

**Quarterly Update on
Medical Device Performance Goals**
— CBER Performance Data —
Actions through December 31, 2008

Data on FY 2003 – FY 2007 Cohorts

PMA and Panel-Track Supplements

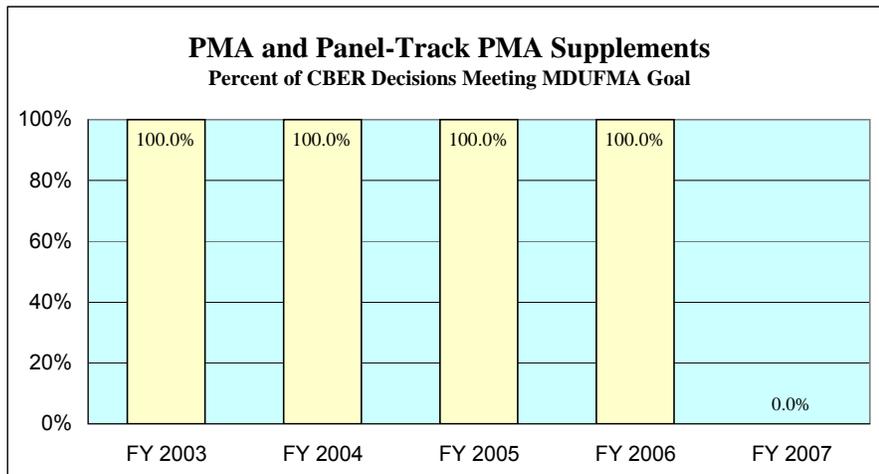
Actions through December 31, 2008

Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
PMA	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	--	--	--	--	--



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

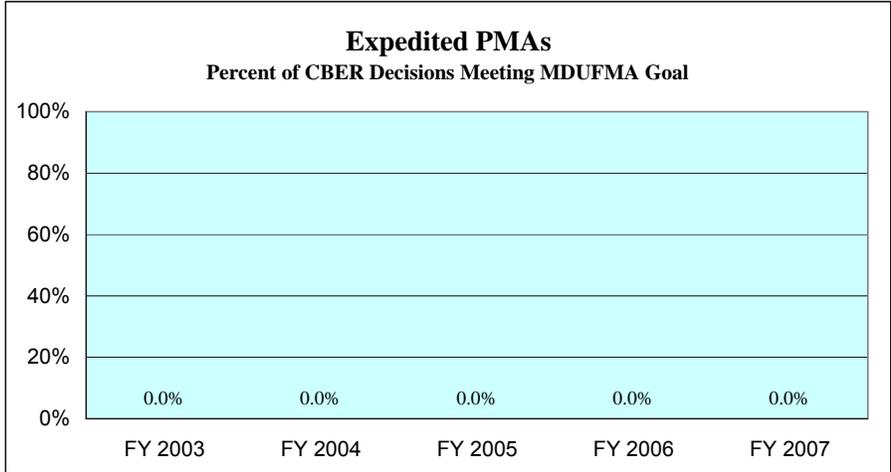
Expedited PMAs
 Actions through December 31, 2008

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 – <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	Complete	Complete	Complete	Complete	Complete



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

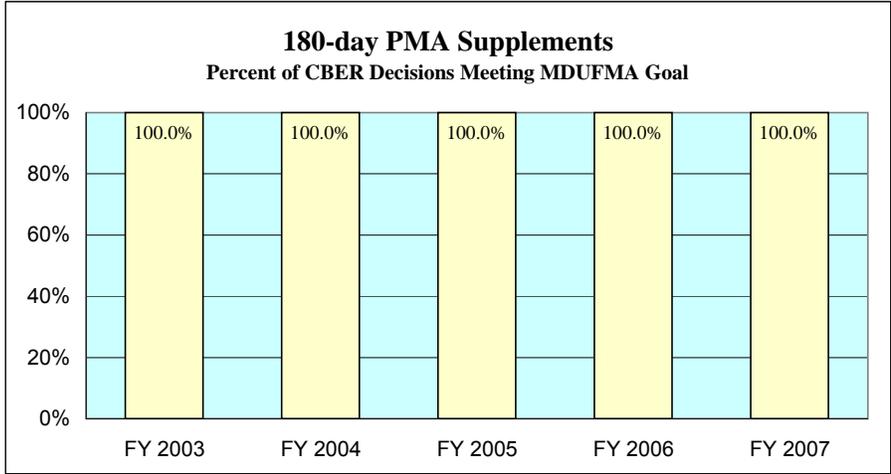
180-day PMA Supplements
 Actions through December 31, 2008

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 – <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	Complete	Complete	Complete	Complete	Complete



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

510(k) Premarket Notifications

Actions through December 31, 2008

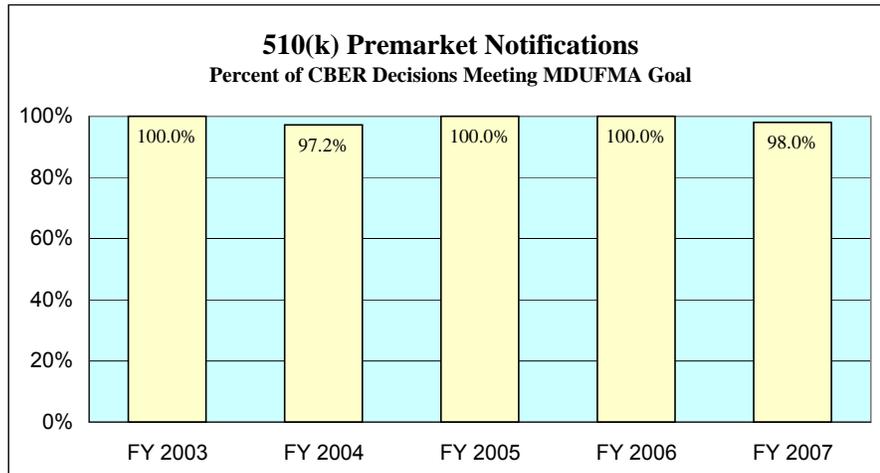
Workload

	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 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 one 510(k) from the FY 2005 cohort, one 510(k) from FY 2006, and two 510(k) from FY 2007 remain without a decision.

