

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

Actions through September 30, 2006

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Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

Summary Tables

Actions through September 30, 2006

Data for FDA

Shading indicates a closed cohort.

Activity	Review Time Goal	Performance Goals and Actual Performance to Date										
		FY 2003		FY 2004		FY 2005		FY 2006		FY 2007		Overall, FY 2003 to Date (Actual)
		Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	
PMAs, Panel-Track Supplements, Premarket Reports												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	—	91.7%	—	91.7%	—	100.0%	80%	100.0%	90%		95.0%
• First action – "major deficiency" letter	150 days	—	84.6%	—	82.1%	75%	91.9%	80%	90.9%	90%		87.6%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	95.8%	—	95.0%	75%	90.0%	80%	90.0%	90%		92.9%
• Second or later action – "major deficiency" letter	120 days	—	100.0%	—	100.0%	75%	70.6%	80%	100.0%	90%		80.8%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	—	92.0%	—	89.7%	75%	91.9%	80%	100.0%	90%		91.6%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	50.0%	90.0%	0.0%	90%	75.0%	90%	--	90%		58.3%
Expedited PMAs												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	—	100.0%	—	92.3%	70%	66.7%	80%	--	90%		89.5%
• First action – "major deficiency" letter	120 days	—	100.0%	—	80.0%	70%	80.0%	80%	--	90%		82.4%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	—	100.0%	—	25.0%	70%	100.0%	80%	100.0%	90%		57.1%
• Second or later action – "major deficiency" letter	100 days	—	--	—	0.0%	70%	100.0%	80%	--	90%		66.7%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	—	100.0%	—	62.5%	70%	100.0%	80%	--	90%		80.0%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	100.0%	90%	50.0%	90%	--	90%	--	90%		66.7%

Activity	Review Time Goal	Performance Goals and Actual Performance to Date										
		FY 2003		FY 2004		FY 2005		FY 2006		FY 2007		Overall, FY 2003 to Date (Actual)
		Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	
180-day PMA Supplements												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	—	94.1%	—	96.2%	80%	95.0%	80%	98.9%	90%		95.7%
• First action – "not approvable" letter	120 days	—	18.8%	—	83.7%	80%	90.0%	85%	84.6%	90%		70.9%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	95.3%	—	96.8%	80%	98.4%	85%	98.6%	90%		96.7%
• Action on an amendment containing a complete response to a "not approvable" letter	160 days	—	96.0%	—	97.6%	80%	90.0%	85%	100.0%	90%		95.2%
510(k)s												
• FDA decision (SE/NSE)	90 days	—	76.1%	—	83.9%	75%	91.5%	75%	96.5%	80%		86.0%
• First action – "additional information" letter	75 days	—	58.6%	—	78.6%	70%	93.8%	80%	95.1%	90%		81.9%
• Second or later action	60 days	—	50.9%	—	81.9%	70%	91.6%	80%	96.7%	90%		79.4%
Biologics Licensing Applications (BLAs)												
• Review and act on standard original BLAs (issue "complete action" letter)	10.0 months	—	--	—	100.0%	—	100.0%	75%	--	90%		100.0%
• Review and act on priority original BLA submissions (issue "complete action" letter)	6.0 months	—	--	—	--	—	--	75%	--	90%		--
BLA Supplements												
• Review and act on standard BLA efficacy supplements (issue "complete action" letter)	10.0 months	—	100.0%	—	--	—	--	75%	--	90%		100.0%
• Review and act on priority BLA efficacy supplements (issue "complete action" letter)	6.0 months	—	--	—	--	—	--	75%	--	90%		--
• Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	4.0 months	—	98.6%	—	100.0%	—	96.0%	75%	100.0%	90%		98.9%
BLA Resubmissions, BLA Supplement Resubmissions												
• Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	2.0 months	—	--	—	--	75%	100.0%	80%	--	90%		100.0%
• Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	6.0 months	—	100.0%	—	80.0%	75%	100.0%	80%	100.0%	90%		94.7%

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

Summary Tables

Actions through September 30, 2006

Data for CBER

Shading indicates a closed cohort.

Activity	Review Time Goal	Performance Goals and Actual Performance to Date										
		FY 2003		FY 2004		FY 2005		FY 2006		FY 2007		Overall, FY 2003 to Date (Actual)
		Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	
PMAs, Panel-Track Supplements, Premarket Reports												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	—	100.0%	—	100.0%	—	100.0%	80%	100.0%	90%	—	100.0%
• First action – "major deficiency" letter	150 days	—	100.0%	—	--	75%	100.0%	80%	100.0%	90%	—	100.0%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	100.0%	—	100.0%	75%	--	80%	--	90%	—	100.0%
• Second or later action – "major deficiency" letter	120 days	—	--	—	--	75%	100.0%	80%	--	90%	—	100.0%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	—	--	—	--	75%	100.0%	80%	100.0%	90%	—	100.0%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	--	90%	--	90%	100.0%	90%	--	90%	—	100.0%
Expedited PMAs												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	—	--	—	--	70%	--	80%	--	90%	—	--
• First action – "major deficiency" letter	120 days	—	--	—	--	70%	--	80%	--	90%	—	--
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	—	--	—	--	70%	--	80%	--	90%	—	--
• Second or later action – "major deficiency" letter	100 days	—	--	—	--	70%	--	80%	--	90%	—	--
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	—	--	—	--	70%	--	80%	--	90%	—	--
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	--	90.0%	--	90%	--	90%	--	90%	—	--

Activity	Review Time Goal	Performance Goals and Actual Performance to Date										
		FY 2003		FY 2004		FY 2005		FY 2006		FY 2007		Overall, FY 2003 to Date (Actual)
		Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	
180-day PMA Supplements												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	—	100.0%	—	100.0%	80%	100.0%	80%	100.0%	90%	—	100.0%
• First action – "not approvable" letter	120 days	—	100.0%	—	--	80%	--	85%	50.0%	90%	—	66.7%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	100.0%	—	100.0%	80%	100.0%	85%	100.0%	90%	—	100.0%
• Action on an amendment containing a complete response to a "not approvable" letter	160 days	—	100.0%	—	--	80%	--	85%	--	90%	—	100.0%
510(k)s												
• FDA decision (SE/NSE)	90 days	—	100.0%	—	97.2%	75%	100.0%	75%	100.0%	80%	—	99.1%
• First action – "additional information" letter	75 days	—	100.0%	—	89.3%	70%	100.0%	80%	91.3%	90%	—	95.3%
• Second or later action	60 days	—	100.0%	—	100.0%	70%	100.0%	80%	100.0%	90%	—	100.0%
Biologics Licensing Applications (BLAs)												
• Review and act on standard original BLAs (issue "complete action" letter)	10.0 months	—	--	—	100.0%	—	100.0%	75%	--	90%	—	100.0%
• Review and act on priority original BLA submissions (issue "complete action" letter)	6.0 months	—	--	—	--	—	--	75%	--	90%	—	--
BLA Supplements												
• Review and act on standard BLA efficacy supplements (issue "complete action" letter)	10.0 months	—	100.0%	—	--	—	--	75%	--	90%	—	100.0%
• Review and act on priority BLA efficacy supplements (issue "complete action" letter)	6.0 months	—	--	—	--	—	--	75%	--	90%	—	--
• Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	4.0 months	—	98.6%	—	100.0%	—	96.0%	75%	100.0%	90%	—	98.9%
BLA Resubmissions, BLA Supplement Resubmissions												
• Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	2.0 months	—	--	—	--	75%	100.0%	80%	--	90%	—	100.0%
• Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	6.0 months	—	100.0%	—	80.0%	75%	100.0%	80%	100.0%	90%	—	94.7%

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

Summary Tables

Actions through September 30, 2006

Data for CDRH

Shading indicates a closed cohort.

Activity	Review Time Goal	Performance Goals and Actual Performance to Date										
		FY 2003		FY 2004		FY 2005		FY 2006		FY 2007		Overall, FY 2003 to Date (Actual)
		Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	
PMAs, Panel-Track Supplements, Premarket Reports												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	—	91.1%	—	91.5%	—	100.0%	80%	100.0%	90%	—	94.7%
• First action – "major deficiency" letter	150 days	—	84.0%	—	82.1%	75%	90.6%	80%	89.5%	90%	—	86.5%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	95.5%	—	94.7%	75%	90.0%	80%	90.0%	90%	—	92.6%
• Second or later action – "major deficiency" letter	120 days	—	100.0%	—	100.0%	75%	66.7%	80%	100.0%	90%	—	79.2%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	—	92.0%	—	89.7%	75%	90.3%	80%	100.0%	90%	—	90.9%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	50.0%	90%	0.0%	90%	60.0%	90%	--	90%	—	44.4%
Expedited PMAs												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	—	100.0%	—	92.3%	70%	66.7%	80%	--	90%	—	89.5%
• First action – "major deficiency" letter	120 days	—	100.0%	—	80.0%	70%	80.0%	80%	--	90%	—	82.4%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	—	100.0%	—	25.0%	70%	100.0%	80%	100.0%	90%	—	57.1%
• Second or later action – "major deficiency" letter	100 days	—	--	—	0.0%	70%	100.0%	80%	--	90%	—	66.7%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	—	100.0%	—	62.5%	70%	100.0%	80%	--	90%	—	80.0%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	100.0%	90%	50.0%	90%	--	90%	--	90%	—	66.7%

Activity	Review Time Goal	Performance Goals and Actual Performance to Date										
		FY 2003		FY 2004		FY 2005		FY 2006		FY 2007		Overall, FY 2003 to Date (Actual)
		Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	Goal	Actual	
180-day PMA Supplements												
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	—	94.0%	—	96.1%	80%	94.9%	80%	98.9%	90%	—	95.6%
• First action – "not approvable" letter	120 days	—	16.1%	—	83.7%	80%	90.0%	85%	87.5%	90%	—	71.0%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	95.3%	—	96.7%	80%	98.3%	85%	98.6%	90%	—	96.7%
• Action on an amendment containing a complete response to a "not approvable" letter	160 days	—	95.5%	—	97.6%	80%	25.0%	85%	100.0%	90%	—	95.1%
510(k)s												
• FDA decision (SE/NSE)	90 days	—	75.7%	—	83.6%	75%	91.4%	75%	96.5%	80%	—	85.8%
• First action – "additional information" letter	75 days	—	58.0%	—	78.4%	70%	93.7%	80%	95.1%	90%	—	81.7%
• Second or later action	60 days	—	49.3%	—	80.9%	70%	91.2%	80%	96.6%	90%	—	78.6%

Quarterly Update on Progress Towards Meeting
MDUFMA Performance Goals

— Performance Data for FDA (Combined CBER and CDRH) —

Actions through September 30, 2006

PMAs and Panel-Track Supplements

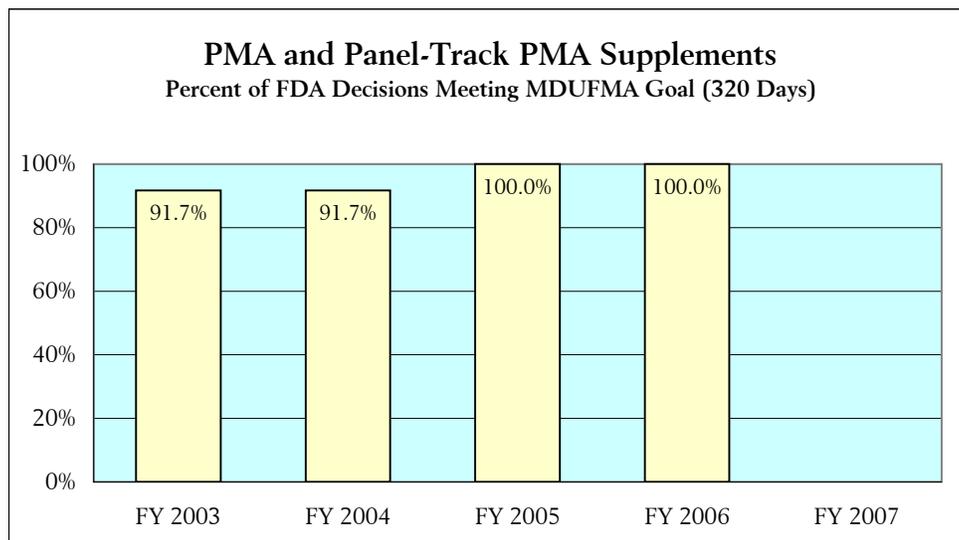
FDA Actions through September 30, 2006

Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
PMAs	43	40	46	37	—
Panel-Track Supplements	7	8	12	14	—
Total Workload	50	48	58	51	—

