 1 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Percent within Tier 2 goal (150 days)	100.0%	—	—	—	—
Tier 2 goal — *Percent within 150 days*	*98%*	*98%*	*98%*	*98%*	*98%*
Cohort status	Open	—	—	—	—



Quarterly Update on Progress Towards Meeting Medical Device Performance Goals

— CDRH Performance Data —

Actions through June 30, 2008

Data on FY 2003 – FY 2007 Cohorts

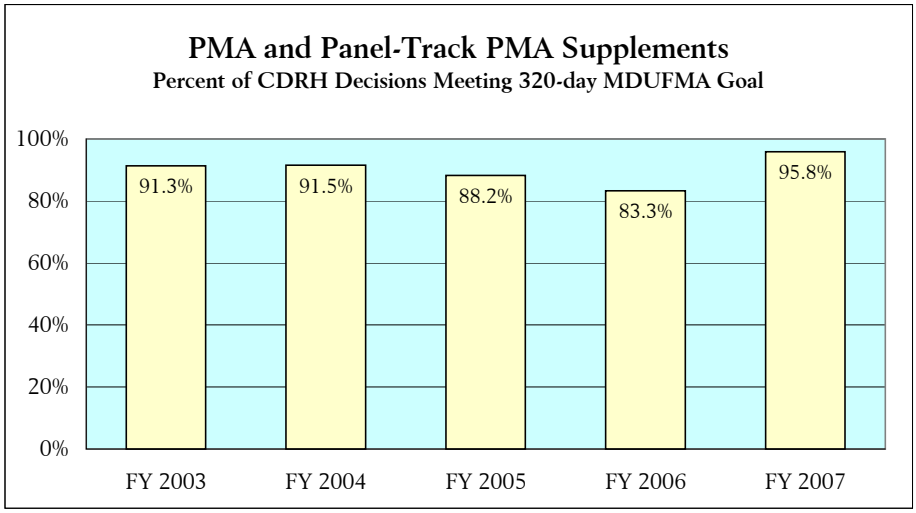
PMAs and Panel-Track Supplements
CDRH Actions through June 30, 2008

Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
PMAs	40	39	41	37	33
Panel-Track Supplements	7	8	11	16	4
Total Workload	**47**	**47**	**52**	**53**	**37**

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	46	47	51	48	24
Goal – *Percent within 320 days*	—	—	—	*80%*	*90%*
Percent of decisions within 320 days	91.3%	91.5%	88.2%	83.3%	95.8%
Applications without a decision	1	0	1	5	13
Cohort status	Open	*Complete*	Open	Open	Open
Goal – *Percent within 180 days*	—	—	—	—	*50%*
Percent of decisions within 180 days	45.7%	36.2%	31.4%	39.6%	54.2%



- Progress to date indicates CDRH will likely meet the goals for FY 2006 and FY 2007.
- The FY 2004 cohort is complete. All other cohorts remain open.

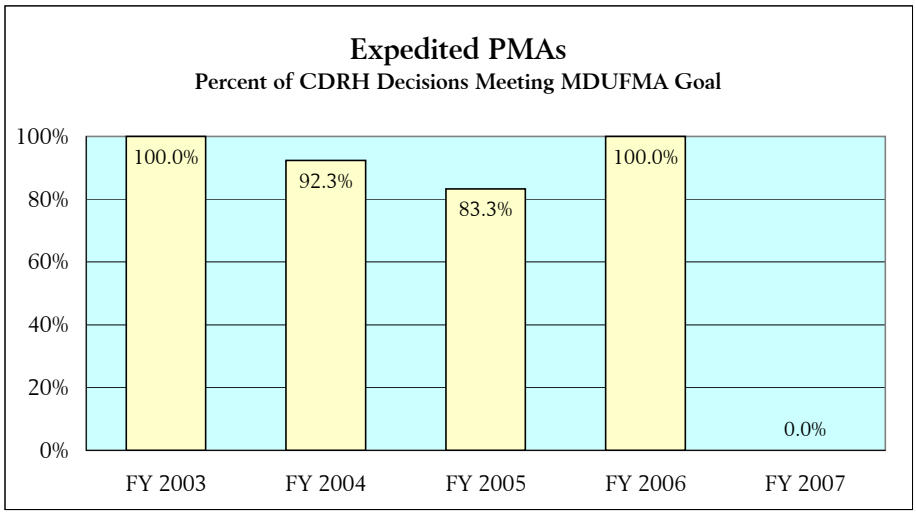
Expedited PMAs
CDRH Actions through June 30, 2008

Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Expedited PMAs	3	14	6	2	2

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	3	13	6	1	0
Goal – *Percent within 300 days*	—	—	*70%*	*80%*	*90%*
Percent of decisions within 300 days	100.0%	92.3%	83.3%	100.0%	--
Applications without a decision	0	1	0	1	2
Cohort status	*Complete*	Open	*Complete*	Open	Open



- FY 2003 and FY 2005 cohorts are complete; all other cohorts remain open.
- Because of the small number of Expedited PMAs, a single action may signficantly affect performance measures.

