

Quarterly Update on  
Medical Device Performance Goals  
— CBER Performance Data —  
Actions through 31 March 2009

## PMAs and Panel-Track Supplements

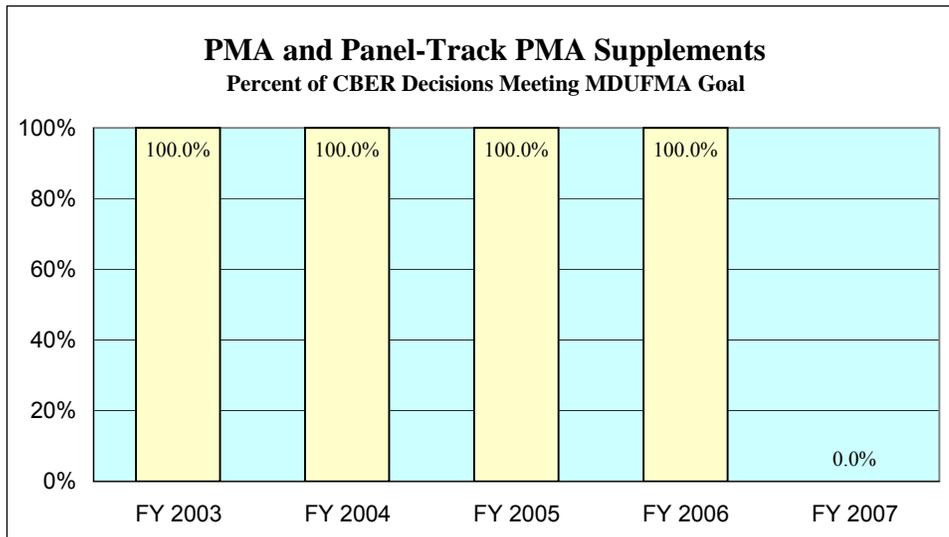
Actions through 31 March 2009

### 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
<b>Total Workload</b>	<b>3</b>	<b>1</b>	<b>5</b>	<b>3</b>	<b>0</b>

### FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
<b>FDA Decisions</b>	3	1	5	3	0
Goal – <i>Percent within 320 days</i>	—	—	—	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	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>
Goal – <i>Percent within 180 days</i>	—	—	—	—	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 specified by MDUFMA performance goals.

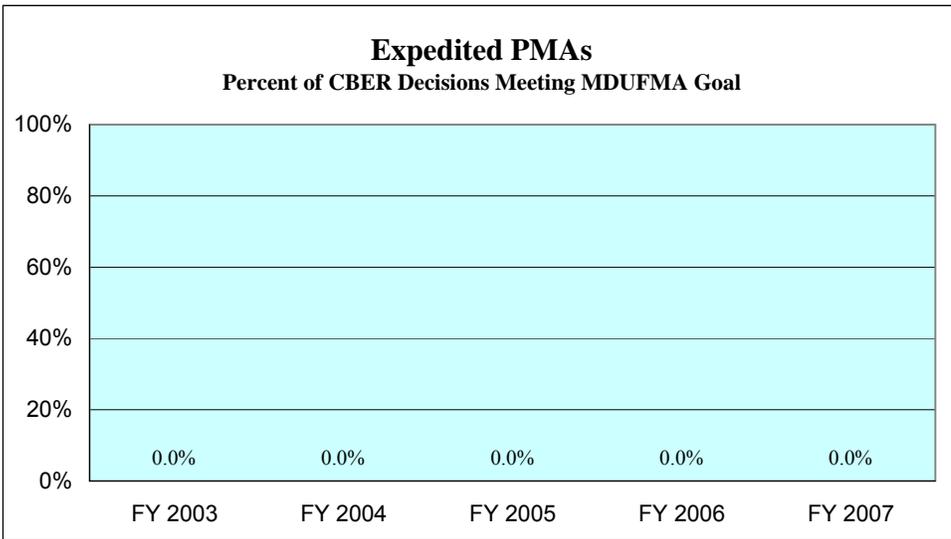
**Expedited PMAs**  
Actions through 31 March 2009

**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
<b>FDA Decisions</b>	0	0	0	0	0
Goal – <i>Percent within 300 days</i>	—	—	70%	80%	90%
Percent of decisions within goal	--	--	--	--	--
Applications without a decision	0	0	0	0	0
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>



- All MDUFMA cohorts are closed.
- No CBER PMA qualified for Expedited status through FY 2007.