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	48	48	45	19	—
Goal – <i>Percent within 320 days</i>	—	—	—	80%	90%
Percent of decisions within goal	91.7%	91.7%	100.0%	100.0%	—
Applications without a decision	2	0	13	32	—
Cohort status	Open	<i>Complete</i>	Open	Open	—



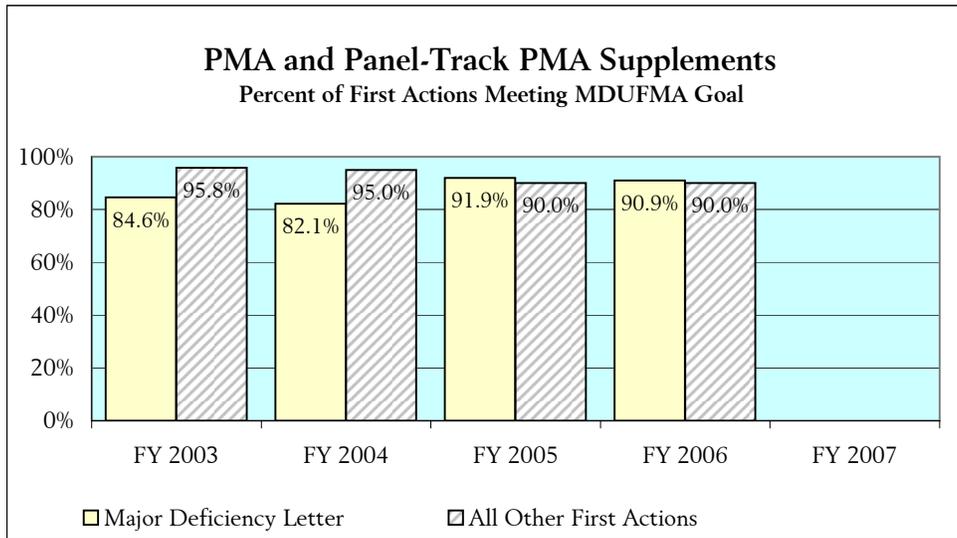
- Progress to date indicates FDA will likely meet the goal for FY 2006.
- FY 2004 cohort is complete. All other cohorts remain open.

PMAs and Panel-Track Supplements

FDA Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "major deficiency"	26	28	37	22	—
Goal – <i>Percent within 150 days</i>	—	—	75%	80%	90%
Percent of actions within goal	84.6%	82.1%	91.9%	90.9%	—
All other first actions	24	20	20	20	—
Goal – <i>Percent within 180 days</i>	—	—	75%	80%	90%
Percent of actions within goal	95.8%	95.0%	90.0%	90.0%	—
Total applications with a first action	50	48	57	42	—
Applications without a first action	0	0	1	9	—
Cohort status	<i>Complete</i>	<i>Complete</i>	Open	Open	—



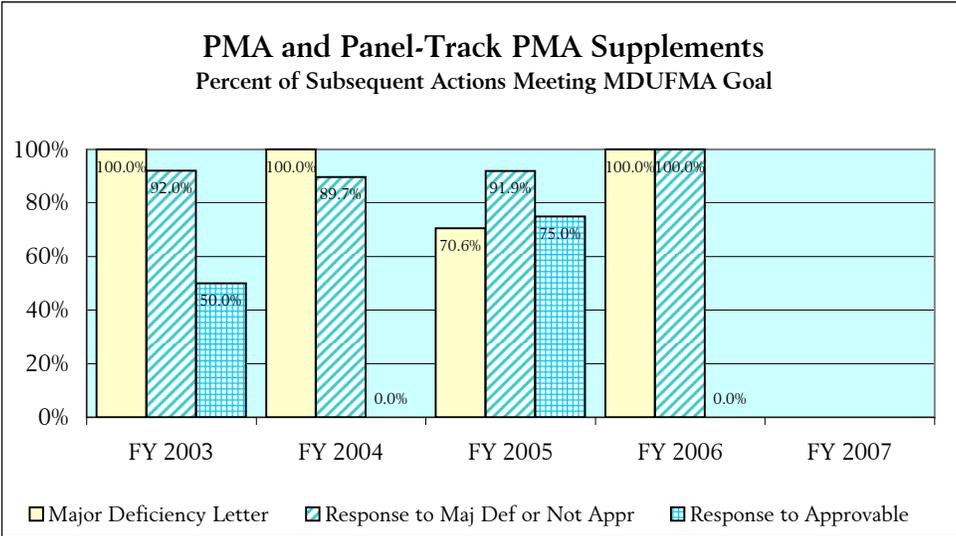
- All FY 2003 and FY 2004 applications have had a first action; these cohorts are complete.
- Progress to date indicates FDA will likely meet both first-action goals for FY 2005 and FY 2006.

PMAs and Panel-Track Supplements

FDA Actions through September 30, 2006

Subsequent Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later action = "major deficiency" letter	2	4	17	3	—
Goal – <i>Percent within 120 days</i>	—	—	75%	80%	90%
Percent of actions within goal	100.0%	100.0%	70.6%	100.0%	—
Cohort status	Open	Open	Open	Open	—
Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter					
	25	29	37	4	—
Goal – <i>Percent within 180 days</i>	—	—	75%	80%	90%
Percent of actions within goal	92.0%	89.7%	91.9%	100.0%	—
Cohort status	Open	Open	Open	Open	—
Action on an amendment containing a complete response to an "approvable" letter					
	2	2	8	0	—
Goal – <i>Percent within 30 days</i>	90%	90%	90%	90%	90%
Percent of actions within goal	50.0%	0.0%	75.0%	--	—
Cohort status	Open	Open	Open	Open	—



- Subsequent action cohorts will necessarily remain open longer than decision and first action cohorts.

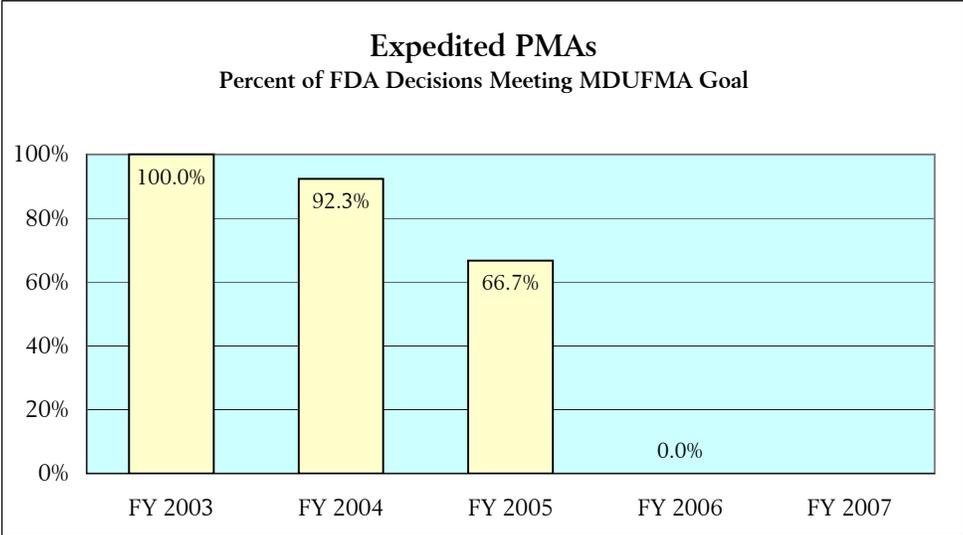
Expedited PMAs
 FDA Actions through September 30, 2006

Workload (Applications Filed to Date)

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

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	3	13	3	0	—
Goal – Percent within 300 days	—	—	70%	80%	90%
Percent of decisions within goal	100.0%	92.3%	66.7%	--	—
Applications without a decision	0	1	3	2	—
Cohort status	Complete	Open	Open	Open	—



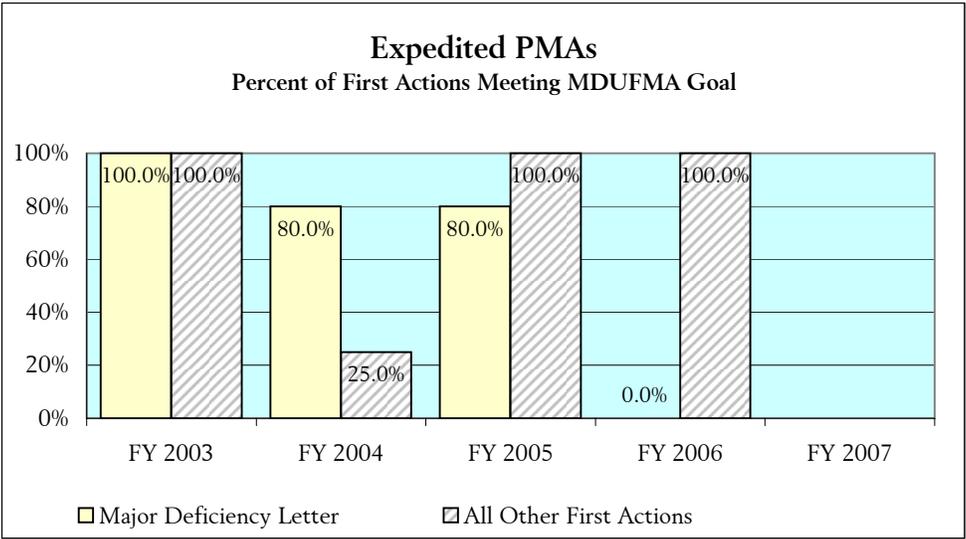
- FY 2003 cohort is complete. All other cohorts remain open.
- Because of the small number of Expedited PMAs, a single action may significantly affect performance measures.
- To date, no CBER PMA has qualified for Expedited status.

Expedited PMAs

FDA Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "major deficiency"	2	10	5	0	—
Goal – Percent within 120 days	—	—	70%	80%	90%
Percent of actions within goal	100.0%	80.0%	80.0%	--	—
All other first actions	1	4	1	1	—
Goal – Percent within 170 days	—	—	70%	80%	90%
Percent of actions within goal	100.0%	25.0%	100.0%	100.0%	—
Total applications with a first action	3	14	6	1	—
Applications without a first action	0	0	0	1	—
Cohort status	Complete	Complete	Complete	Open	—



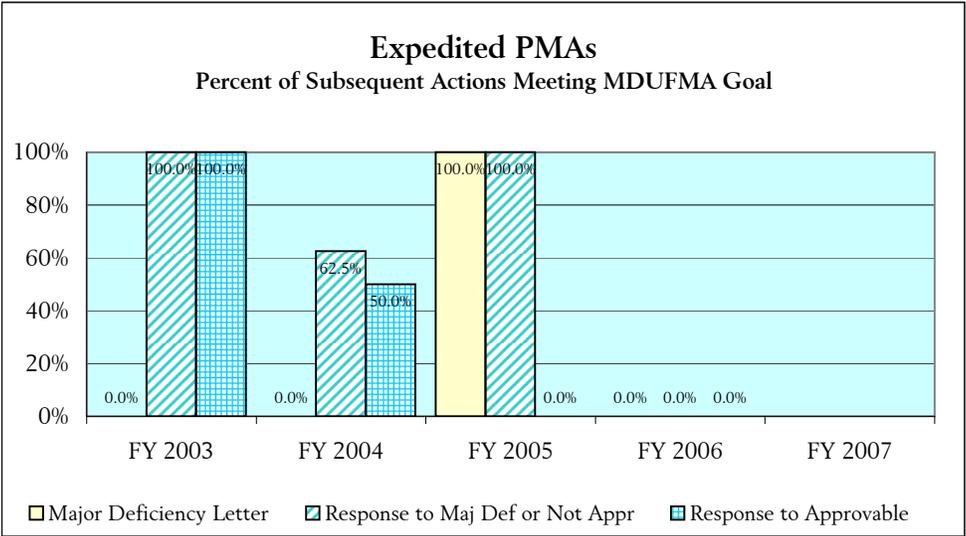
- All FY 2003, FY 2004, and FY 2005 applications have had a first action; these cohorts are complete.