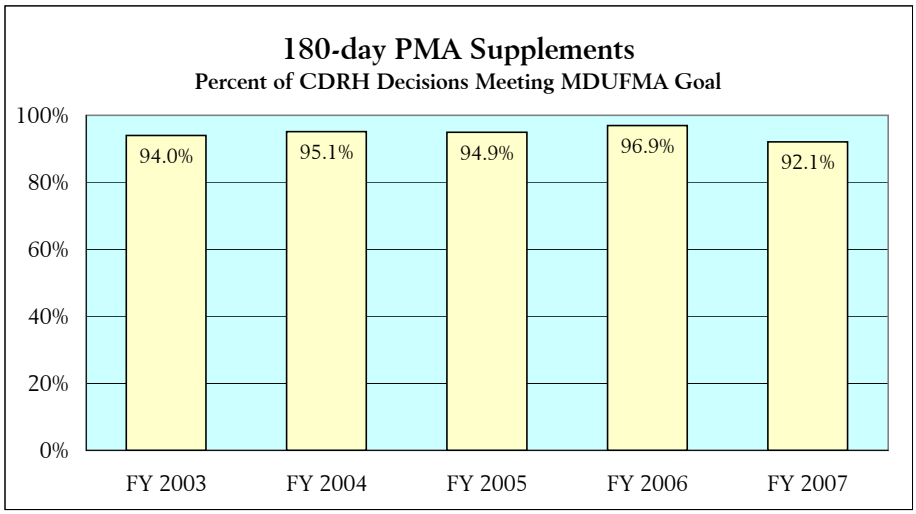
180-day PMA Supplements
CDRH Actions through June 30, 2008

Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
180-day PMA Supplements	201	103	99	133	140

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	201	103	99	131	139
Goal – *Percent within 180 days*	—	—	*80%*	*80%*	*90%*
Percent of decisions within 180 days	94.0%	95.1%	94.9%	96.9%	92.1%
Applications without a decision	0	0	0	2	1
Cohort status	*Complete*	*Complete*	*Complete*	Open	Open



- FY 2003, FY 2004, and FY 2005 cohorts are complete.

510(k) Premarket Notifications
CDRH Actions through June 30, 2008

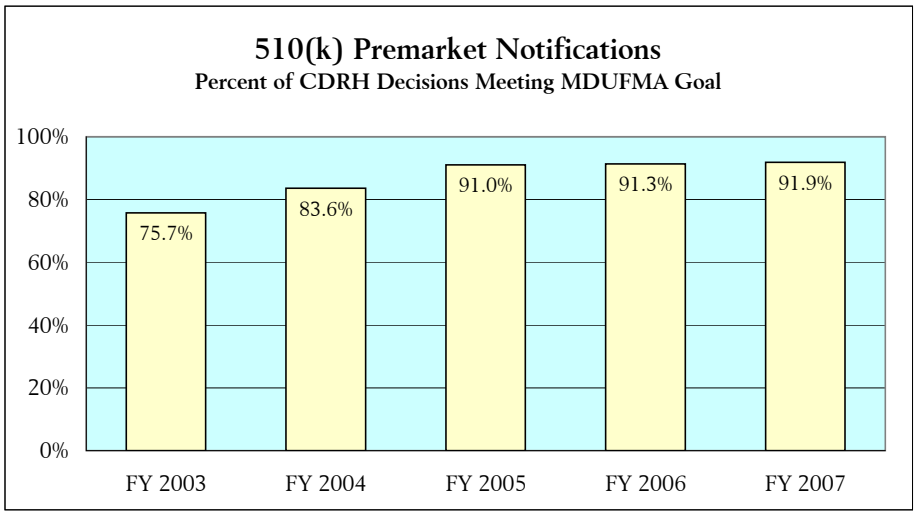
Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Received	4,225	3,632	3,650	3,853	3,656
MDUFMA Cohort[1]	3,741	3,309	3,344	3,453	3,251

[1] The MDUFMA Cohort excludes 510(k)s that were closed for any reason other than an SE or NSE decision (*e.g.* , when FDA finds that a 510(k) was not required). The number of 510(k)s in the MDUMFA Cohort is subject to change until the cohort is complete.