# 180-day PMA Supplements

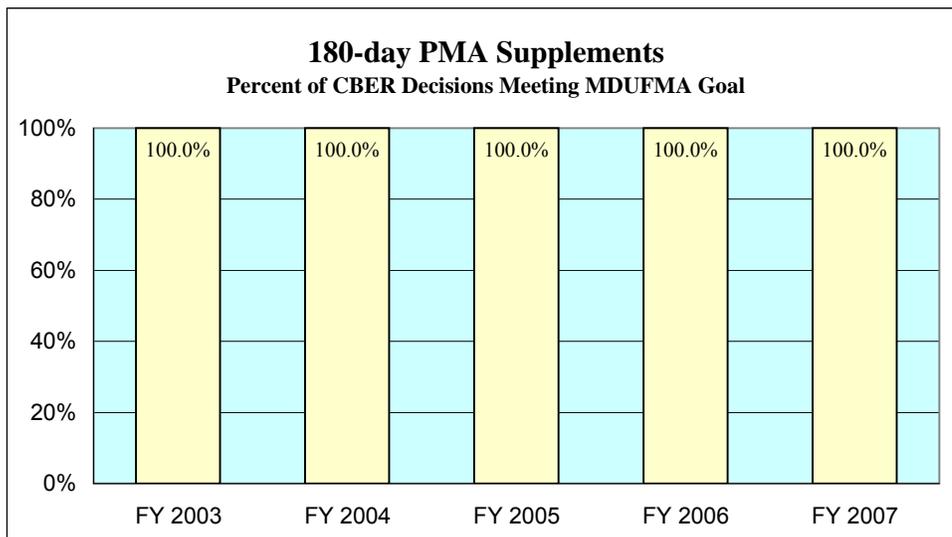
Actions through 31 March 2009

## 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
<b>FDA Decisions</b>	3	3	2	3	2
Goal – <i>Percent within 180 days</i>	—	—	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	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>



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

## 510(k) Premarket Notifications

Actions through 31 March 2009

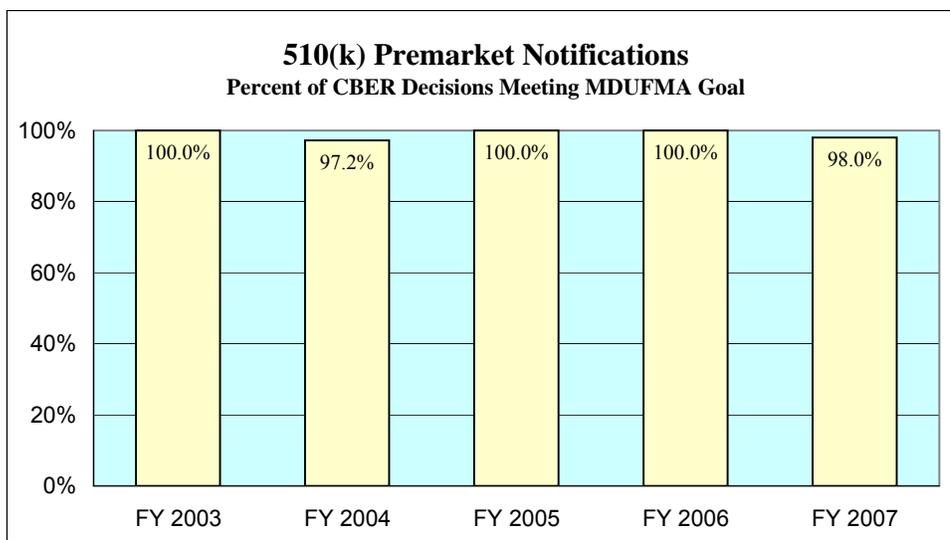
### Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Received	65	78	63	60	58
MDUFMA Cohort1	54	72	58	55	53

<sup>1</sup> 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 MDUFMA 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	54	51
Goal – Percent within 90 days	—	—	75%	75%	80%
Percent of decisions within goal	100.0%	97.2%	100.0%	100.0%	98.0%
Cohort status	Complete	Complete	Open	Open	Open



- FY 2003 and FY 2004 cohorts are complete.
- Only four 510(k)s submitted through FY 2007 remain without a decision: one from the FY 2005 cohort, one from the FY 2006 cohort, and two from the FY 2007 cohort.