Expedited PMAs

FDA Actions through September 30, 2006

Subsequent (Second or Later) Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later action = "major deficiency" letter	0	1	2	0	—
<i>Goal – Percent within 100 days</i>	—	—	70%	80%	90%
Percent of actions within goal	--	0.0%	100.0%	--	—
Cohort status	Complete	Open	Open	Open	—
<hr/>					
Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	2	8	5	0	—
<i>Goal – Percent within 170 days</i>	—	—	70%	80%	90%
Percent of actions within goal	100.0%	62.5%	100.0%	--	—
Cohort status	Complete	Open	Open	Open	—
<hr/>					
Action on an amendment containing a complete response to an "approvable" letter	1	2	0	0	—
<i>Goal – Percent within 30 days</i>	90%	90%	90%	90%	90%
Percent of actions within goal	100.0%	50.0%	--	0.0%	—
Cohort status	Complete	Open	Open	Open	—



180-day PMA Supplements

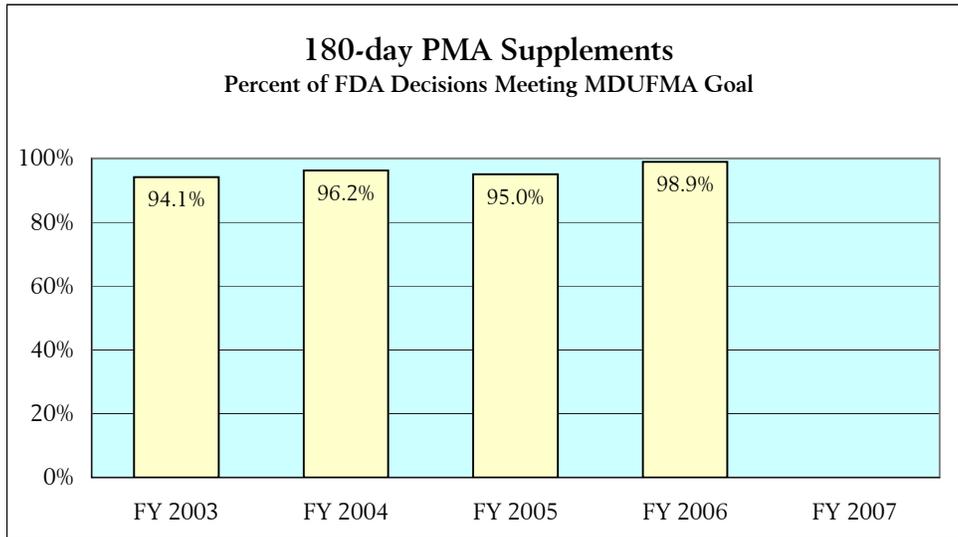
FDA Actions through September 30, 2006

Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
180-day PMA Supplements	204	106	101	131	—

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	204	106	101	95	—
Goal – Percent within 180 days	—	—	80%	80%	90%
Percent of decisions within goal	94.1%	96.2%	95.0%	98.9%	—
Applications without a decision	0	0	0	36	—
Cohort status	Complete	Complete	Complete	Open	—



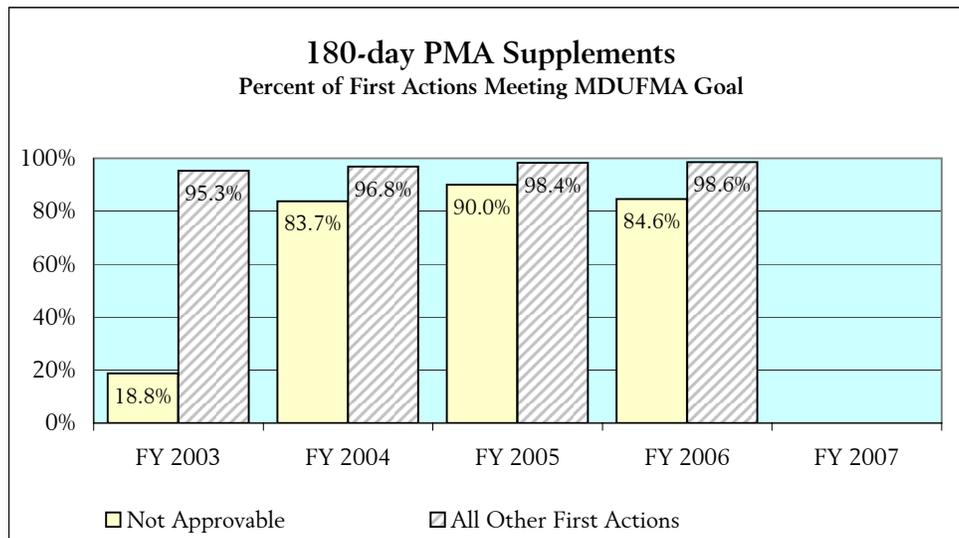
- FDA has made a decision on all 180-day PMA supplements received from FY 2003 through FY 2005. These cohorts are complete.

180-day PMA Supplements

FDA Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "not approvable"	32	43	40	26	—
<i>Goal – Percent within 120 days</i>	—	—	80%	85%	90%
Percent of actions within goal	18.8%	83.7%	90.0%	84.6%	—
All other first actions	172	63	61	71	—
<i>Goal – Percent within 180 days</i>	—	—	80%	85%	90%
Percent of actions within goal	95.3%	96.8%	98.4%	98.6%	—
Total applications with a first action	204	106	101	97	—
Applications without a first action	0	0	0	34	—
Cohort status	Complete	Complete	Complete	Open	—



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

510(k) Premarket Notifications

FDA Actions through September 30, 2006

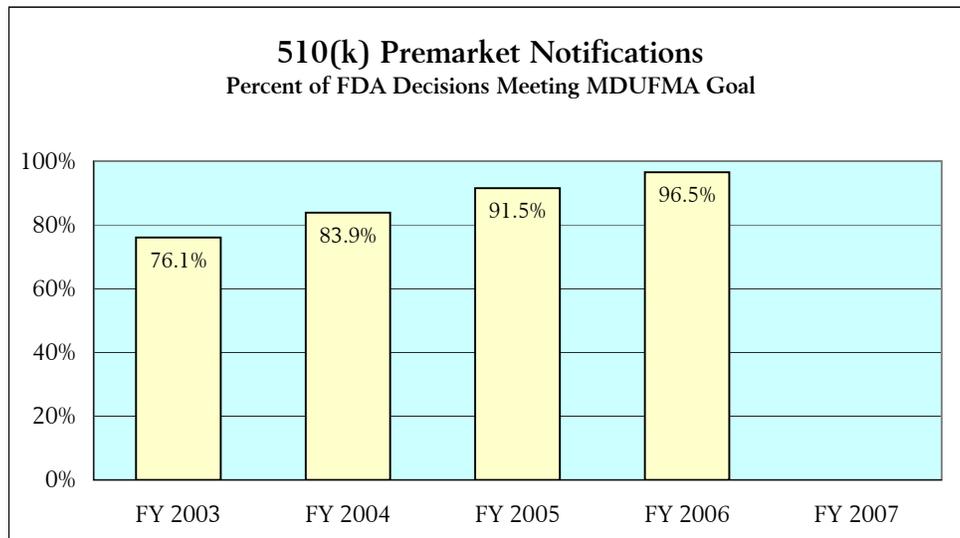
Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Received	4,290	3,710	3,713	3,913	—
MDUFMA Cohort ¹	3,795	3,383	3,415	3,732	—

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)	3,795	3,381	3,376	2,503	—
Goal – Percent within 90 days	—	—	75%	75%	80%
Percent of decisions within goal	76.1%	83.9%	91.5%	96.5%	—
Cohort status	Complete	Open	Open	Open	—



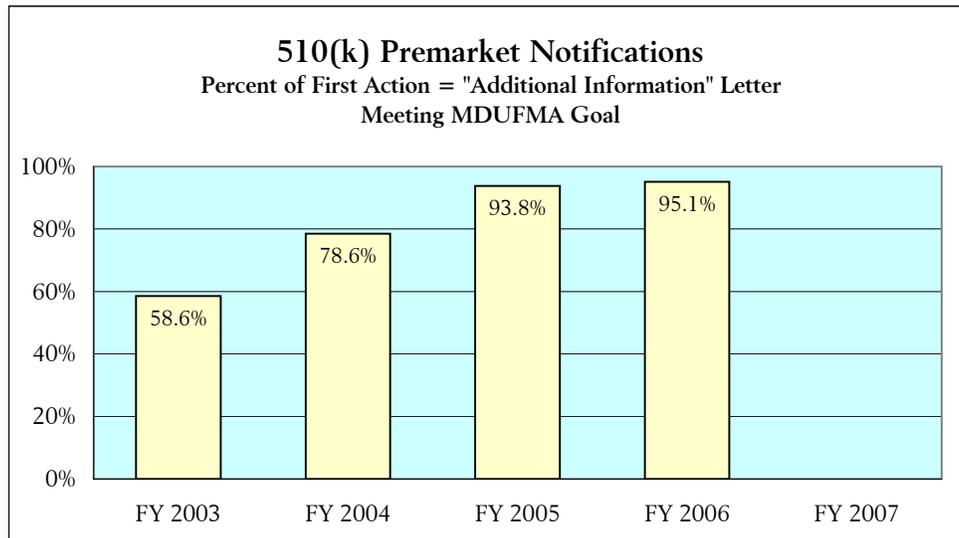
- FY 2003 cohort is complete.

510(k) Premarket Notifications

FDA Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "additional information" letter	1,726	1,618	1,847	1,814	—
Goal – Percent within 75 days	—	—	70%	80%	90%
Percent of actions within goal	58.6%	78.6%	93.8%	95.1%	—
Cohort status	Complete	Open	Open	Open	—



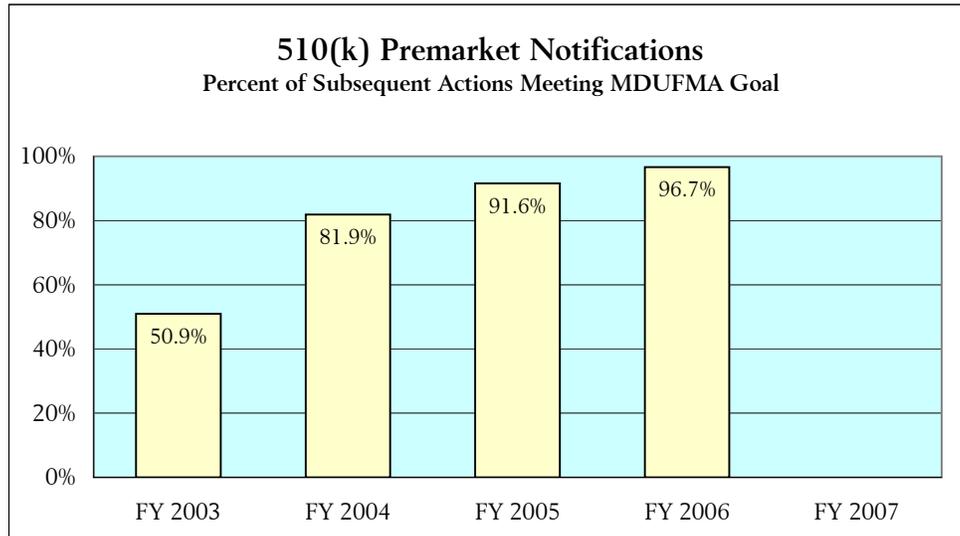
- FY 2003 cohort is complete.

510(k) Premarket Notifications

FDA Actions through September 30, 2006

Subsequent (Second or Later) Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later actions	611	586	667	449	—
Goal – Percent within 60 days	—	—	70%	80%	90%
Percent of actions within goal	50.9%	81.9%	91.6%	96.7%	—
Cohort status	<i>Complete</i>	Open	Open	Open	—



- FY 2003 cohort is complete.