Data on FY 2003 – FY 2009 Biologics Workloads

Note: No Commitment Goals After FY 2007

Biologics Licensing Applications

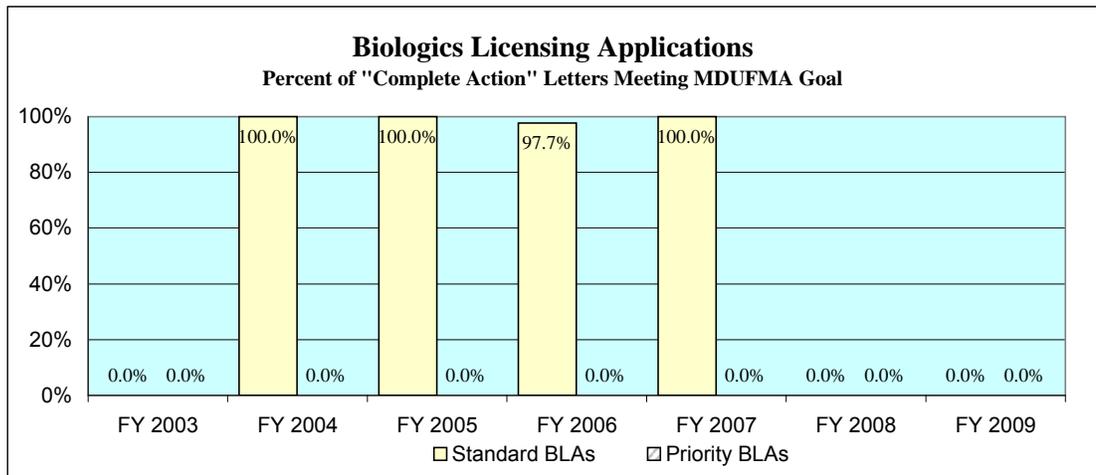
Actions through December 31, 2008

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	14	0
Priority BLAs	0	0	0	0	0	0	0
Total Workload	0	9	15	44	2	14	0

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	14	0
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 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 specified by MDUFMA performance goals.
- CBER is voluntarily continuing to report on goals identified in the MDUFMA commitment letter that were not continued as MDUFA/FDAAA

BLA Supplements
Actions through December 31, 2008

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	0
Priority BLA Efficacy Supplements	0	0	0	0	0	0	0
BLA Manufacturing Supplements that Require Prior Approval	73	62	25	26	149	226	53
Total Workload	76	62	25	26	149	226	53

Review and Act on BLA Supplements

Standard BLA Efficacy Supplements

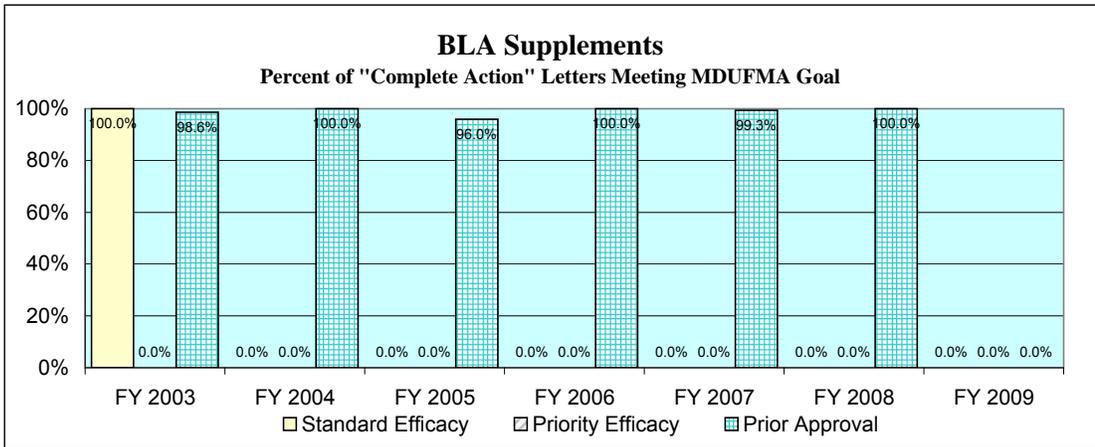
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
"Complete Action" Letter	3	0	0	0	0	0	0
Goal – Percent within 10 months	—	—	—	75%	90%	—	—
Percent of actions within goal	100.0%	--	--	--	--	--	--
Applications without an action	0	0	0	0	0	0	0
Cohort status	Complete	Complete	Complete	Complete	Complete	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	220	0
Goal – Percent within 4 months	—	—	—	75%	90%	—	—
Percent of actions within goal	98.6%	100.0%	96.0%	100.0%	99.3%	100.0%	--
Applications without an action	0	0	0	0	0	6	53
Cohort status	Complete	Complete	Complete	Complete	Complete	Open	Open



- All cohorts prior to FY 2008 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 December 31, 2008

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
Total Workload	2	5	14	5	42	104	0