## Data on FY 2003 – FY 2009 Biologics Workloads

Note: No Commitment Goals After FY 2007

### Biologics Licensing Applications

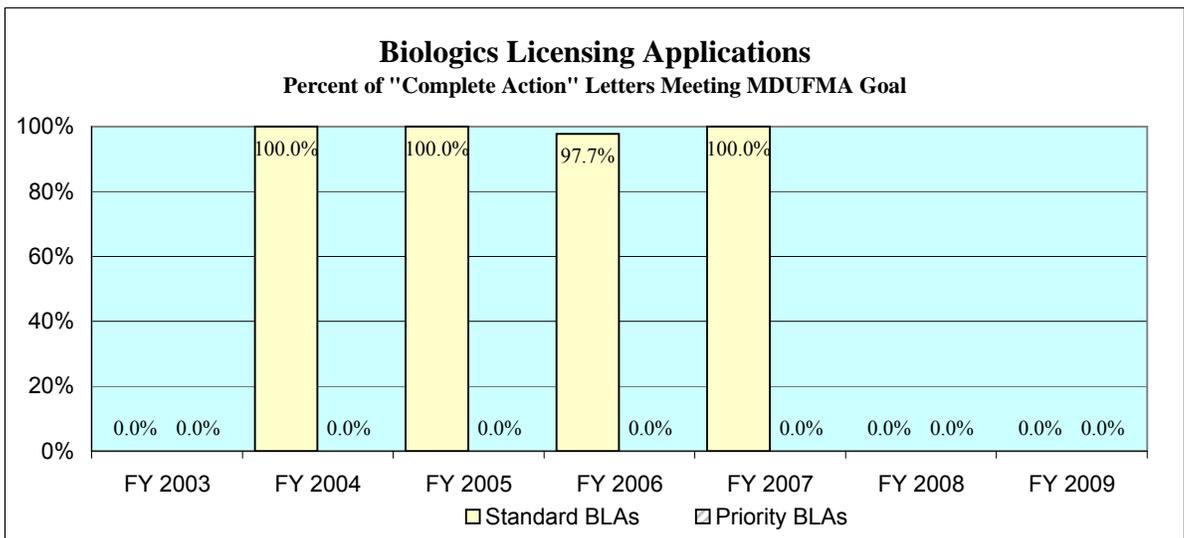
Actions through 31 March 2009

#### Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Standard BLAs	0	9	15	44	2	15	7
Priority BLAs	0	0	0	0	0	0	0
<b>Total Workload</b>	<b>0</b>	<b>9</b>	<b>15</b>	<b>44</b>	<b>2</b>	<b>15</b>	<b>7</b>

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

<i>Standard BLAs</i> —	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
"Complete Action" Letter	0	9	15	44	2	0	0
Goal – Percent within 10 months	—	—	—	75%	90%	—	—
Percent of actions within goal	--	100.0%	100.0%	97.7%	100%	--	--
Applications without an action	0	0	0	0	0	15	7
Cohort status	Complete	Complete	Complete	Complete	Complete	Open	Open
<i>Priority BLAs</i> —	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
"Complete Action" Letter	0	0	0	0	0	0	0
Goal – Percent within 6 months	—	—	—	75%	90%	—	—
Percent of actions within goal	--	--	--	--	--	--	--
Applications without an action	0	0	0	0	0	0	0
Cohort status	Complete	Complete	Complete	Complete	Complete	Complete	Open



- All cohorts prior to FY 2008 are closed for standard BLAs.
- All cohorts prior to FY 2009 are closed for priority BLAs.
- All decisions to date have been made within the time specified by MDUFMA performance
- CBER is voluntarily continuing to report on goals identified in the MDUFMA commitment letter that were not continued as MDUFMA/FDAAA goals. No specific goals apply to the cohorts after FY 2007.