Biologics Licensing Applications

FDA Actions through September 30, 2006

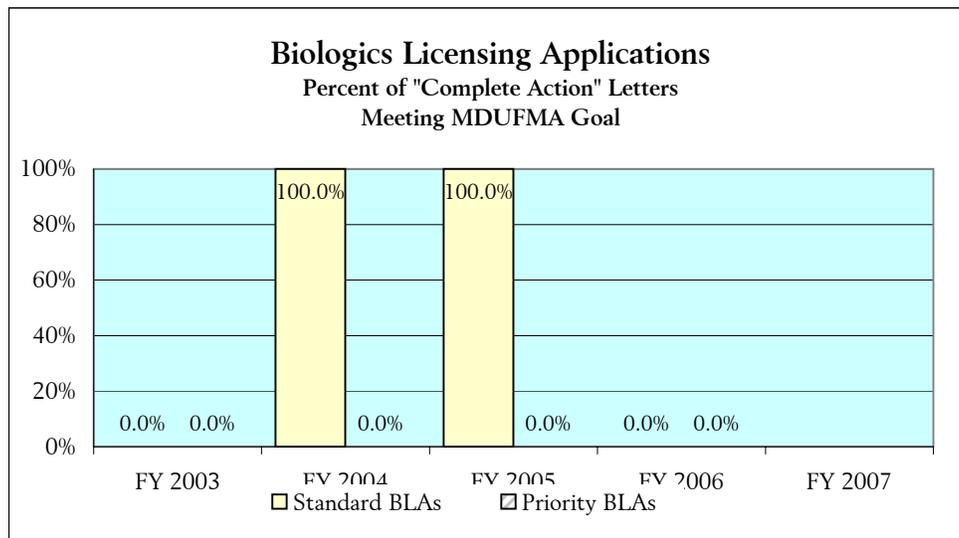
Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Standard BLAs	0	9	15	43	—
Priority BLAs	0	0	0	0	—
Total Workload	0	9	15	43	—

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

<i>Standard BLAs</i> —	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	0	9	15	0	—
Goal – <i>Percent within 10 months</i>	—	—	—	75%	90%
Percent of actions within goal	--	100.0%	100.0%	--	—
Applications without an action	0	0	0	43	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Open</i>	—

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



- FY 2003, FY 2004, and FY 2005 cohorts are closed for both standard and priority BLAs.

BLA Supplements

FDA Actions through September 30, 2006

Workload

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

Review and Act on BLA Supplements

Standard BLA Efficacy Supplements

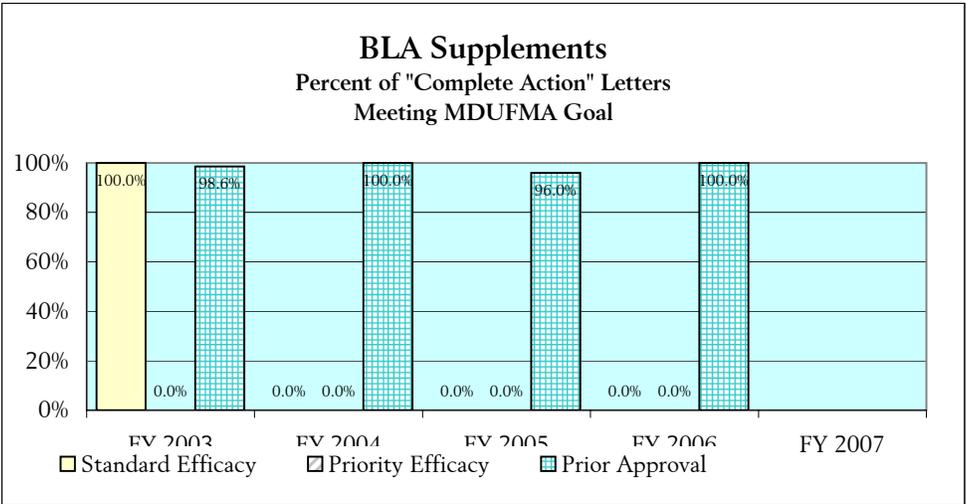
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	3	0	0	0	—
Goal – Percent within 10 months	—	—	—	75%	90%
Percent of actions within goal	100.0%	--	--	--	—
Applications without an action	0	0	0	0	—
Cohort status	Complete	Complete	Complete	Open	—

Priority BLA Efficacy Supplements

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

Prior Approval Manufacturing Supplements

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	73	62	25	21	—
Goal – Percent within 4 months	—	—	—	75%	90%
Percent of actions within goal	98.6%	100.0%	96.0%	100.0%	—
Applications without an action	0	0	0	4	—
Cohort status	Complete	Complete	Complete	Open	—



- Small numbers of Efficacy Supplements mean a single action may significantly affect results.
- FY 2003 , FY 2004, and FY 2005 cohorts are complete for every type of supplement.

Resubmissions of BLAs and BLA Supplements

FDA Actions through September 30, 2006

Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Class 1 resubmission of an original BLA or BLA efficacy supplement	0	0	5	0	—
Class 2 resubmission of an original BLA or BLA efficacy supplement	2	5	9	4	—
Total Workload	2	5	14	4	—

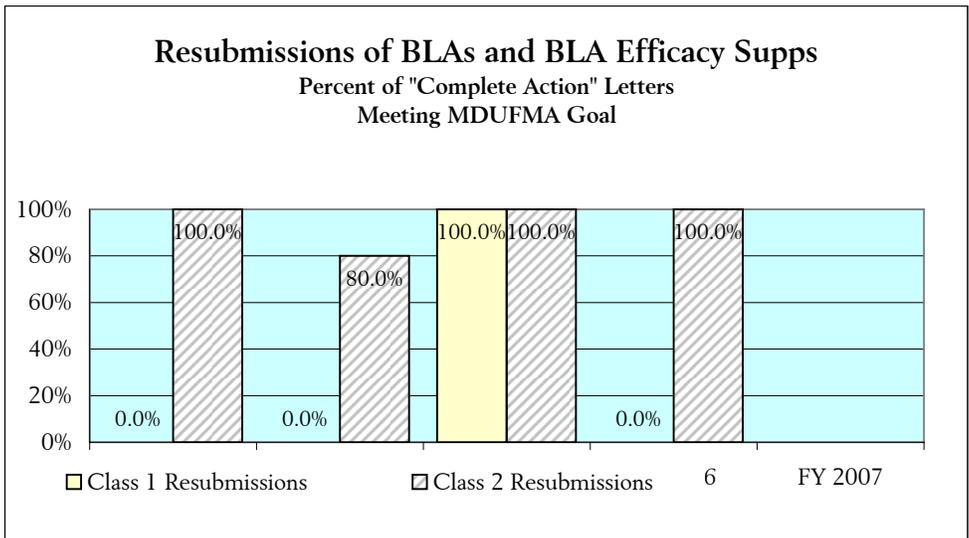
Review and Act on Resubmissions

Class 1 Resubmissions —

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

Class 2 Resubmissions —

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	2	5	9	3	—
Goal – Percent within 6 months	—	—	75%	80%	90%
Percent of actions within goal	100.0%	80.0%	100.0%	100.0%	—
Applications without an action	0	0	0	1	—
Cohort status	Complete	Complete	Complete	Open	—



- Because of the small number of Resubmissions, a single action may significantly affect performance measures.
- FY 2003, FY 2004, and FY 2005 cohorts are closed for both class 1 and class 2 resubmissions.

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

FY 2003 Receipt Cohort

Actions through September 30, 2006

Total Data for FDA (Includes CBER and CDRH)

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

PMA and Panel-Track Supplements

Type of Application	Filed	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	43	42	39	90.7%	92.9%	3	7.0%	7.1%	1	2.3%
Panel-track Supplement	7	6	5	71.4%	83.3%	1	14.3%	16.7%	1	14.3%
Total	50	48	44	88.0%	91.7%	4	8.0%	8.3%	2	4.0%

Type of Application	Total Actions	<i>Complete</i> First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	21	17	39.5%	81.0%	4	9.3%	19.0%
Panel-track Supplement	5	5	71.4%	100.0%	0	0.0%	0.0%
Total	26	22	44.0%	84.6%	4	8.0%	15.4%

Type of Application	Total Actions	<i>Complete</i> All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	22	21	48.8%	95.5%	1	2.3%	4.5%	43	100.0%
Panel-track Supplement	2	2	28.6%	100.0%	0	0.0%	0.0%	7	100.0%
Total	24	23	46.0%	95.8%	1	2.0%	4.2%	50	100.0%

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total	≤ 120 days		> 120 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	2	2	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	2	2	100.0%	0	0.0%

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total	≤ 180 days		> 180 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	20	19	95.0%	1	5.0%
Panel-track Supplement	5	4	80.0%	1	20.0%
Total	25	23	92.0%	2	8.0%

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total	≤ 30 days		> 30 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	2	1	50.0%	1	50.0%
Panel-track Supplement	0	0	--	0	--
Total	2	1	50.0%	1	50.0%

Expedited PMAs

Filed	Complete 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		
3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

Complete First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
2	2	66.7%	100.0%	0	0.0%	0.0%

Complete All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
1	1	33.3%	100.0%	0	0.0%	0.0%	3	100.0%

Complete Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
2	2	100.0%	0	0.0%

Complete Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
1	1	100.0%	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		
204	204	192	94.1%	94.1%	12	5.9%	5.9%	0	0.0%

<i>Complete</i>		First Action = "Not Approvable" Letter				
Total Actions	Number	≤ 120 days		> 120 days		
		% of Filed	% of Actions	Number	% of Filed	% of Actions
32	6	2.9%	18.8%	26	12.7%	81.3%

<i>Complete</i>		All Other First Actions					Total 180-day Supplements with a First Action	
Total Actions	Number	≤ 180 days		> 180 days		Number	% of Filed	
		% of Filed	% of Actions	Number	% of Actions			
172	164	80.4%	95.3%	8	3.9%	4.7%	204	100.0%

<i>Complete</i>		Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter			
Total Actions	Number	≤ 160 days		> 160 days	
		% of Actions	Number	% of Actions	
25	24	96.0%	1	4.0%	

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
4,290	3,795	-	-	-	-

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
3,795	2,887	67.3%	76.1%	76.1%	908	21.2%	23.9%	23.9%

Complete First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
1,726	1,011	23.6%	26.6%	58.6%	715	16.7%	18.8%	41.4%

Complete Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
498	611	311	50.9%	300	49.1%

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.
			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

<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.
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions		
Standard	3	3	3	100.0%	100.0%	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	73	72	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 Progress Towards Achieving MDUFMA Performance Goals

FY 2004 Receipt Cohort

Actions through September 30, 2006

Total Data for FDA (Includes CBER and CDRH)

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

PMA 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	40	40	36	90.0%	90.0%	4	10.0%	10.0%	0	0.0%
Panel-track Supplement	8	8	8	100.0%	100.0%	0	0.0%	0.0%	0	0.0%
Total	48	48	44	91.7%	91.7%	4	8.3%	8.3%	0	0.0%

Type of Application	Total Actions	<i>Complete</i> First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	24	20	50.0%	83.3%	4	10.0%	16.7%
Panel-track Supplement	4	3	37.5%	75.0%	1	12.5%	25.0%
Total	28	23	47.9%	82.1%	5	10.4%	17.9%

Type of Application	Total Actions	<i>Complete</i> All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	16	15	37.5%	93.8%	1	2.5%	6.3%	40	100.0%
Panel-track Supplement	4	4	50.0%	100.0%	0	0.0%	0.0%	8	100.0%
Total	20	19	39.6%	95.0%	1	2.1%	5.0%	48	100.0%

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total Actions	≤ 120 days		> 120 days	
		Number	% of Actions	Number	% of Actions
Original PMA	4	4	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	4	4	100.0%	0	0.0%

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total Actions	≤ 180 days		> 180 days	
		Number	% of Actions	Number	% of Actions
Original PMA	24	21	87.5%	3	12.5%
Panel-track Supplement	5	5	100.0%	0	0.0%
Total	29	26	89.7%	3	10.3%

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total Actions	≤ 30 days		> 30 days	
		Number	% of Actions	Number	% of Actions
Original PMA	1	0	0.0%	1	100.0%
Panel-track Supplement	1	0	0.0%	1	100.0%
Total	2	0	0.0%	2	100.0%

Expedited PMAs

Filed	FDA Decisions							Awaiting MDUFMA Decision	
	Total Decisions	Decisions ≤ 300 days			Decisions > 300 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
14	13	12	85.7%	92.3%	1	7.1%	7.7%	1	7.1%

<i>Complete</i> First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
10	8	57.1%	80.0%	2	14.3%	20.0%

<i>Complete</i> All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
4	1	7.1%	25.0%	3	21.4%	75.0%	14	100.0%

Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
1	0	0.0%	1	100.0%

Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
8	5	62.5%	3	37.5%

Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
2	1	50.0%	1	50.0%

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		
106	106	102	96.2%	96.2%	4	3.8%	3.8%	0	0.0%

<i>Complete</i>		First Action = "Not Approvable" Letter				
Total Actions	Number	≤ 120 days		> 120 days		
		% of Filed	% of Actions	Number	% of Filed	% of Actions
43	36	34.0%	83.7%	7	6.6%	16.3%

<i>Complete</i>		All Other First Actions					Total 180-day Supplements with a First Action	
Total Actions	Number	≤ 180 days		> 180 days		Number	% of Filed	
		% of Filed	% of Actions	Number	% of Actions			
63	61	57.5%	96.8%	2	1.9%	3.2%	106	100.0%

Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total Actions	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
42	41	97.6%	1	2.4%

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
3,710	3,383	2	1	1	1

¹ For 510(k)s, 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).