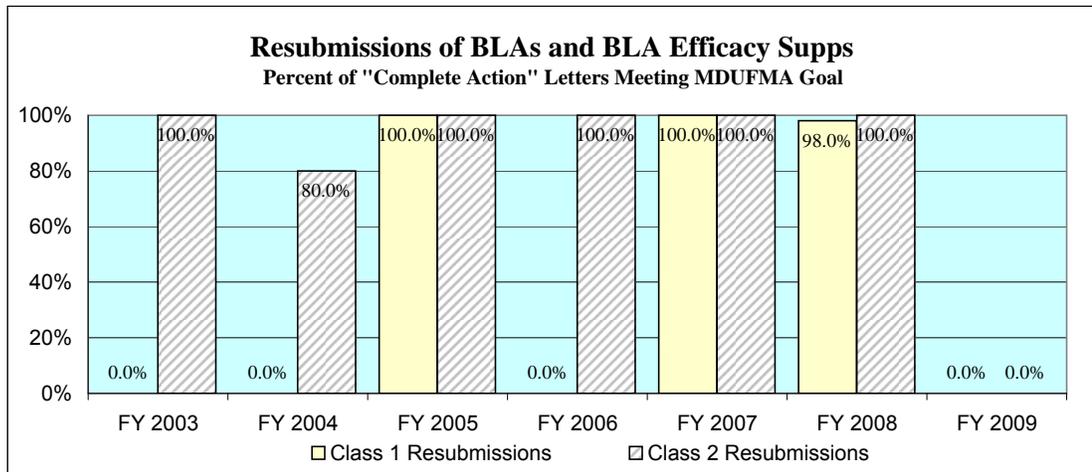
Review and Act on Resubmissions

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						

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	1	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	1	0
Cohort status	Complete	Complete	Complete	Complete	Complete	Open	Open



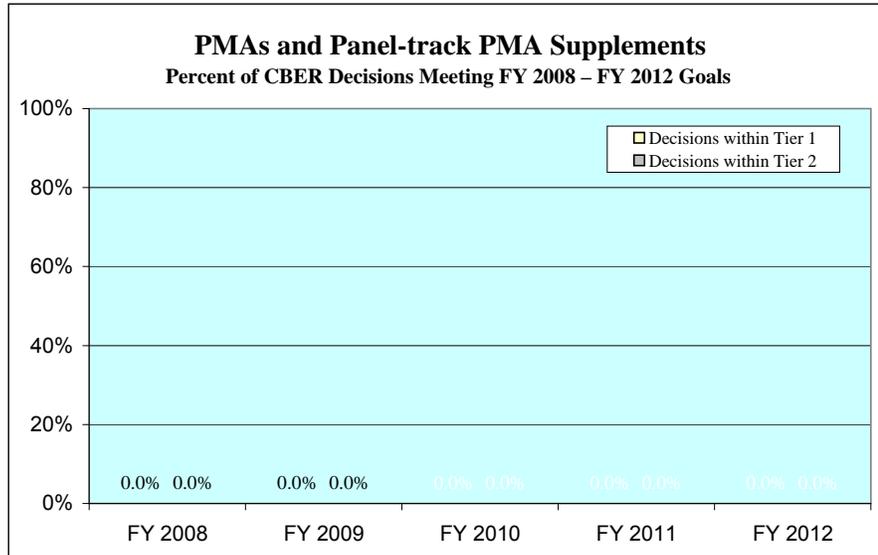
- All MDUFMA cohorts prior to FY 2008 are closed for both class 1 and class 2 resubmissions. Only 1 class 2 resubmission from FY 2008

Data on FY 2008 – FY 2012 Cohorts

Actions through December 31, 2008

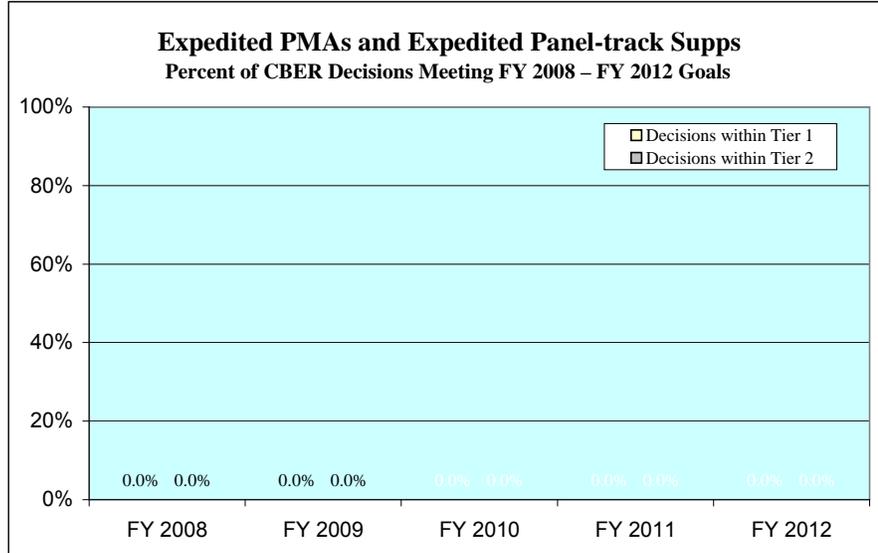
PMA and Panel-track Supplements

	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	Complete	Open	—	—	—



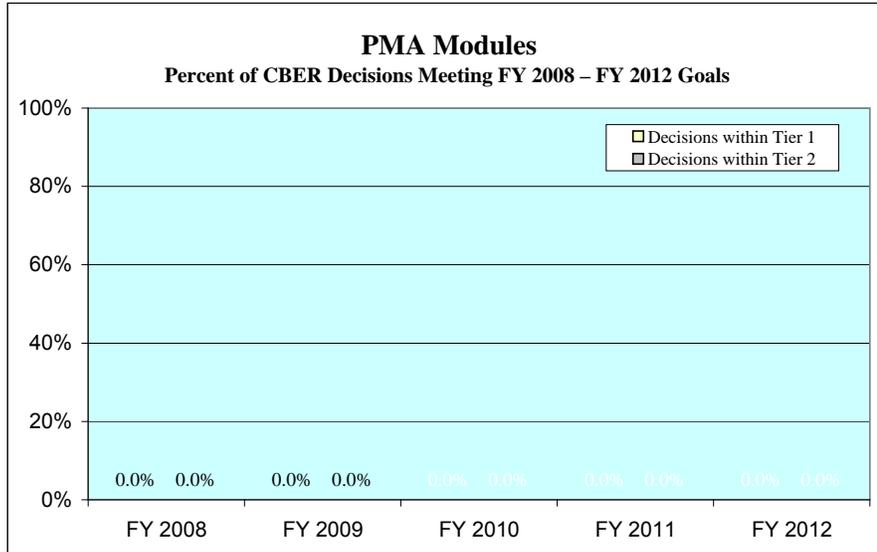
Expedited PMAs and Expedited Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	—	—	—
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	Complete	Open	—	—	—