## BLA Supplements

Actions through 31 March 2009

### Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Standard BLA Efficacy Supplements	3	0	0	0	0	0	1
Priority BLA Efficacy Supplements	0	0	0	0	0	0	0
BLA Manufacturing Supplements that Require Prior Approval	73	62	25	26	149	227	77
<b>Total Workload</b>	<b>76</b>	<b>62</b>	<b>25</b>	<b>26</b>	<b>149</b>	<b>227</b>	<b>78</b>

### Review and Act on BLA Supplements

#### Standard BLA Efficacy Supplements

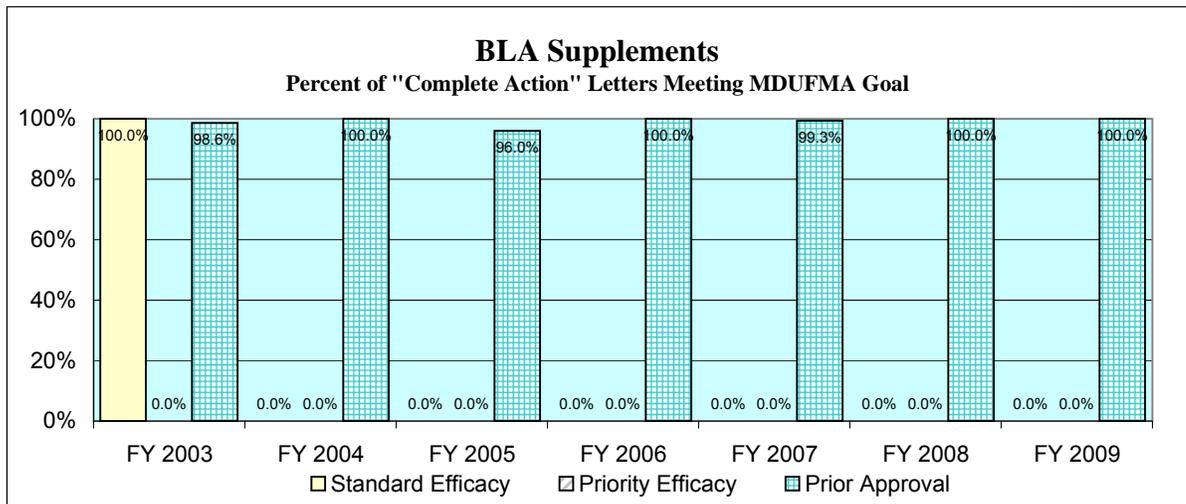
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
"Complete Action" Letter	3	0	0	0	0	0	0
Goal – Percent within 10 months	—	—	—	75%	90%	—	—
Percent of actions within goal	100.0%	--	--	--	--	--	--
Applications without an action	0	0	0	0	0	0	1
Cohort status	Complete	Complete	Complete	Complete	Complete	Complete	Open

#### Priority BLA Efficacy Supplements

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
"Complete Action" Letter	0	0	0	0	0	0	0
Goal – Percent within 6 months	—	—	—	75%	90%	—	—
Percent of actions within goal	--	--	--	--	--	--	--
Applications without an action	0	0	0	0	0	0	0
Cohort status	Complete	Complete	Complete	Complete	Complete	Complete	Open

#### Prior Approval Manufacturing Supplements

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
"Complete Action" Letter	73	62	25	26	149	227	55
Goal – Percent within 4 months	—	—	—	75%	90%	—	—
Percent of actions within goal	98.6%	100.0%	96.0%	100.0%	99.3%	100.0%	100.0%
Applications without an action	0	0	0	0	0	0	22
Cohort status	Complete	Complete	Complete	Complete	Complete	Complete	Open



- All cohorts prior to FY 2009 are complete.
- FY 2007 and FY 2008 saw a significant surge of BLA Manufacturing Supplements that require prior approval.

# Resubmissions of BLAs and BLA Supplements

Actions through 31 March 2009

## Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Class 1 resubmission of an original BLA or BLA efficacy supplement	0	0	5	0	29	102	0
Class 2 resubmission of an original BLA or BLA efficacy supplement	2	5	9	5	13	2	0
<b>Total Workload</b>	<b>2</b>	<b>5</b>	<b>14</b>	<b>5</b>	<b>42</b>	<b>104</b>	<b>0</b>