FDA Decisions (SE and NSE Determinations)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions (SE and NSE)	3,741	3,309	3,344	3,445	3,108
Goal – *Percent within 90 days*	—	—	*75%*	*75%*	*80%*
Percent of decisions within 90 days	75.7%	83.6%	91.0%	91.3%	91.9%
Cohort status	*Complete*	*Complete*	Open	Open	Open

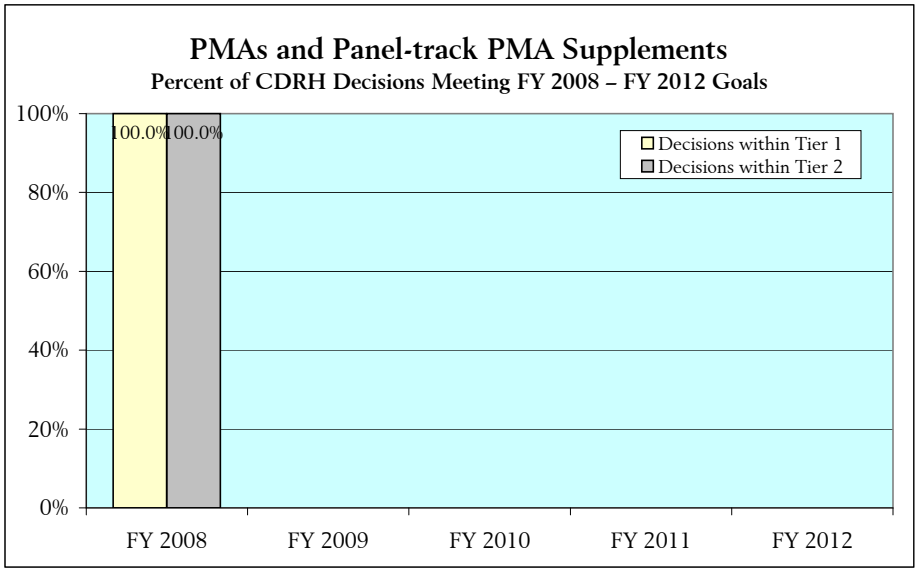


- FY 2003 and FY 2004 cohorts are closed; only one 510(k) remains open in the FY 2005 cohort, and 12 in the FY 2006 cohort.

Data on FY 2008 – FY 2012 Cohorts

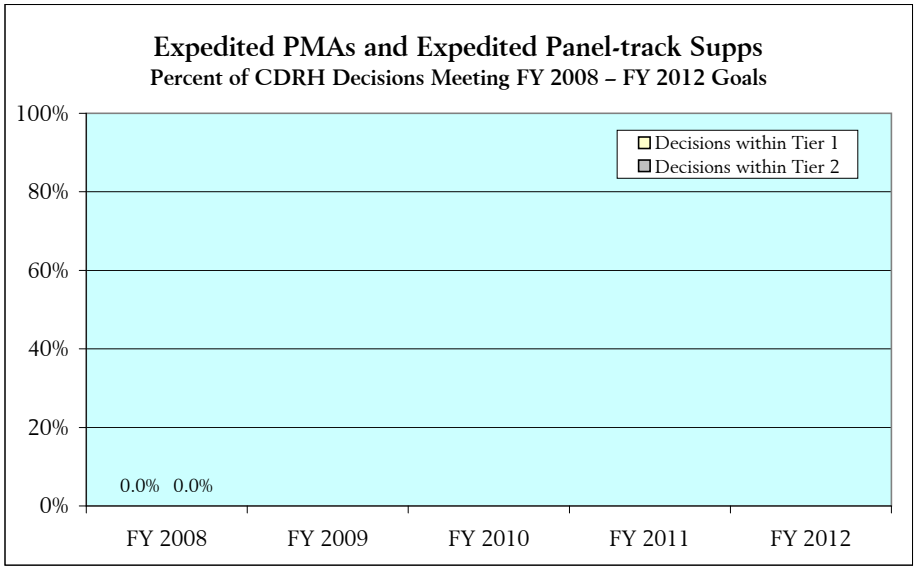
PMAs and Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	19	—	—	—	—
Total FDA Decisions	1	—	—	—	—
Percent within Tier 1 goal (180 days)	100.0%	—	—	—	—
Tier 1 goal — *Percent within 180 days*	*60%*	*60%*	*60%*	*60%*	*60%*
Percent within Tier 2 goal (295 days)	100.0%	—	—	—	—
Tier 2 goal — *Percent within 295 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	Open	—	—	—	—