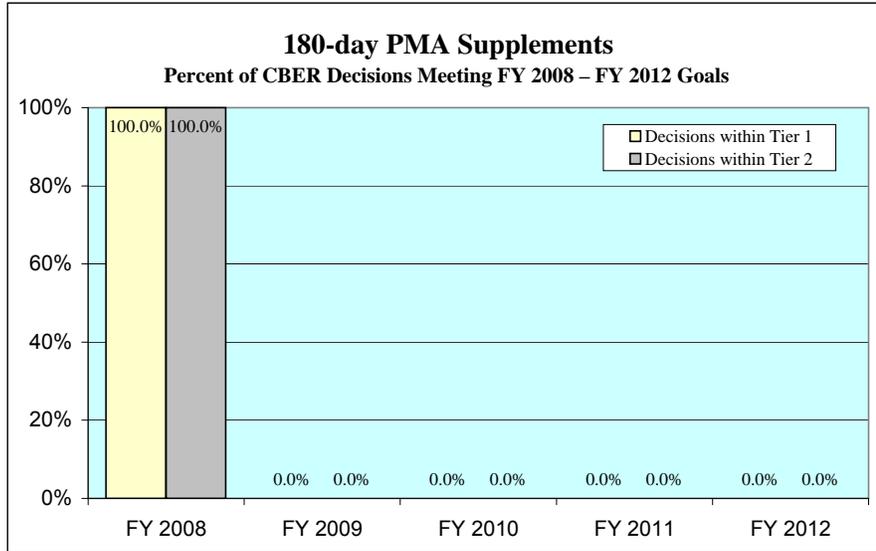
PMA Modules

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
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>	—	—	—



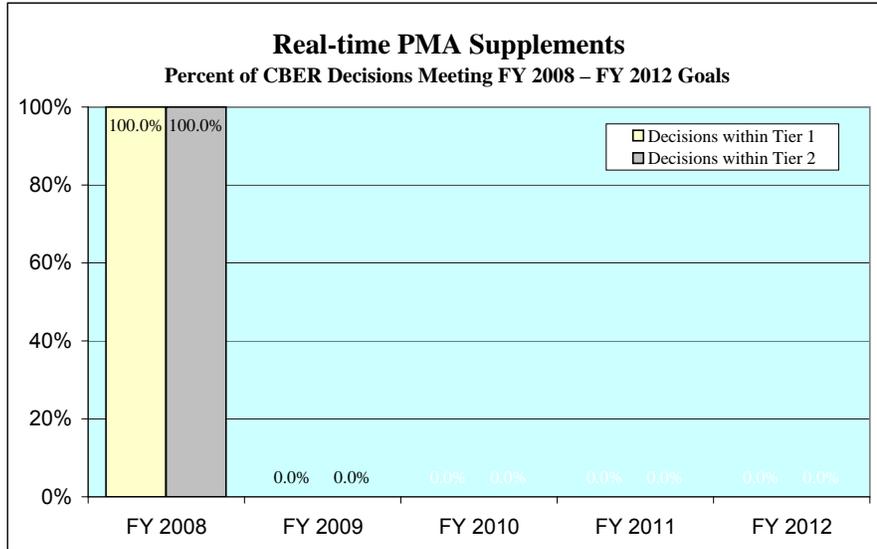
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	0	—	—	—
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	—	—	—



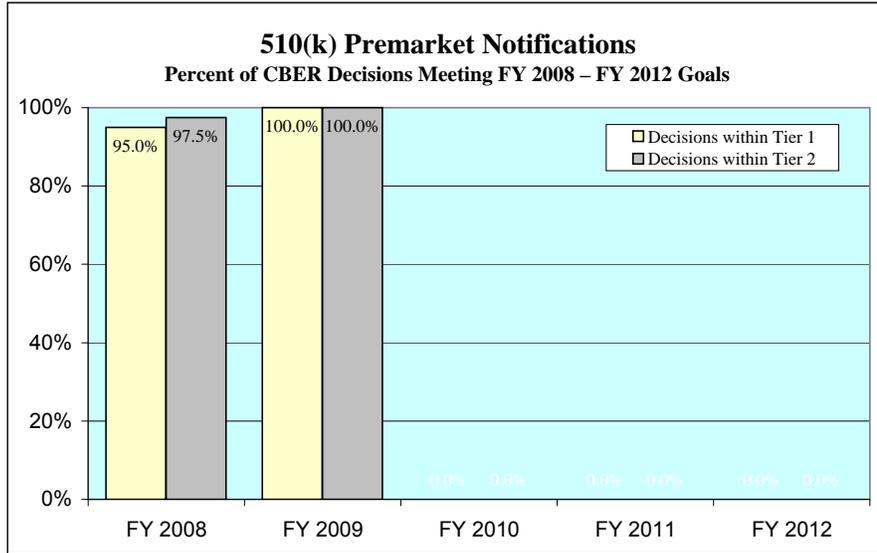
Real-time PMA Supplements

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



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	53	12	—	—	—
MDUFMA Cohort	52	12	—	—	—
Total FDA Decisions	40	3	—	—	—
Percent within Tier 1 goal (90 days)	95.0%	100.0%	—	—	—
Tier 1 goal — <i>Percent within 90 days</i>	90%	90%	90%	90%	90%
Percent within Tier 2 goal (150 days)	97.5%	100.0%	—	—	—
Tier 2 goal — <i>Percent within 150 days</i>	98%	98%	98%	98%	98%
Cohort status	Open	Open	—	—	—