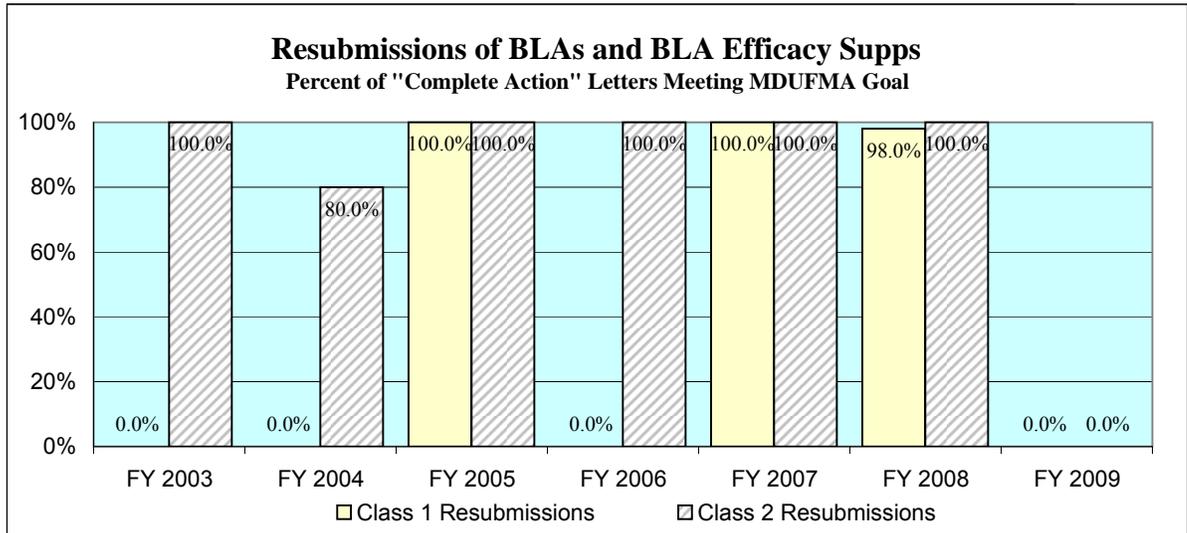
## Review and Act on Resubmissions

### Class 1 Resubmissions —

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
"Complete Action" Letter	0	0	5	0	29	102	0
Goal – Percent within 2 months	—	—	75%	80%	90%	—	—
Percent of actions within goal	--	--	100.0%	--	100.0%	98.0%	--
Applications without an action	0	0	0	0	0	0	0
Cohort status	Complete	Complete	Complete	Complete	Complete	Complete	Open

### Class 2 Resubmissions —

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
"Complete Action" Letter	2	5	9	5	13	2	0
Goal – Percent within 6 months	—	—	75%	80%	90%	—	—
Percent of actions within goal	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%	--
Applications without an action	0	0	0	0	0	0	0
Cohort status	Complete	Complete	Complete	Complete	Complete	Complete	Open



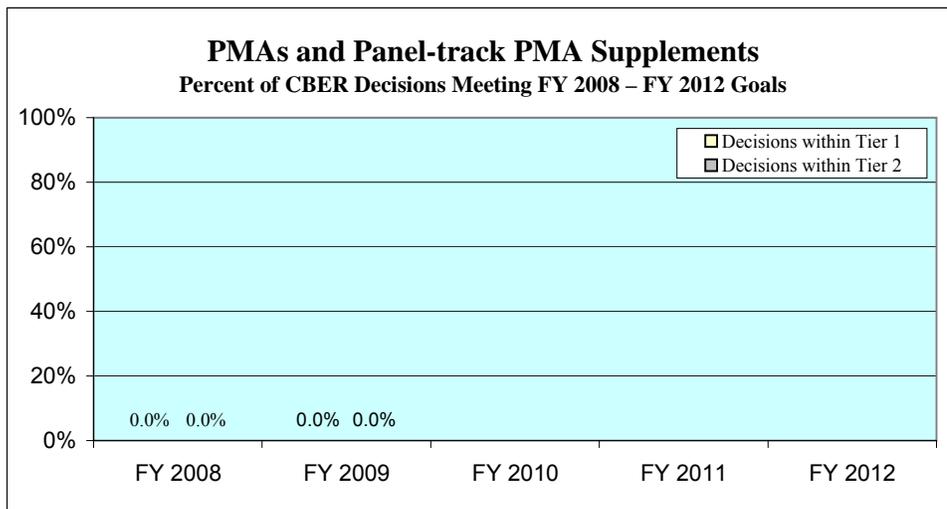
- All cohorts prior to FY 2009 are closed for both class 1 and class 2 resubmissions.