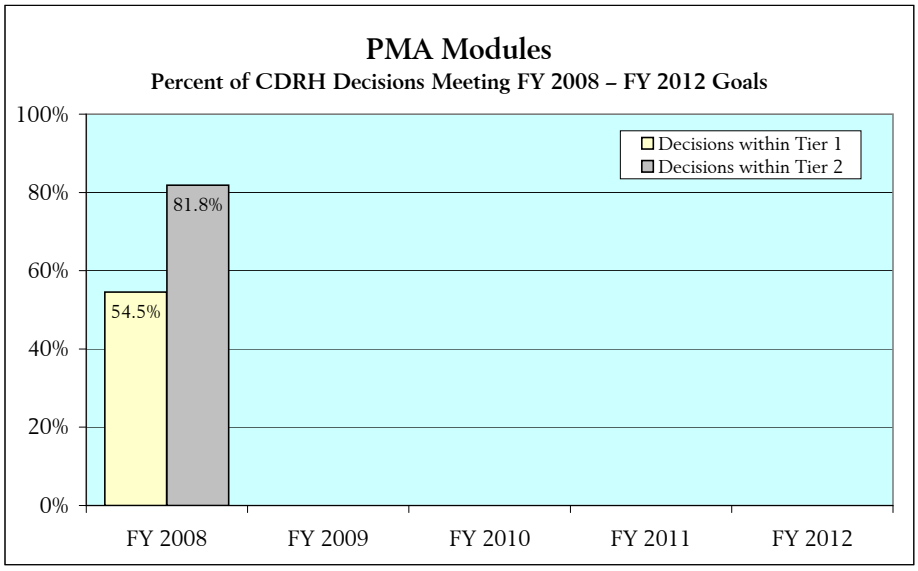
Expedited PMAs and Expedited Panel-track Supplements

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



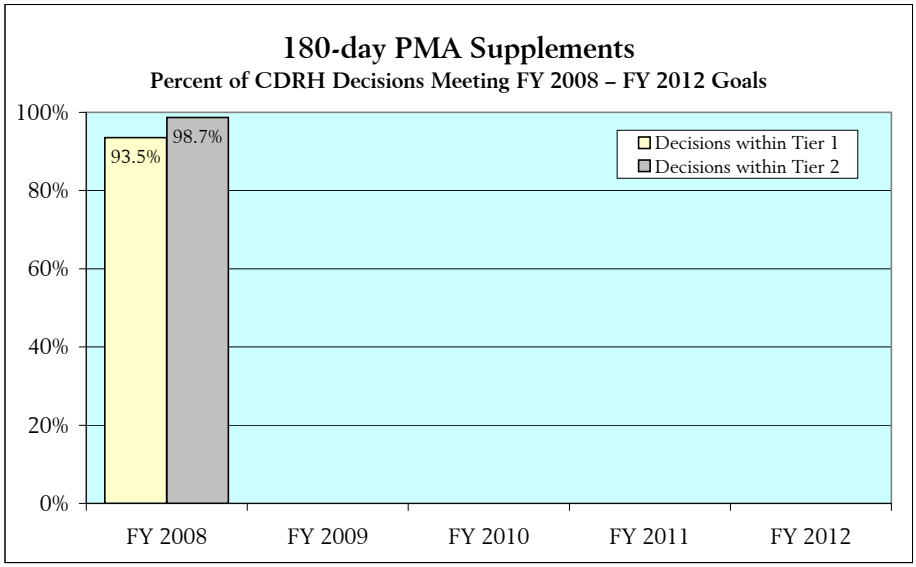
PMA Modules

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	28	—	—	—	—
MDUFMA Cohort	25	—	—	—	—
Total FDA Decisions	22	—	—	—	—
Percent within Tier 1 goal (90 days)	54.5%	—	—	—	—
Tier 1 goal — *Percent within 90 days*	*75%*	*75%*	*75%*	*75%*	*75%*
Percent within Tier 2 goal (120 days)	81.8%	—	—	—	—
Tier 2 goal — *Percent within 120 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	Open	—	—	—	—