Quarterly Report on Medical Device Performance Goals

FY 2003 Receipt Cohort

— All Cohorts are Closed —

Data for CBER

Complete = Cohort Closed for this Performance Goal (No Additional Actions Are Possible)

PMA's and Panel-Track Supplements

Type of Application	Filed	<i>Complete</i> FDA Decisions								Awaiting MDUFMA Decision	
		Total Decisions	≤ 320 days			> 320 days			Number	% of Filed	
			Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions			
Original PMA	3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%	
Panel-track Supplement	0	0	0	--	--	0	--	--	0	--	
Total	3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%	

Type of Application	<i>Complete</i> FDA Decisions within 180 Days (Goal Applies Only to FY 2007)					
	≤ 180 days			> 180 days		
	Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions
Original PMA	2	66.7%	66.7%	1	33.3%	33.3%
Panel-track Supplement	0	--	--	0	--	--
Total	2	66.7%	66.7%	1	33.3%	33.3%

Expedited PMA's

Filed	<i>Complete</i> FDA Decision							Awaiting MDUFMA Decision	
	Total Decisions	Decisions ≤ 300 days			Decisions > 300 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
0	0	0	--	--	0	--	--	0	--

180-day Supplements

Filed	Total Decisions	<i>Complete</i> FDA Decisions						Awaiting MDUFMA Decision	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
65	54	-	0	0	0

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 here is *Total SE/NSE Decisions + Total Remaining Awaiting MDUFMA Decision*; some 510(k)s currently awaiting a MDUFMA decision may ultimately be excluded from the MDUFMA cohort.

Complete SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
54	54	83.1%	100.0%	100.0%	0	0.0%	0.0%	0.0%

BLAs

Complete First Action = "Complete Action Letter"									Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)			Number	% of Rcvd.
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions		
Standard	0	0	0	--	--	0	--	--	0	--
Priority	0	0	0	--	--	0	--	--	0	--

BLA Efficacy Supplements

Complete First Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)			Number	% of Rcvd.
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions		
Standard	3	3	3	100%	100%	0	0.0%	0.0%	0	0.0%
Priority	0	0	0	--	--	0	--	--	0	--

BLA Prior Approval Manufacturing Supplements

<i>Complete</i> First Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 4 months			> 4 months			Number	% of Rcvd.
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions		
Standard	73			98.6%	98.6%	1	1.4%	1.4%	0	0.0%

BLA /BLA Supplement Resubmissions

<i>Complete</i> Second or Later Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total Actions	≤ 2 months (Class 1) or ≤ 6 months (Class 2)			> 2 months (Class 1) or > 6 months (Class 2)			Number	% of Rcvd.
			Number	% of Rcvd.	% of Actions	Number	% of Rcvd.	% of Actions		
Class 1	0	0	0	--	--	0	--	--	0	--
Class 2	2	2	2	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

Quarterly Report on Medical Device Performance Goals

FY 2004 Receipt Cohort

— All Cohorts are Closed —

Data for CBER

Complete = Cohort Closed for this Performance Goal (No Additional Actions Are Possible)

PMAs and Panel-Track Supplements

Type of Application	Filed	<i>Complete</i> FDA Decisions							Awaiting MDUFMA Decision	
		Total Decisions	≤ 320 days			> 320 days			Number	% of Filed
			Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
Original PMA	1	1	1	100.0%	100.0%	0	0.0%	0.0%	0	0.0%
Panel-track Supplement	0	0	0	--	--	0	--	--	0	--
Total	1	1	1	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

Type of Application	<i>Complete</i> FDA Decisions within 180 Days (Goal Applies Only to FY 2007)					
	≤ 180 days			> 180 days		
	Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions
Original PMA	1	100.0%	100.0%	0	0.0%	0.0%
Panel-track Supplement	0	--	--	0	--	--
Total	1	100.0%	100.0%	0	0.0%	0.0%

Expedited PMAs

Filed	<i>Complete</i> FDA Decision							Awaiting MDUFMA Decision	
	Total Decisions	Decisions ≤ 300 days			Decisions > 300 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
0	0	0	--	--	0	--	--	0	--

180-day Supplements

Filed	<i>Complete</i> FDA Decisions							Awaiting MDUFMA Decision	
	Total Decisions	≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
78	72	-	0	0	0

other than an SE or NSE decision (e.g., when FDA finds that a 510(k) was not required). The number here is Total SE/NSE Decisions + Total Remaining Awaiting MDUFMA Decision; some 510(k)s currently awaiting a MDUFMA decision may ultimately be excluded from the MDUFMA cohort.

Complete SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
72	70	89.7%	97.2%	97.2%	2	2.6%	2.8%	2.8%

BLAs

Complete First Action = "Complete Action Letter"										Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) ≤ 6 months (priority)			> 10 months (standard) > 6 months (priority)			Number	% of Rcvd.	
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions			
Standard	9	9	9	100.0%	100.0%	0	0.0%	0.0%	0	0.0%	
Priority	0	0	0	--	--	0	--	--	0	--	

BLA Efficacy Supplements

<i>Complete</i> First Action = "Complete Action" Letter										Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) ≤ 6 months (priority)			> 10 months (standard) > 6 months (priority)			Number		
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions			
Standard	0	0	0	--	--	0	--	--	0	--	
Priority	0	0	0	--	--	0	--	--	0	--	

BLA Prior Approval Manufacturing Supplements

<i>Complete</i> First Action = "Complete Action" Letter										Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 4 months			> 4 months			Number		
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions			
Standard	62			100.0%	100.0%	0	0.0%	0.0%	0	0.0%	