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
3,381	2,835	76.4%	83.8%	83.9%	546	14.7%	16.1%	16.1%

First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
1,618	1,271	34.3%	37.6%	78.6%	347	9.4%	10.3%	21.4%

Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
513	586	480	81.9%	106	18.1%

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	9	9	9	100.0%	100.0%	0	0.0%	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	0	0	0	--	--	0	--	--	0	--
Priority	0	0	0	--	--	0	--	--	0	--

BLA Prior Approval Manufacturing Supplements

Complete										
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	62	62	62	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

BLA /BLA Supplement Resubmissions

Complete										
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	4	80.0%	80.0%	1	20.0%	20.0%	0	0

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

FY 2005 Receipt Cohort

Actions through September 30, 2006

Total Data for FDA (Includes CBER and CDRH)

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

PMA and Panel-Track Supplements

Type of Application	Filed	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	46	36	36	78.3%	100.0%	0	0.0%	0.0%	10	21.7%
Panel-track Supplement	12	9	9	75.0%	100.0%	0	0.0%	0.0%	3	25.0%
Total	58	45	45	77.6%	100.0%	0	0.0%	0.0%	13	22.4%

Type of Application	Total Actions	First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	32	30	65.2%	93.8%	2	4.3%	6.3%
Panel-track Supplement	5	4	33.3%	80.0%	1	8.3%	20.0%
Total	37	34	58.6%	91.9%	3	5.2%	8.1%

Type of Application	Total Actions	All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	14	12	26.1%	85.7%	2	4.3%	14.3%	46	100.0%
Panel-track Supplement	6	6	50.0%	100.0%	0	0.0%	0.0%	11	91.7%
Total	20	18	31.0%	90.0%	2	3.4%	10.0%	57	98.3%

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total	≤ 120 days		> 120 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	16	11	68.8%	5	31.3%
Panel-track Supplement	1	1	100.0%	0	0.0%
Total	17	12	70.6%	5	29.4%

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total	≤ 180 days		> 180 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	35	32	91.4%	3	8.6%
Panel-track Supplement	2	2	100.0%	0	0.0%
Total	37	34	91.9%	3	8.1%

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total	≤ 30 days		> 30 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	7	6	85.7%	1	14.3%
Panel-track Supplement	1	0	0.0%	1	100.0%
Total	8	6	75.0%	2	25.0%

Expedited PMAs

Filed	FDA Decisions							Awaiting MDUFMA Decision	
	Total Decisions	Decisions ≤ 300 days			Decisions > 300 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
6	3	2	33.3%	66.7%	1	16.7%	33.3%	3	50.0%

<i>Complete</i> First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
5	4	66.7%	80.0%	1	16.7%	20.0%

<i>Complete</i> All Other First Actions							Total Applications with a First Action	
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
1	1	16.7%	100.0%	0	0.0%	0.0%	6	100.0%

Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
2	2	100.0%	0	0.0%

Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
5	5	100.0%	0	0.0%

Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
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		
101	101	96	95.0%	95.0%	5	5.0%	5.0%	0	0.0%

<i>Complete</i>		First Action = "Not Approvable" Letter				
Total Actions		≤ 120 days			> 120 days	
		Number	% of Filed	% of Actions	Number	% of Filed
40	36	35.6%	90.0%	4	4.0%	10.0%

<i>Complete</i>		All Other First Actions					Total 180-day Supplements with a First Action	
Total Actions		≤ 180 days			> 180 days		Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed		
61	60	59.4%	98.4%	1	1.0%	1.6%	101	100.0%

Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total Actions		≤ 160 days		> 160 days
		Number	% of Actions	Number
30	27	90.0%	3	10.0%

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
3,713	3,415	39	29	10	22

¹ For 510(k)s, 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).

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
3,376	3,090	83.2%	90.5%	91.5%	286	7.7%	8.4%	8.5%

First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
1,847	1,732	46.6%	50.7%	93.8%	115	3.1%	3.4%	6.2%

Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
612	667	611	91.6%	56	8.4%

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	15	15	15	100.0%	100.0%	0	0.0%	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	0	0	0	--	--	0	--	--	0	--
Priority	0	0	0	--	--	0	--	--	0	--

BLA Prior Approval Manufacturing Supplements

Complete										
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	25	24	96.0%	96.0%	1	4.0%	4.0%	0	0.0%

BLA /BLA Supplement Resubmissions

Complete										
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	5	5	5	100.0%	100.0%	0	0.0%	0.0%	0	0
Class 2	9	9	9	100.0%	100.0%	0	0.0%	0.0%	0	0

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

FY 2006 Receipt Cohort

Actions through September 30, 2006

Total Data for FDA (Includes CBER and CDRH)

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

PMA and Panel-Track Supplements

Type of Application	Filed	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	37	14	14	37.8%	100.0%	0	0.0%	0.0%	23	62.2%
Panel-track Supplement	14	5	5	35.7%	100.0%	0	0.0%	0.0%	9	64.3%
Total	51	19	19	37.3%	100.0%	0	0.0%	0.0%	32	62.7%

Type of Application	Total Actions	First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	19	18	48.6%	94.7%	1	2.7%	5.3%
Panel-track Supplement	3	2	14.3%	66.7%	1	7.1%	33.3%
Total	22	20	39.2%	90.9%	2	3.9%	9.1%

Type of Application	Total Actions	All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	14	12	32.4%	85.7%	2	5.4%	14.3%	33	89.2%
Panel-track Supplement	6	6	42.9%	100.0%	0	0.0%	0.0%	9	64.3%
Total	20	18	35.3%	90.0%	2	3.9%	10.0%	42	82.4%

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total Actions	≤ 120 days		> 120 days	
		Number	% of Actions	Number	% of Actions
Original PMA	3	3	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	3	3	100.0%	0	0.0%

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total Actions	≤ 180 days		> 180 days	
		Number	% of Actions	Number	% of Actions
Original PMA	4	4	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	4	4	100.0%	0	0.0%

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total Actions	≤ 30 days		> 30 days	
		Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Expedited PMAs

Filed	FDA Decisions							Awaiting MDUFMA Decision	
	Total Decisions	Decisions ≤ 300 days			Decisions > 300 days			Number	% of Filed
		Number	% of Filed	% of Decisions	Number	% of Filed	% of Decisions		
2	0	0	0.0%	--	0	0.0%	--	2	100.0%

First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
0	0	0.0%	--	0	0.0%	--

All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
1	1	50.0%	100.0%	0	0.0%	0.0%	1	50.0%

Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

180-day Supplements

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		
131	95	94	71.8%	98.9%	1	0.8%	1.1%	36	27.5%

First Action = "Not Approvable" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
26	22	16.8%	84.6%	4	3.1%	15.4%

All Other First Actions							Total 180-day Supplements with a First Action	
Total Actions	≤ 180 days			> 180 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
71	70	53.4%	98.6%	1	0.8%	1.4%	97	74.0%

Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total Actions	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
8	8	100.0%	0	0.0%

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
3,913	3,732	1,229	487	742	51

¹ For 510(k)s, 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).

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
2,503	2,416	61.7%	64.7%	96.5%	87	2.2%	2.3%	3.5%

First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
1,814	1,725	44.1%	46.2%	95.1%	89	2.3%	2.4%	4.9%

Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
422	449	434	96.7%	15	3.3%

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	43	0	0	0.0%	--	0	0.0%	--	43	1
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	25	21	21	84.0%	100.0%	0	0.0%	0.0%	4	16.0%

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.	% of Actions	Number	% of Rcvd.	% of Actions	Number	% of Rcvd.
Class 1	0	0	0	--	--	0	--	--	0	--
Class 2	4	3	3	75.0%	100.0%	0	0.0%	0.0%	1	0.25

Quarterly Update on Progress Towards Meeting
MDUFMA Performance Goals
— CBER Performance Data —
Actions through September 30, 2006

PMAs and Panel-Track Supplements

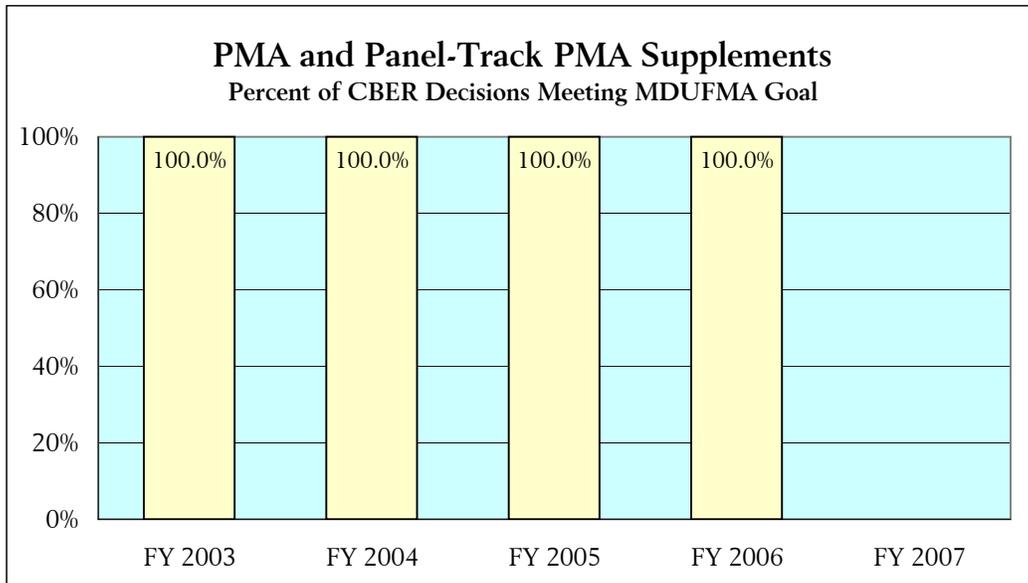
CBER Actions through September 30, 2006

Workload (Applications Filed to Date)

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

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	3	1	4	1	—
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	1	2	—
Cohort status	<i>Complete</i>	<i>Complete</i>	Open	Open	—



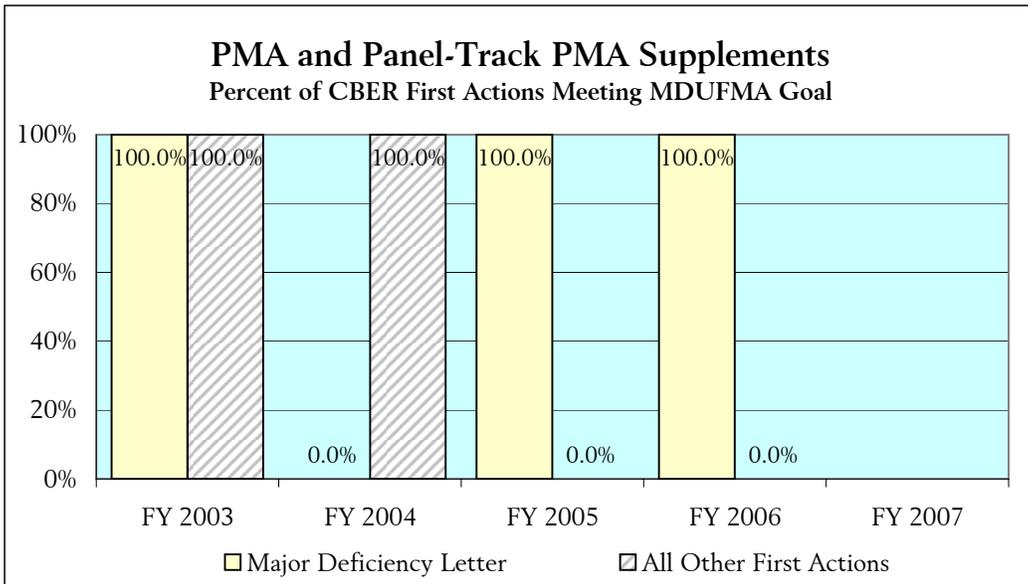
- FY 2003 and FY 2004 cohorts are complete.
- To date, all decisions have been within the time specified by MDUFMA performance goals.