## Data on FY 2008 – FY 2012 Cohorts

Actions through 31 March 2009

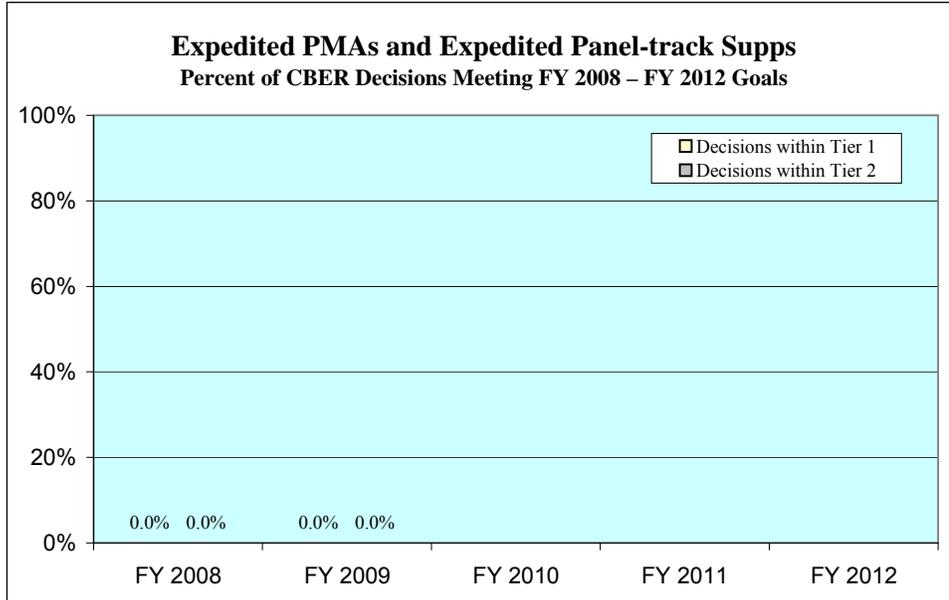
### PMA and Panel-track Supplements

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



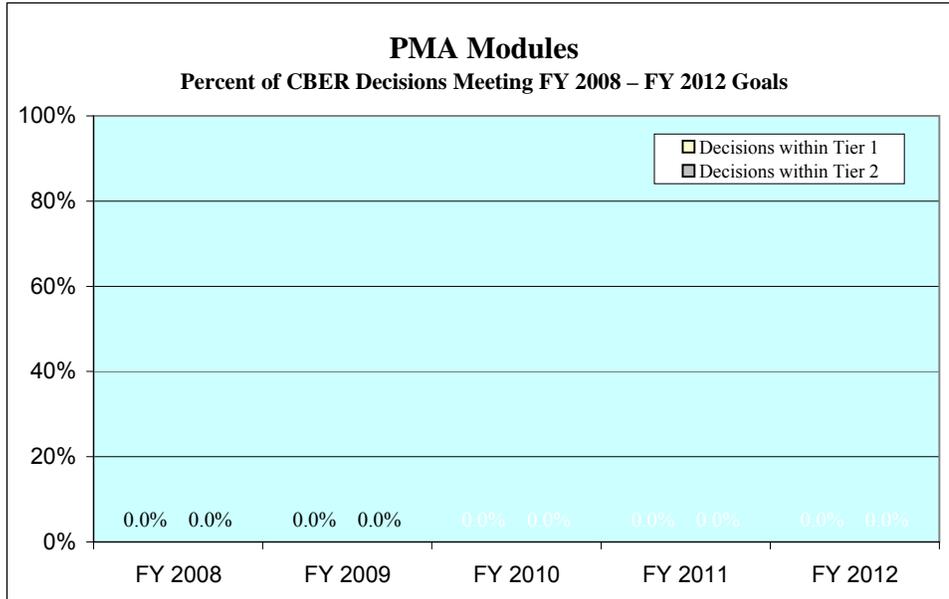
### Expedited PMAs and Expedited Panel-track Supplements