BLA /BLA Supplement Resubmissions

<i>Complete</i> Second or Later Action = "Complete Action" Letter										Awaiting MDUFMA Decision	
	Total Received	Total Actions	≤ 2 months (Class 1) or ≤ 6 months (Class 2)			> 2 months (Class 1) or > 6 months (Class 2)			Number		
			Number	% of Rcvd.	% of Actions	Number	% of Rcvd.	% of Actions			
Class 1	0	0	0	--	--	0	--	--	0	--	
Class 2	5	5	4	80.0%	80.0%	1	20.0%	20.0%	0	0.0%	

Quarterly Report on Medical Device Performance Goals

FY 2005 Receipt Cohort

Actions through December 31, 2008

Data for CBER

Complete = Cohort Closed for this Performance Goal (No Additional Actions Are Possible)

PMAs and Panel-Track Supplements

Type of Application	Filed	<i>Complete</i> FDA Decisions							Awaiting MDUFMA Decision	
		Total Decisions	≤ 320 days			> 320 days			Number	% of Filed
			Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
Original PMA	5	5	5	100.0%	100.0%	0	0.0%	0.0%	0	0.0%
Panel-track Supplement	0	0	0	--	--	0	--	--	0	--
Total	5	5	5	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

Type of Application	<i>Complete</i> FDA Decisions within 180 Days (Goal Applies Only to FY 2007)					
	≤ 180 days			> 180 days		
	Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions
Original PMA	1	20.0%	20.0%	4	80.0%	80.0%
Panel-track Supplement	0	--	--	0	--	--
Total	1	20.0%	20.0%	4	80.0%	80.0%

Expedited PMAs

Filed	<i>Complete</i> FDA Decision						Awaiting MDUFMA Decision		
	Total Decisions	Decisions ≤ 300 days			Decisions > 300 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
0	0	0	--	--	0	--	--	0	--

180-day Supplements

<i>Complete</i>		FDA Decisions						Awaiting MDUFMA Decision	
Filed	Total Decisions	≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
2	2	2	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
63	58	1	1	0	0

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 here is *Total SE/NSE Decisions + Total Remaining Awaiting MDUFMA Decision*; some 510(k)s currently awaiting a MDUFMA decision may ultimately be excluded from the MDUFMA cohort.

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
57	57	90.5%	98.3%	100.0%	0	0.0%	0.0%	0.0%

BLAs

<i>Complete</i> First Action = "Complete Action Letter"										
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)			Awaiting MDUFMA Decision	
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	15	15	15	100.0%	100%	0	0	0%	0	0.0%
Priority	0	0	0	--	--	0	--	--	0	--

BLA Efficacy Supplements

<i>Complete</i> First Action = "Complete Action" Letter										
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)			Awaiting MDUFMA Decision	
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	0	0	0	--	--	0	--	--	0	--
Priority	0	0	0	--	--	0	--	--	0	--

BLA Prior Approval Manufacturing Supplements

<i>Complete</i> First Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 4 months			> 4 months			Number	% of Rcvd.
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions		
Standard	25			96.0%	96.0%	1	4.0%	4.0%	0	0.0%

25

24

BLA /BLA Supplement Resubmissions

<i>Complete</i> Second or Later Action = "Complete Action" Letter										Awaiting MDUFMA Decision	
	Total Received	Total Actions	≤ 2 months (Class 1) or ≤ 6 months (Class 2)			> 2 months (Class 1) or > 6 months (Class 2)			Number		
			Number	% of Rcvd.	% of Actions	Number	% of Rcvd.	% of Actions			
Class 1	5	5	5	100.0%	100.0%	0	0.0%	0.0%	0	0.0%	
Class 2	9	9	9	100.0%	100.0%	0	0.0%	0.0%	0	0.0%	

Quarterly Report on Medical Device Performance Goals

FY 2006 Receipt Cohort

Actions through December 31, 2008

Data for CBER

Complete = Cohort Closed for this Performance Goal (No Additional Actions Are Possible)

PMAs and Panel-Track Supplements

Type of Application	Filed	<i>Complete</i> FDA Decisions							Awaiting MDUFMA Decision	
		Total Decisions	≤ 320 days			> 320 days			Number	% of Filed
			Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
Original PMA	3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%
Panel-track Supplement	0	0	0	--	--	0	--	--	0	--
Total	3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

Type of Application	<i>Complete</i> FDA Decisions within 180 Days (Goal Applies Only to FY 2007)					
	≤ 180 days			> 180 days		
	Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions
Original PMA	1	33.3%	33.3%	2	66.7%	66.7%
Panel-track Supplement	0	--	--	0	--	--
Total	1	33.3%	33.3%	2	66.7%	66.7%

Expedited PMAs

Filed	<i>Complete</i> FDA Decision						Awaiting MDUFMA Decision		
	Total Decisions	Decisions ≤ 300 days			Decisions > 300 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
0	0	0	--	--	0	--	--	0	--

180-day Supplements

<i>Complete</i>		FDA Decisions						Awaiting MDUFMA Decision	
Filed	Total Decisions	≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
60	55	1	1	0	1

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 here is *Total SE/NSE Decisions + Total Remaining Awaiting MDUFMA Decision*; some 510(k)s currently awaiting a MDUFMA decision may ultimately be excluded from the MDUFMA cohort.