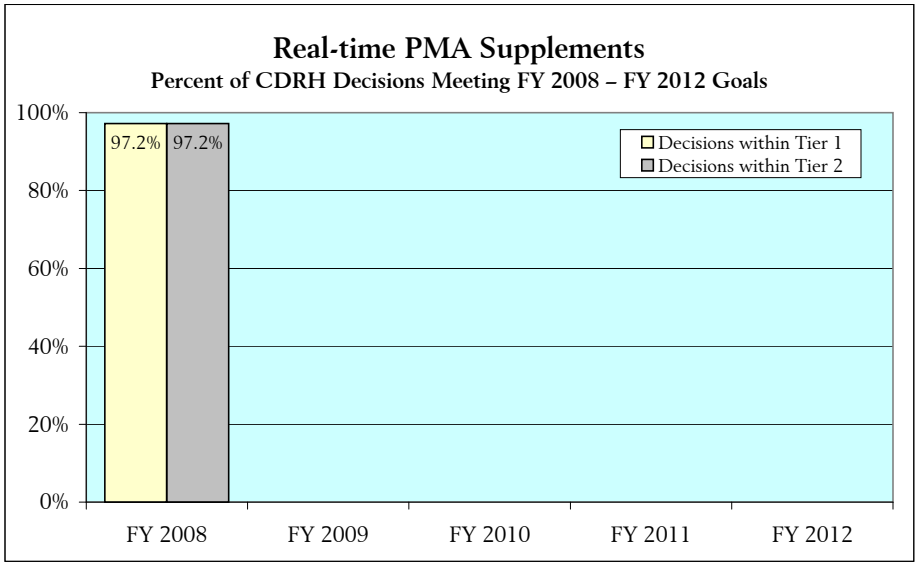
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	172	—	—	—	—
Total FDA Decisions	155	—	—	—	—
Percent within Tier 1 goal (180 days)	93.5%	—	—	—	—
Tier 1 goal — *Percent within 180 days*	*85%*	*85%*	*85%*	*85%*	*85%*
Percent within Tier 2 goal (210 days)	98.7%	—	—	—	—
Tier 2 goal — *Percent within 210 days*	*95%*	*95%*	*95%*	*95%*	*95%*
Cohort status	Open	—	—	—	—



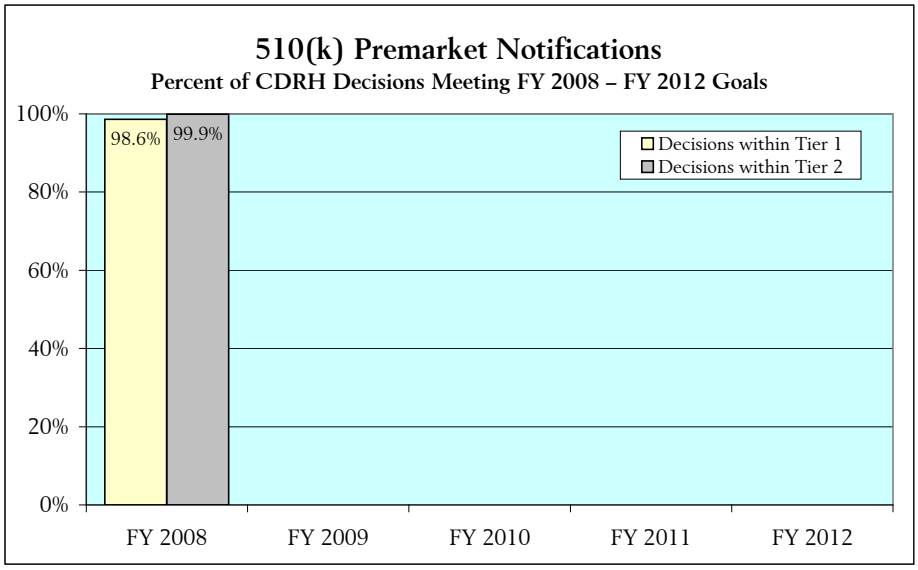
Real-time PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	97	—	—	—	—
Total FDA Decisions	36	—	—	—	—
Percent within Tier 1 goal (60 days)	97.2%	—	—	—	—
Tier 1 goal — *Percent within 60 days*	*80%*	*80%*	*80%*	*80%*	*80%*
Percent within Tier 2 goal (90 days)	97.2%	—	—	—	—
Tier 2 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	Open	—	—	—	—