PMAs and Panel-Track Supplements

CBER Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "major deficiency"	1	0	5	3	—
Goal – Percent within 150 days	—	—	75%	80%	90%
Percent of actions within goal	100.0%	--	100.0%	100.0%	—
All other first actions	2	1	0	0	—
Goal – Percent within 180 days	—	—	75%	80%	90%
Percent of actions within goal	100.0%	100.0%	--	--	—
Total applications with a first action	3	1	5	3	—
Applications without a first action	0	0	0	0	—
Cohort status	Complete	Complete	Complete	Complete	—



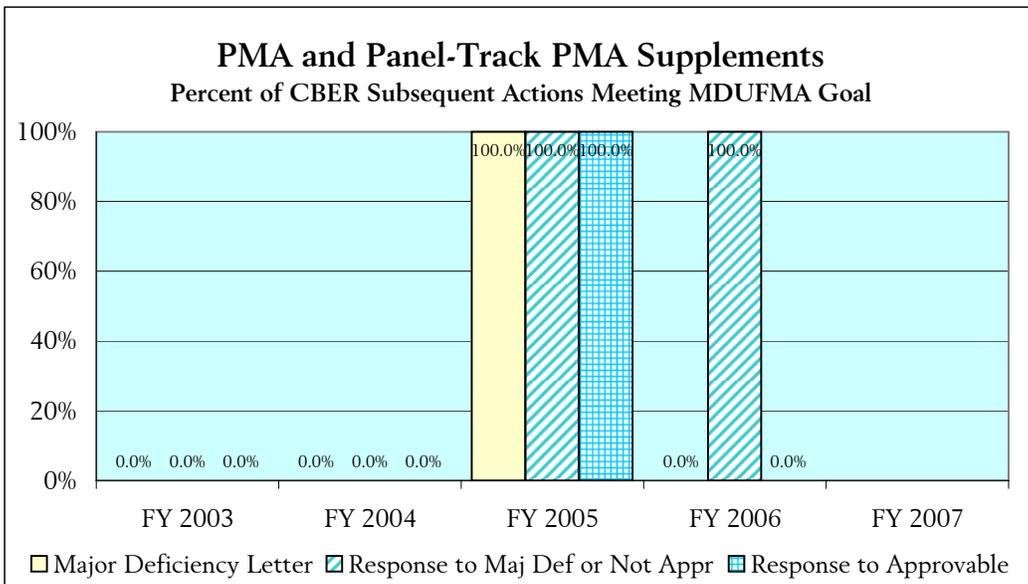
- All applications received from FY 2003 through FY 2006 have had a first action; these cohorts are complete.
- To date, all first actions have been within the time specified by MDUFMA performance goals.

PMAs and Panel-Track Supplements

CBER Actions through September 30, 2006

Subsequent Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later action = "major deficiency" letter	0	0	2	0	—
Goal – <i>Percent within 120 days</i>	—	—	75%	80%	90%
Percent of actions within goal	--	--	100.0%	--	—
Cohort status	Open	Complete	Open	Open	—
<hr/>					
Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	0	0	6	1	—
Goal – <i>Percent within 180 days</i>	—	—	75%	80%	90%
Percent of actions within goal	--	--	100.0%	100.0%	—
Cohort status	Open	Complete	Open	Open	—
<hr/>					
Action on an amendment containing a complete response to an "approvable" letter	0	0	3	0	—
Goal – <i>Percent within 30 days</i>	90%	90%	90%	90%	90%
Percent of actions within goal	--	--	100.0%	--	—
Cohort status	Open	Complete	Open	Open	—



- Subsequent action cohorts will remain open longer than decision and first action cohorts.
- Because of the small number of applications involved, a single action may significantly affect performance measures.

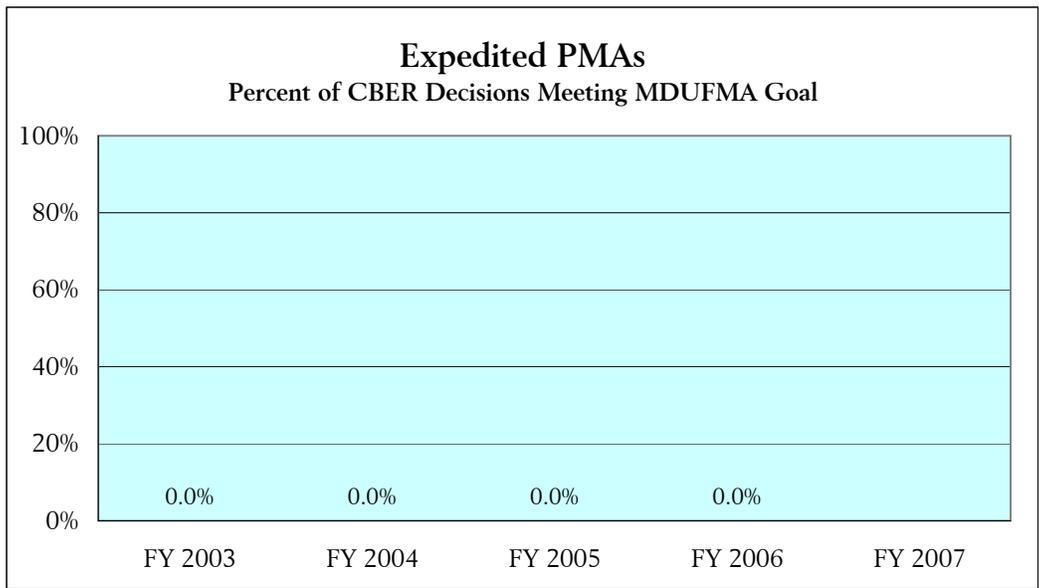
Expedited PMAs
 CBER Actions through September 30, 2006

Workload (Applications Filed to Date)

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

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	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	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	—



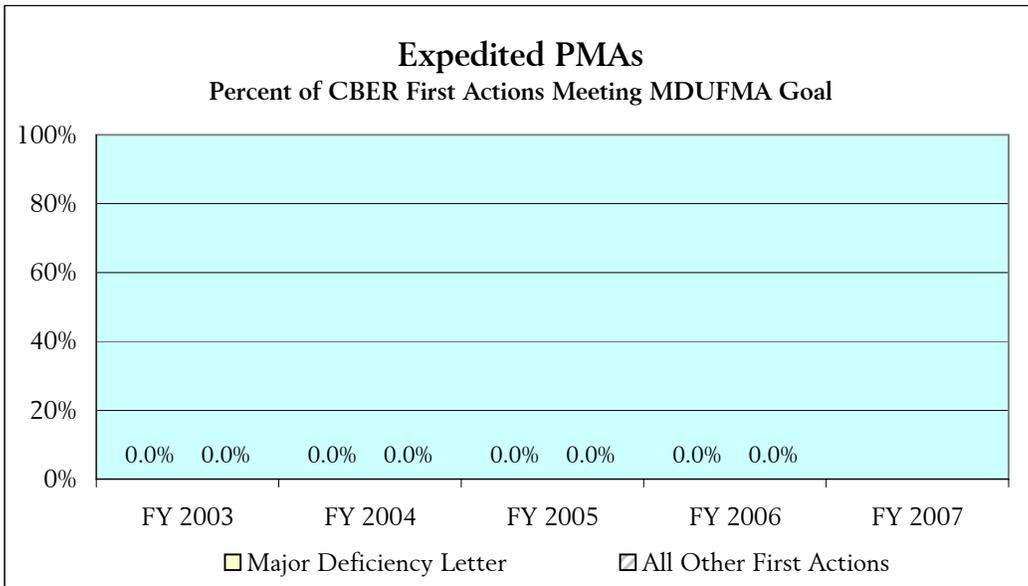
- To date, no CBER PMA has qualified for Expedited status under MDUFMA.

Expedited PMAs

CBER Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "major deficiency"	0	0	0	0	—
Goal – Percent within 120 days	—	—	70%	80%	90%
Percent of actions within goal	--	--	--	--	—
All other first actions	0	0	0	0	—
Goal – Percent within 170 days	—	—	70%	80%	90%
Percent of actions within goal	--	--	--	--	—
Total applications with a first action	0	0	0	0	—
Applications without a first action	0	0	0	0	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	—



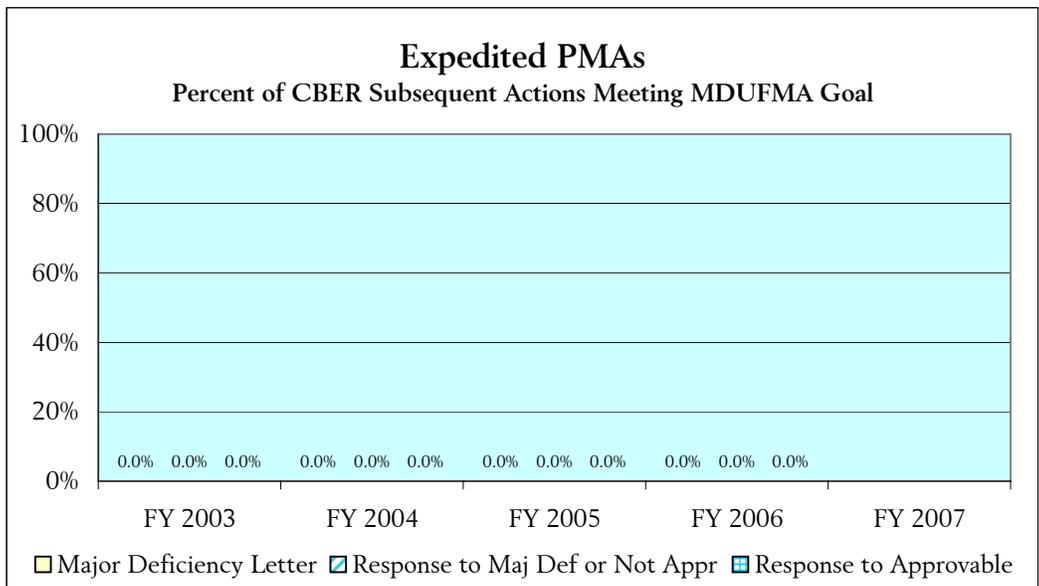
- To date, no CBER PMA has qualified for Expedited status under MDUFMA.

Expedited PMAs

CBER Actions through September 30, 2006

Subsequent (Second or Later) Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later action =					
"major deficiency" letter	0	0	0	0	—
<i>Goal – Percent within 100 days</i>	—	—	70%	80%	90%
Percent of actions within goal	--	--	--	--	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	—
Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	0	0	0	0	—
<i>Goal – Percent within 170 days</i>	—	—	70%	80%	90%
Percent of actions within goal	--	--	--	--	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	—
Action on an amendment containing a complete response to an "approvable" letter	0	0	0	0	—
<i>Goal – Percent within 30 days</i>	90%	90%	90%	90%	90%
Percent of actions within goal	--	--	--	--	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	—



- To date, no CBER PMA has qualified for Expedited status under MDUFMA.