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



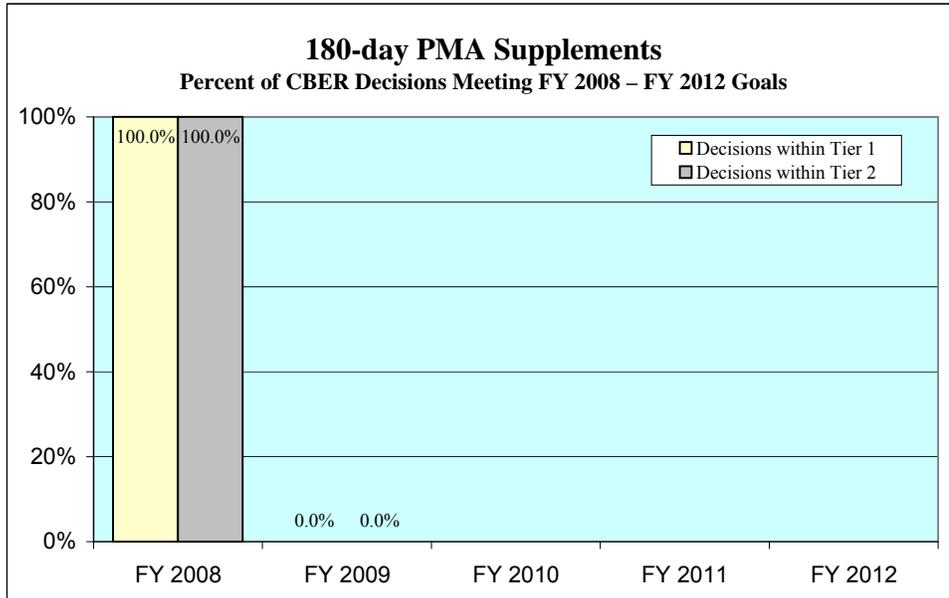
**PMA Modules**

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



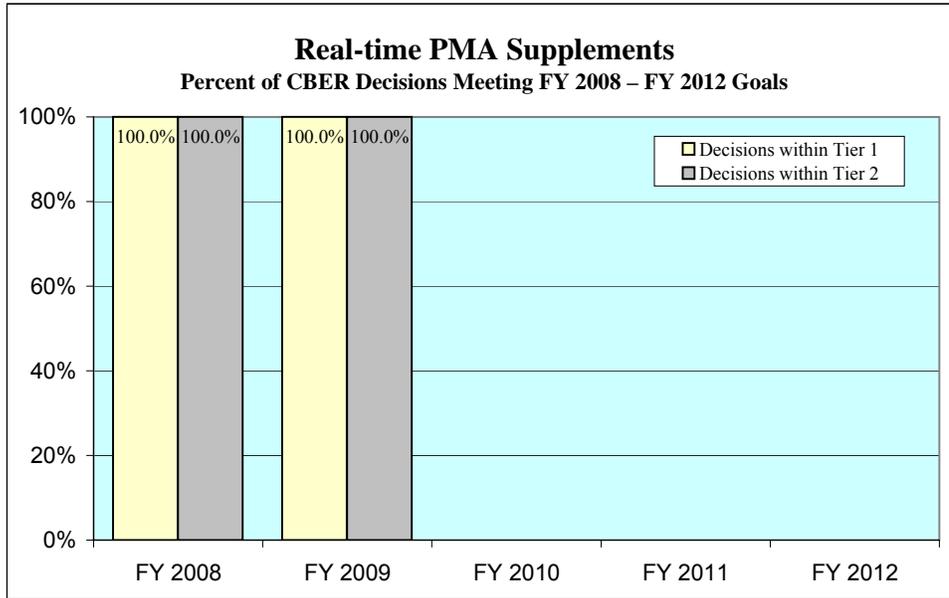
### 180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	2	—	—	—
Total FDA Decisions	4	0	—	—	—
Percent within Tier 1 goal (180 days)	100.0%	--	—	—	—
Tier 1 goal — <i>Percent within 180 days</i>	85%	85%	85%	85%	85%
Percent within Tier 2 goal (210 days)	100.0%	--	—	—	—
Tier 2 goal — <i>Percent within 210 days</i>	95%	95%	95%	95%	95%
Cohort status	Open	Open	—	—	—



## Real-time PMA Supplements

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



**510(k)s**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
Workload (Received to Date)	53	24	—	—	—
MDUFMA Cohort	52	24	—	—	—
Total FDA Decisions	43	9	—	—	—
Percent within Tier 1 goal (90 days)	95.3%	100.0%	—	—	—
Tier 1 goal — <i>Percent within 90 days</i>	90%	90%	90%	90%	90%
Percent within Tier 2 goal (150 days)	97.7%	100.0%	—	—	—
Tier 2 goal — <i>Percent within 150 days</i>	98%	98%	98%	98%	98%
Cohort status	Open	Open	—	—	—