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
54	54	90.0%	98.2%	100.0%	0	0.0%	0.0%	0.0%

BLAs

<i>Complete</i>		First Action = "Complete Action Letter"							Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)				
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	44	44	43	97.7%	97.7%	1	2.3%	2.3%	0	0.0%
Priority	0	0	0	--	--	0	--	--	0	--

BLA Efficacy Supplements

<i>Complete</i>		First Action = "Complete Action" Letter							Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)				
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	0	0	0	--	--	0	--	--	0	--
Priority	0	0	0	--	--	0	--	--	0	--

BLA Prior Approval Manufacturing Supplements

<i>Complete</i>		First Action = "Complete Action" Letter							Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 4 months			> 4 months				
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	26	26	26	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

BLA /BLA Supplement Resubmissions

<i>Complete</i>		Second or Later Action = "Complete Action" Letter							Awaiting MDUFMA Decision	
	Total Received	Total Actions	≤ 2 months (Class 1) or ≤ 6 months (Class 2)			> 2 months (Class 1) or > 6 months (Class 2)			Number	% of Rcvd.
			Number	% of Rcvd.	% of Actions	Number	% of Rcvd.	% of Actions		
Class 1	0	0	0	--	--	0	--	--	0	--
Class 2	5	5	5	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

Quarterly Report on Medical Device Performance Goals

FY 2007 Receipt Cohort

Actions through December 31, 2008

Data for CBER

Complete = Cohort Closed for this Performance Goal (No Additional Actions Are Possible)

PMAs and Panel-Track Supplements

Type of Application	Filed	<i>Complete</i> FDA Decisions							Awaiting MDUFMA Decision	
		Total Decisions	≤ 320 days			> 320 days			Number	% of Filed
			Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
Original PMA	0	0	0	--	--	0	--	--	0	--
Panel-track Supplement	0	0	0	--	--	0	--	--	0	--
Total	0	0	0	--	--	0	--	--	0	--

Type of Application	<i>Complete</i> FDA Decisions within 180 Days (Goal Applies Only to FY 2007)					
	≤ 180 days			> 180 days		
	Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions
Original PMA	0	--	--	0	--	--
Panel-track Supplement	0	--	--	0	--	--
Total	0	--	--	0	--	--

Expedited PMAs

Filed	<i>Complete</i> FDA Decision							Awaiting MDUFMA Decision	
	Total Decisions	Decisions ≤ 300 days			Decisions > 300 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
0	0	0	--	--	0	--	--	0	--

180-day Supplements

<i>Complete</i>		FDA Decisions						Awaiting MDUFMA Decision	
Filed	Total Decisions	≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
2	2	2	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
58	53	2	2	0	0

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 here is *Total SE/NSE Decisions + Total Remaining Awaiting MDUFMA Decision*; some 510(k)s currently awaiting a MDUFMA decision may ultimately be excluded from the MDUFMA cohort.

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
51	50	86.2%	94.3%	98.0%	1	1.7%	1.9%	2.0%

BLAs

<i>Complete</i> First Action = "Complete Action Letter"										Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)			Number		
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions			
Standard	2	2	2	100.0%	100.0%	0	0.0	0.0	0	0.0%	
Priority	0	0	0	--	--	0	--	--	0	--	

BLA Efficacy Supplements

<i>Complete</i> First Action = "Complete Action" Letter										Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)			Number		
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions			
Standard	0	0	0	--	--	0	--	--	0	--	
Priority	0	0	0	--	--	0	--	--	0	--	

BLA Prior Approval Manufacturing Supplements

<i>Complete</i> First Action = "Complete Action" Letter										Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 4 months			> 4 months			Number		
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions			
Standard	149	149	148	99.3%	99.3%	1	0.7%	0.7%	0	0.0%	

BLA /BLA Supplement Resubmissions

<i>Complete</i>		Second or Later Action = "Complete Action" Letter							Awaiting MDUFMA Decision	
	Total Received	Total Actions	≤ 2 months (Class 1) or ≤ 6 months (Class 2)			> 2 months (Class 1) or > 6 months (Class 2)			Number	% of Rcvd.
			Number	% of Rcvd.	% of Actions	Number	% of Rcvd.	% of Actions		
Class 1	29	29	29	100.0%	100.0%	0	0.0%	0.0%	0	0.0%
Class 2	13	13	13	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

Quarterly Report on Medical Device Performance Goals

FY 2008 Receipt Cohort

Actions through December 31, 2008

Data for CBER

PMA and Panel-Track Supplements

Filed	Complete FDA Decisions						Awaiting FDA Decision	
	Tier 1 ≤ 180 days (Goal: 60%)		Tier 2 ≤ 295 days (Goal: 90%)		> 295 days			
	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Filed
0	0	--	0	--	0	--	0	--

Expedited PMAs and Expedited PMA Supplements

Filed	Complete FDA Decisions						Awaiting FDA Decision	
	Tier 1 ≤ 180 days (Goal: 50%)		Tier 2 ≤ 280 days (Goal: 90%)		> 280 days			
	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Filed
0	0	--	0	--	0	--	0	--

PMA Modules

Received	Excluded from Cohort ¹	MDUFMA Cohort ¹	Complete FDA Decisions						Awaiting FDA Decision	
			Tier 1 ≤ 90 days (Goal: 75%)		Tier 2 ≤ 120 days (Goal: 90%)		> 120 days			
			Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions
0	0	-	0	--	0	--	0	--	-	--

180-day Supplements

Filed	Complete FDA Decisions						Awaiting FDA Decision	
	Tier 1 ≤ 180 days (Goal: 85%)		Tier 2 ≤ 210 days (Goal: 95%)		> 210 days			
	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Filed
5	4	100.0%	4	100.0%	0	0.0%	1	20.0%

Real-time PMA Supplements

Filed	Complete FDA Decisions						Awaiting FDA Decision	
	Tier 1 ≤ 60 days (Goal: 80%)		Tier 2 ≤ 90 days (Goal: 90%)		> 90 days			
	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Filed
2	2	100.0%	2	100.0%	0	0.0%	0	0.0%

510(k)s

Received	Excluded from Cohort ²	MDUFMA Cohort ²	FDA Decisions						Awaiting FDA Decision	
			Tier 1 ≤ 90 days (Goal: 90%)		Tier 2 ≤ 150 days (Goal: 98%)		> 150 days			
			Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Cohort
53	1	52	38	95.0%	39	97.5%	1	2.5%	12	23.1%

² 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). Some 510(k)s currently awaiting a MDUFMA decision may ultimately be excluded from the MDUFMA cohort.