180-day PMA Supplements

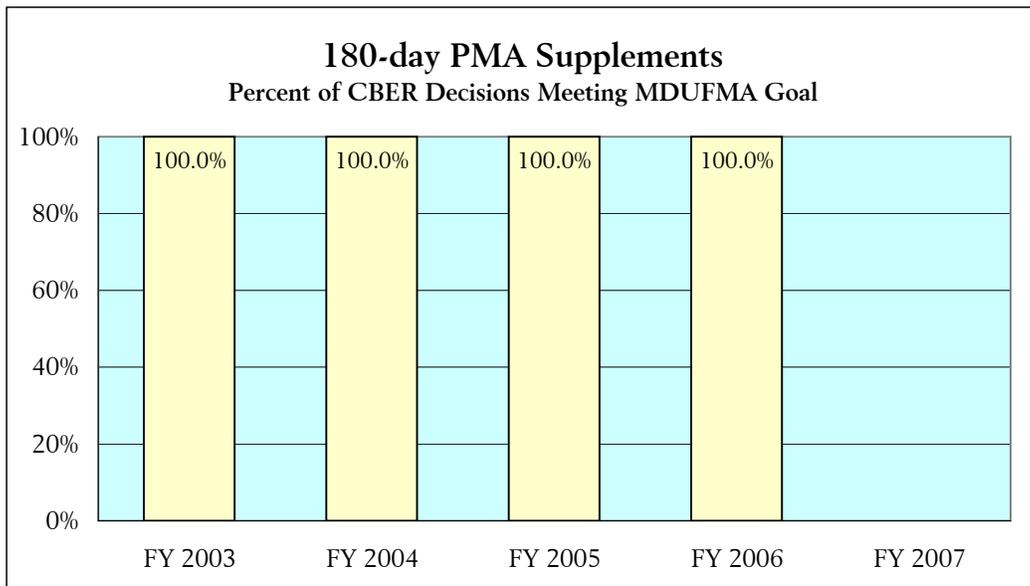
CBER Actions through September 30, 2006

Workload

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

FDA Decisions

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



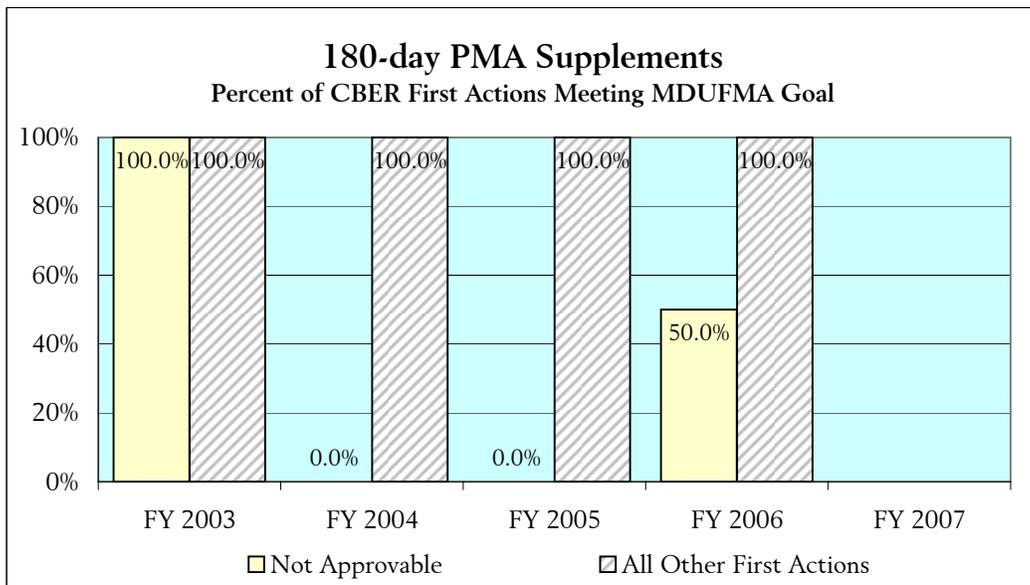
- FY 2003 , FY 2004, and FY 2005 cohorts are complete.
- To date, all decisions have been within the time specified by MDUFMA performance goals.

180-day PMA Supplements

CBER Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "not approvable"	1	0	0	2	—
<i>Goal – Percent within 120 days</i>	—	—	80%	85%	90%
Percent of actions within goal	100.0%	--	--	50.0%	—
All other first actions	2	3	2	1	—
<i>Goal – Percent within 180 days</i>	—	—	80%	85%	90%
Percent of actions within goal	100.0%	100.0%	100.0%	100.0%	—
Total applications with a first action	3	3	2	3	—
Applications without a first action	0	0	0	0	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	—



- FY 2003 , FY 2004, and FY 2005 cohorts are complete.
- Because of the small number of applications involved, a single action may significantly affect performance measures.

510(k) Premarket Notifications

CBER Actions through September 30, 2006

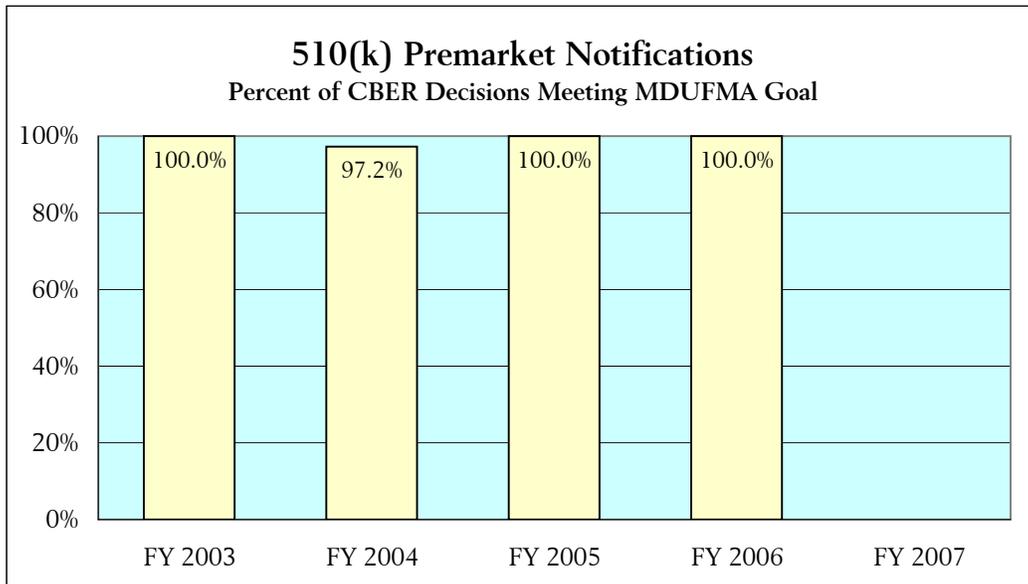
Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Received	65	78	63	59	—
MDUFMA Cohort ¹	54	72	59	57	—

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	55	33	—
Goal – Percent within 90 days	—	—	75%	75%	80%
Percent of decisions within goal	100.0%	97.2%	100.0%	100.0%	—
Cohort status	Complete	Complete	Open	Open	—



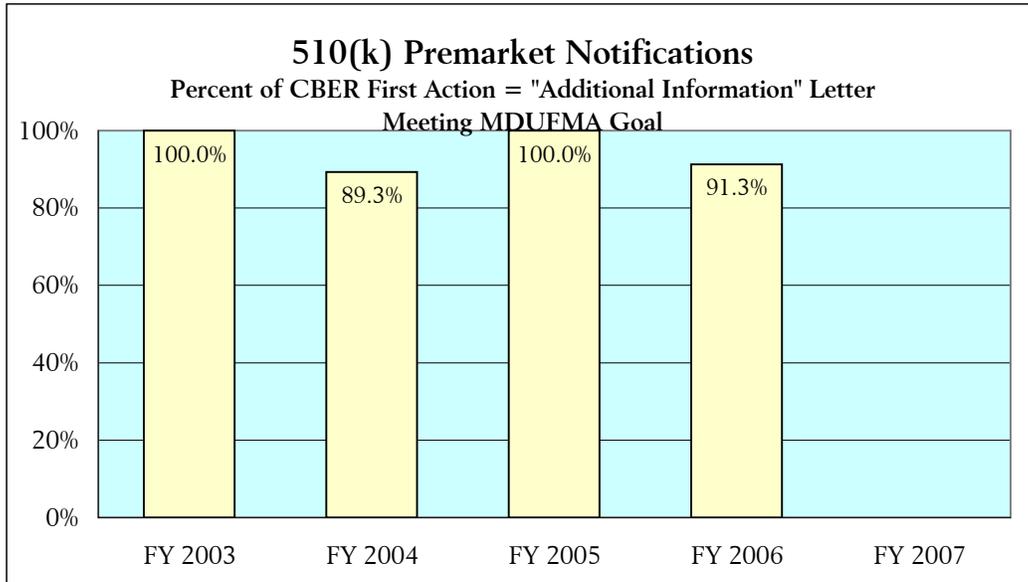
- FY 2003 and FY 2004 cohorts are complete.

510(k) Premarket Notifications

CBER Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action =					
"additional information" letter	25	28	31	23	—
Goal – Percent within 75 days	—	—	70%	80%	90%
Percent of actions within goal	100.0%	89.3%	100.0%	91.3%	—
Cohort status	Complete	Complete	Open	Open	—



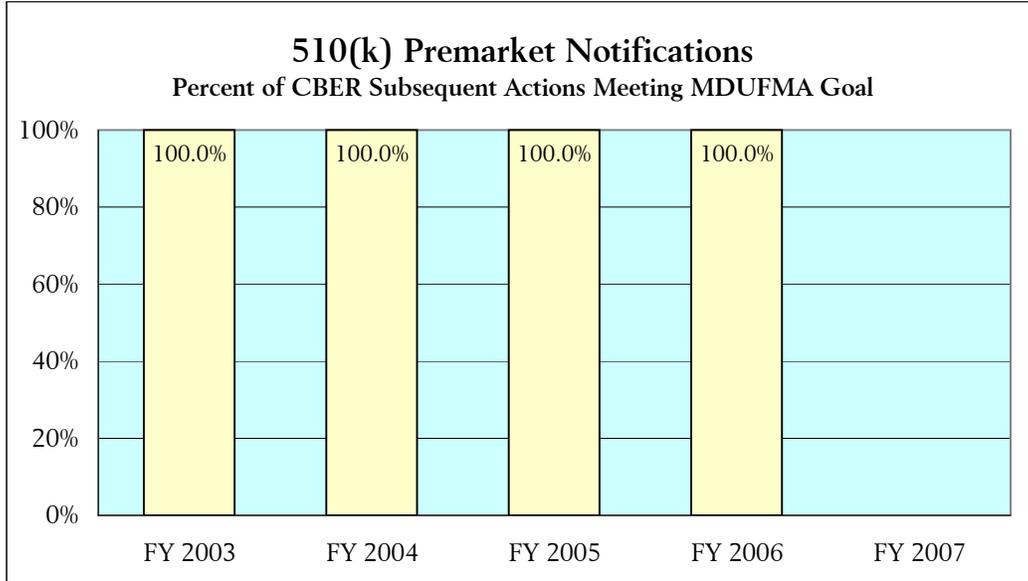
- FY 2003 and FY 2004 cohorts are complete.

510(k) Premarket Notifications

CBER Actions through September 30, 2006

Subsequent (Second or Later) Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later actions	19	31	29	10	—
Goal – Percent within 60 days	—	—	70%	80%	90%
Percent of actions within goal	100.0%	100.0%	100.0%	100.0%	—
Cohort status	Complete	Complete	Open	Open	—



- FY 2003 and FY 2004 cohorts are complete.

Biologics Licensing Applications

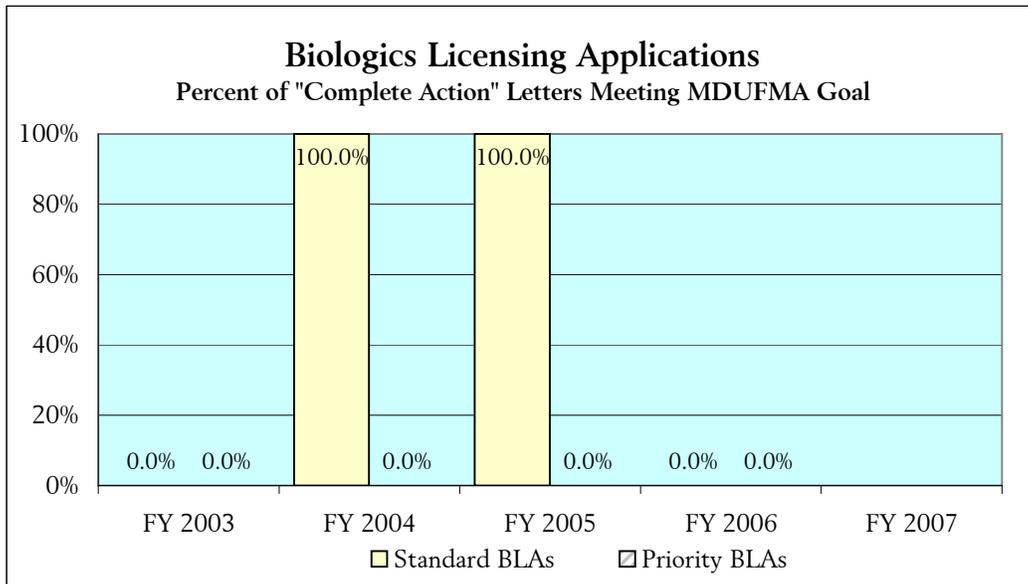
CBER Actions through September 30, 2006

Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Standard BLAs	0	9	15	43	—
Priority BLAs	0	0	0	0	—
Total Workload	0	9	15	43	—

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

<i>Standard BLAs</i> —	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	0	9	15	0	—
Goal – Percent within 10 months	—	—	—	75%	90%
Percent of actions within goal	--	100.0%	100.0%	--	—
Applications without an action	0	0	0	43	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	Open	—
<i>Priority BLAs</i> —	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	0	0	0	0	—
Goal – Percent within 6 months	—	—	—	75%	90%
Percent of actions within goal	--	--	--	--	—
Applications without an action	0	0	0	0	—
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	Open	—



- FY 2003, FY 2004, and FY 2005 cohorts are closed for both standard and priority BLAs.