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	2,677	—	—	—	—
MDUFMA Cohort	2,562	—	—	—	—
Total FDA Decisions	1490	—	—	—	—
Percent within Tier 1 goal (90 days)	98.6%	—	—	—	—
Tier 1 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Percent within Tier 2 goal (150 days)	99.9%	—	—	—	—
Tier 2 goal — *Percent within 150 days*	*98%*	*98%*	*98%*	*98%*	*98%*
Cohort status	Open	—	—	—	—



Medical Device Guidance Documents
Issued During the Third Quarter FY 2008

April 1, 2008 – June 30, 2008

FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Performance Assessment - Guidance for Industry and FDA Staff — 06/30/2008
Available at http://www.fda.gov/cdrh/mdufma/guidance/1218.pdf

Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System — 05/30/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1616.pdf

Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters — 05/30/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1608.pdf

Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) — 05/30/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1617.pdf

Guidance for Industry - Medical Device Tracking; Guidance for Industry and FDA Staff — 05/23/2008
Available at http://www.fda.gov/cdrh/comp/guidance/169.pdf

Guidance for Industry and FDA Staff: Hemodialysis Blood Tubing Sets – Premarket Notification [510(k)] Submissions — 04/23/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1649.pdf

Guidance for Industry and FDA Staff: Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis — 04/15/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1650.pdf

Guidance for Industry and FDA Staff: Preparation and Review of Investigational Device Exemption Applications (IDEs for Total Artificial Discs — 04/11/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1637.pdf

Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Plasmodium Species Antigen Detection Assays — 05/20/2008
Available at http://www.fda.gov/cdrh/oivd/guidance/1646.pdf

Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization — 05/07/2008
Available at http://www.fda.gov/cdrh/oivd/guidance/1143.pdf

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MDUFMA Quarterly Update

Establishment Registration Fees

Actions Since April 2008

- Sent 15,000 Untitled Letters to firms that did not complete FY 2008 Annual Registration (5K to firms we believed should pay based on past registrations and 10K to firms that we believe did not have to pay the fee)
- Approximately 2K returned by Post Office
- Any firm not registered for FY 2008 removed from list of active registrants in June.
- Continuing to get new registrations

Establishments Registered and Registration Fees Paid

	Inventory as of 7/29/08			Paid as of 6/30/08
	Domestic	Foreign	Total	
Subject to Registration Fee	6,317	6,650	12,967	13,239
Initial Distributor — Not subject to registration fee (No higher activity)	3,826		3,826	
All Other Operations — Not subject to registration fee (No higher activity)	1,124	954	2,078	
Total Registered Establishments	11,267	7,604	18,871	13,239

Baseline target of 12,750 has been met.

Changes in FY 2009

- Fee increases to $1,851 per establishment
- Online credit card/electronic checks accepted
- Firms will pay first, get payment confirmation, then complete annual registration

FY 2008 Medical Device User Fee Collections

As of June 30, 2008

Source	FY 2008 Authorized		FY 2008 Fee Revenues				Potential EoY Surplus (Deficit)
	Full Year	Expected to Date	Actual to Date	% of Year	% of Expected	Potential EoY[5]	
Establishment Registration Fees[1]	$ 21,751,500	$ 21,751,500	$ 22,585,445	103.8%	103.8%	$ 22,585,445	$ 833,945
Application / Reporting Fees[2]	$ 26,679,500	$ 20,009,625	$ 19,337,773	72.5%	96.6%	$ 25,783,697	$ (895,803)
Refunds[3]			$ (590,121)		50.0%	$ (1,180,242)	$ (1,180,242)
Total[4]	$ 48,431,000	$ 41,761,125	$ 41,333,097	85.3%	99.0%	$ 47,779,021	$ (1,242,100)

Notes:

1. The Authorized revenues shown for Establishment Registration fees assume 12,750 establishments will register and pay the fee. To date, roughly 13,239 establishments have registered and paid
2. The Authorized revenues shown for Application / Reporting Fees represents the difference between total authorized fee revenues and the amount
3. Processing of refunds is currently backlogged, and the data cannot be yet broken down by source (*e.g.* , the amount attributable to applications / reports, and the amount attributable to establishment registration). This data is preliminary, as of March 31, 2008.
4. FY 2008 authorized fee revenues are specified in section 738(h)(3) of the FD&C Act.
5. Potential EoY assumes the current % of Expected will also apply at the end of the year, except for refunds, where we assume an equal amount of refunds in Qs 3 & 4 as were experienced in Qs 1 & 2..

Comparison:
Medical Deivce User Fee Collection in Prior Years
Excludes Unearned Fees, Includes Refunds

FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
$21,620,549	$25,280,073	$31,801,091	$34,567,188	$26,893,394