BLAs

First Action = "Complete Action Letter"									Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)				
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	14	0	0	0.0%	--	0	0.0	--	14	100.0%
Priority	0	0	0	--	--	0	--	--	0	--

BLA Efficacy Supplements

First Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)				
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	0	0	0	--	--	0	--	--	0	--
Priority	0	0	0	--	--	0	--	--	0	--

BLA Prior Approval Manufacturing Supplements

First Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 4 months			> 4 months				
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	226	220	220	97.3%	100.0%	0	0.0%	0.0%	6	2.7%

BLA /BLA Supplement Resubmissions

Second or Later Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total Actions	≤ 2 months (Class 1) or ≤ 6 months (Class 2)			> 2 months (Class 1) or > 6 months (Class 2)				
			Number	% of Rcvd.	% of Actions	Number	% of Rcvd.	% of Actions	Number	% of Rcvd.
Class 1	102	102	100	98.0%	98.0%	2	2.0%	2.0%	0	0.0%
Class 2	2	1	1	50.0%	100.0%	0	0.0%	0.0%	1	50.0%

Quarterly Report on Medical Device Performance Goals

FY 2009 Receipt Cohort

Actions through December 31, 2008

Data for CBER

PMA and Panel-Track Supplements

Filed	FDA Decisions						Awaiting FDA Decision	
	Tier 1 ≤ 180 days (Goal: 60%)		Tier 2 ≤ 295 days (Goal: 90%)		> 295 days			
	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Filed
0	0	#DIV/0!	0	#DIV/0!	0	#DIV/0!	0	#DIV/0!

Expedited PMAs and Expedited PMA Supplements

Filed	FDA Decisions						Awaiting FDA Decision	
	Tier 1 ≤ 180 days (Goal: 50%)		Tier 2 ≤ 280 days (Goal: 90%)		> 280 days			
	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Filed
0	0	#DIV/0!	0	#DIV/0!	0	#DIV/0!	0	#DIV/0!

PMA Modules

Received	Excluded from Cohort ¹	MDUFMA Cohort ¹	FDA Decisions						Awaiting FDA Decision	
			Tier 1 ≤ 90 days (Goal: 75%)		Tier 2 ≤ 120 days (Goal: 90%)		> 120 days			
			Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Cohort
0	0	-	0	#DIV/0!	0	#DIV/0!	0	#DIV/0!	-	#DIV/0!

180-day Supplements

Filed	FDA Decisions						Awaiting FDA Decision	
	Tier 1 ≤ 180 days (Goal: 85%)		Tier 2 ≤ 210 days (Goal: 95%)		> 210 days			
	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Filed
0	0	#DIV/0!	0	#DIV/0!	0	#DIV/0!	0	#DIV/0!

Real-time PMA Supplements

Filed	FDA Decisions						Awaiting FDA Decision	
	Tier 1 ≤ 60 days (Goal: 80%)		Tier 2 ≤ 90 days (Goal: 90%)		> 90 days			
	Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Filed
1	0	#DIV/0!	0	#DIV/0!	0	#DIV/0!	1	100.0%

510(k)s

Received	Excluded from Cohort ²	MDUFMA Cohort ²	FDA Decisions						Awaiting FDA Decision	
			Tier 1 ≤ 90 days (Goal: 90%)		Tier 2 ≤ 150 days (Goal: 98%)		> 150 days			
			Number	% of Decisions	Number	% of Decisions	Number	% of Decisions	Number	% of Cohort
12	0	12	3	100.0%	3	100.0%	0	0.0%	9	75.0%

² 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). Some 510(k)s currently awaiting a MDUFMA decision may ultimately be excluded from the MDUFMA cohort.

BLAs

	Total Received	Total First Actions	First Action = "Complete Action Letter"						Awaiting MDUFMA Decision	
			≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)				
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	0	0	0	#DIV/0!	#DIV/0!	0	#DIV/0!	#DIV/0!	0	#DIV/0!
Priority	0	0	0	#DIV/0!	#DIV/0!	0	#DIV/0!	#DIV/0!	0	#DIV/0!

BLA Efficacy Supplements

	Total Received	Total First Actions	First Action = "Complete Action" Letter						Awaiting MDUFMA Decision	
			≤ 10 months (standard) or ≤ 6 months (priority)			> 10 months (standard) or > 6 months (priority)				
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.
Standard	0	0	0	#DIV/0!	#DIV/0!	0	#DIV/0!	#DIV/0!	0	#DIV/0!

Priority	0	0	0	#DIV/0!	#DIV/0!	0	#DIV/0!	#DIV/0!	0	#DIV/0!
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BLA Prior Approval Manufacturing Supplements

First Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total First Actions	≤ 4 months			> 4 months			Number	% of Rcvd.
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions		
Standard	53	0	0	0.0%	#DIV/0!	0	0.0%	#DIV/0!	53	100.0%

BLA /BLA Supplement Resubmissions

Second or Later Action = "Complete Action" Letter									Awaiting MDUFMA Decision	
	Total Received	Total Actions	≤ 2 months (Class 1) or ≤ 6 months (Class 2)			> 2 months (Class 1) or > 6 months (Class 2)			Number	% of Rcvd.
			Number	% of Rcvd.	% of Actions	Number	% of Rcvd.	% of Actions		
Class 1	0	0	0	#DIV/0!	#DIV/0!	0	#DIV/0!	#DIV/0!	0	#DIV/0!
Class 2	0	0	0	#DIV/0!	#DIV/0!	0	#DIV/0!	#DIV/0!	0	#DIV/0!