BLA Supplements

CBER Actions through September 30, 2006

Workload

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

Review and Act on BLA Supplements

Standard BLA Efficacy Supplements

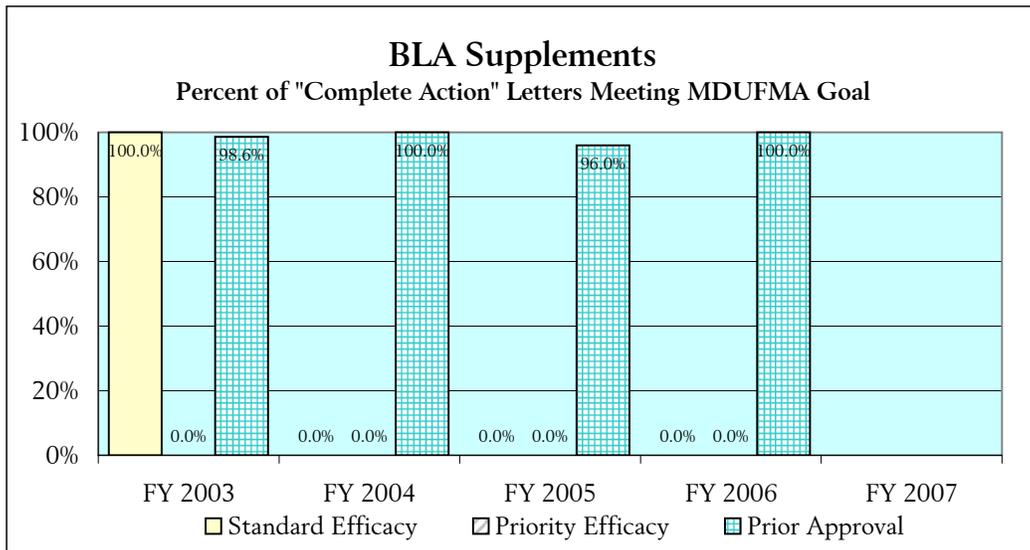
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	3	0	0	0	—
Goal – Percent within 10 months	—	—	—	75%	90%
Percent of actions within goal	100.0%	--	--	--	—
Applications without an action	0	0	0	0	—
Cohort status	Complete	Complete	Complete	Open	—

Priority BLA Efficacy Supplements

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

Prior Approval Manufacturing Supplements

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	73	62	25	21	—
Goal – Percent within 4 months	—	—	—	75%	90%
Percent of actions within goal	98.6%	100.0%	96.0%	100.0%	—
Applications without an action	0	0	0	4	—
Cohort status	Complete	Complete	Complete	Open	—



- Small numbers of Efficacy Supplements mean a single action may significantly affect results.
- FY 2003 , FY 2004, and FY 2005 cohorts are complete for every type of supplement.

Resubmissions of BLAs and BLA Supplements

CBER Actions through September 30, 2006

Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Class 1 resubmission of an original BLA or BLA efficacy supplement	0	0	5	0	—
Class 2 resubmission of an original BLA or BLA efficacy supplement	2	5	9	4	—
Total Workload	2	5	14	4	—

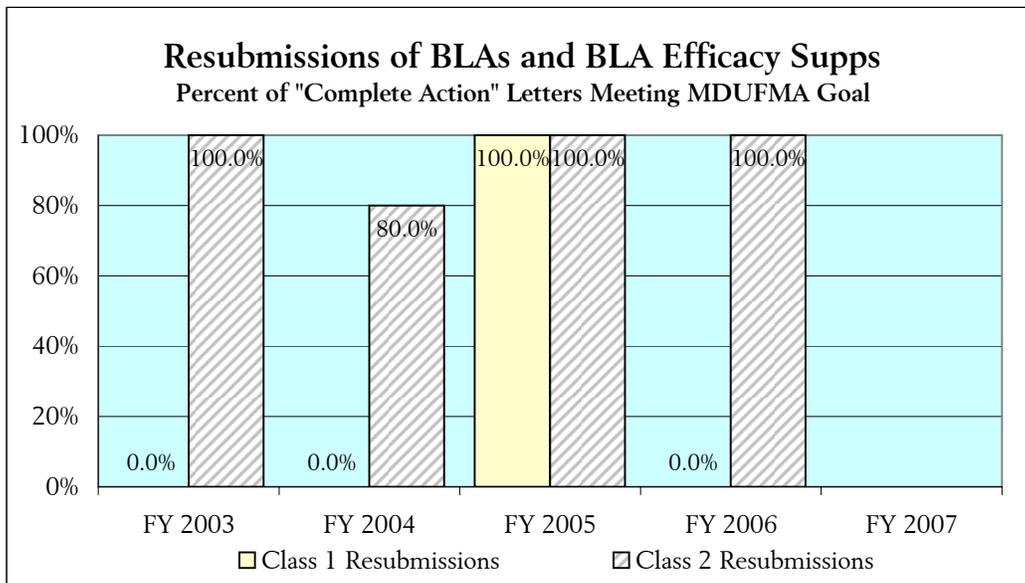
Review and Act on Resubmissions

Class 1 Resubmissions —

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

Class 2 Resubmissions —

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	2	5	9	3	—
Goal – Percent within 6 months	—	—	75%	80%	90%
Percent of actions within goal	100.0%	80.0%	100.0%	100.0%	—
Applications without an action	0	0	0	1	—
Cohort status	Complete	Complete	Complete	Open	—



- Because of the small number of Resubmissions, a single action may significantly affect performance measures.
- FY 2003, FY 2004, and FY 2005 cohorts are closed for both class 1 and class 2 resubmissions.

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

FY 2003 Receipt Cohort

Actions through September 30, 2006

Data for CBER

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

PMA 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	Total Actions	<i>Complete</i> First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	1	1	33.3%	100.0%	0	0.0%	0.0%
Panel-track Supplement	0	0	--	--	0	--	--
Total	1	1	33.3%	100.0%	0	0.0%	0.0%

Type of Application	Total Actions	<i>Complete</i> All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	2	2	66.7%	100.0%	0	0.0%	0.0%	3	100.0%
Panel-track Supplement	0	0	--	--	0	--	--	0	--
Total	2	2	66.7%	100.0%	0	0.0%	0.0%	3	100.0%

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total	≤ 120 days		> 120 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total	≤ 180 days		> 180 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total	≤ 30 days		> 30 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Expedited PMAs

Filed	Complete 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	--

Complete First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
0	0	--	--	0	--	--

Complete All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
0	0	--	--	0	--	--	0	--

Complete Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
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%

<i>Complete</i> First Action = "Not Approvable" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
1	1	33.3%	100.0%	0	0.0%	0.0%

<i>Complete</i> All Other First Actions							Total 180-day Supplements with a First Action	
Total Actions	≤ 180 days			> 180 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
2	2	66.7%	100.0%	0	0.0%	0.0%	3	100.0%

<i>Complete</i> Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
3	3	100.0%	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%

Complete First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
25	25	38.5%	46.3%	100.0%	0	0.0%	0.0%	0.0%

Complete Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
19	19	19	100.0%	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.
			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

<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.
			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	73	72	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 Progress Towards Achieving MDUFMA Performance Goals

FY 2004 Receipt Cohort

Actions through September 30, 2006

Data for CBER

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

PMA 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	Total Actions	<i>Complete</i> First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	0	0	0.0%	--	0	0.0%	--
Panel-track Supplement	0	0	--	--	0	--	--
Total	0	0	0.0%	--	0	0.0%	--

Type of Application	Total Actions	<i>Complete</i> All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	1	1	100.0%	100.0%	0	0.0%	0.0%	1	100.0%
Panel-track Supplement	0	0	--	--	0	--	--	0	--
Total	1	1	100.0%	100.0%	0	0.0%	0.0%	1	100.0%

Type of Application	<i>Complete</i> Second or Later Action = "Major Deficiency" Letter				
	Total	≤ 120 days		> 120 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Type of Application	<i>Complete</i> Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total	≤ 180 days		> 180 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Type of Application	<i>Complete</i> Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total	≤ 30 days		> 30 days	
	Actions	Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Expedited PMAs

Filed	Complete 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	--

Complete First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
0	0	--	--	0	--	--

Complete All Other First Actions							Total Applications with a First Action	
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
0	0	--	--	0	--	--	0	--

Complete Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
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%

<i>Complete</i> First Action = "Not Approvable" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
0	0	0.0%	--	0	0.0%	--

<i>Complete</i> All Other First Actions							Total 180-day Supplements with a First Action	
Total Actions	≤ 180 days			> 180 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
3	3	100.0%	100.0%	0	--	0.0%	3	100.0%

<i>Complete</i> Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total Actions	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
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

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

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%

Complete First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
28	25	32.1%	34.7%	89.3%	3	3.8%	4.2%	10.7%

Complete Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
28	31	31	100.0%	0	0.0%

BLAs

<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	% 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	% 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 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	62	62	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	% of Rcvd.
			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 Progress Towards Achieving MDUFMA Performance Goals

FY 2005 Receipt Cohort

Actions through September 30, 2006

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	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	4	4	80.0%	100.0%	0	0.0%	0.0%	1	20.0%
Panel-track Supplement	0	0	0	--	--	0	--	--	0	--
Total	5	4	4	80.0%	100.0%	0	0.0%	0.0%	1	20.0%

Type of Application	<i>Complete</i> First Action = "Major Deficiency" Letter						
	Total Actions	≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	5	5	100.0%	100.0%	0	0.0%	0.0%
Panel-track Supplement	0	0	--	--	0	--	--
Total	5	5	100.0%	100.0%	0	0.0%	0.0%

Type of Application	<i>Complete</i> All Other First Actions							Total Applications with a First Action	
	Total Actions	≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	0	0	0.0%	--	0	0.0%	--	5	100.0%
Panel-track Supplement	0	0	--	--	0	--	--	0	--
Total	0	0	0.0%	--	0	0.0%	--	5	100.0%

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total Actions	≤ 120 days		> 120 days	
		Number	% of Actions	Number	% of Actions
Original PMA	2	2	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	2	2	100.0%	0	0.0%

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total Actions	≤ 180 days		> 180 days	
		Number	% of Actions	Number	% of Actions
Original PMA	6	6	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	6	6	100.0%	0	0.0%

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total Actions	≤ 30 days		> 30 days	
		Number	% of Actions	Number	% of Actions
Original PMA	3	3	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	3	3	100.0%	0	0.0%

Expedited PMAs

Filed	Complete 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	--

Complete First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
0	0	--	--	0	--	--

Complete All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
0	0	--	--	0	--	--	0	--

Complete Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
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%

<i>Complete</i> First Action = "Not Approvable" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
0	0	0.0%	--	0	0.0%	--

<i>Complete</i> All Other First Actions							Total 180-day Supplements with a First Action	
Total Actions	≤ 180 days			> 180 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
2	2	100.0%	100.0%	0	0.0%	0.0%	2	100.0%

<i>Complete</i> Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
63	59	4	4	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
55	55	87.3%	93.2%	100.0%	0	0.0%	0.0%	0.0%

First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
31	31	49.2%	52.5%	100.0%	0	0.0%	0.0%	0.0%

Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
26	29	29	100.0%	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.
			Number	% of Rcvd.	% of First Actions	Number	% of Rcvd.	% of First Actions		
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							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 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	25	24	96.0%	96.0%	1	4.0%	4.0%	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	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 Progress Towards Achieving MDUFMA Performance Goals

FY 2006 Receipt Cohort

Actions through September 30, 2006

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	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	1	1	33.3%	100.0%	0	0.0%	0.0%	2	66.7%
Panel-track Supplement	0	0	0	--	--	0	--	--	0	--
Total	3	1	1	33.3%	100.0%	0	0.0%	0.0%	2	66.7%

Type of Application	<i>Complete</i> First Action = "Major Deficiency" Letter						
	Total Actions	≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	3	3	100.0%	100.0%	0	0.0%	0.0%
Panel-track Supplement	0	0	--	--	0	--	--
Total	3	3	100.0%	100.0%	0	0.0%	0.0%

Type of Application	<i>Complete</i> All Other First Actions							Total Applications with a First Action	
	Total Actions	≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	0	0	0.0%	--	0	0.0%	--	3	100.0%
Panel-track Supplement	0	0	--	--	0	--	--	0	--
Total	0	0	0.0%	--	0	0.0%	--	3	100.0%

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total Actions	≤ 120 days		> 120 days	
		Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total Actions	≤ 180 days		> 180 days	
		Number	% of Actions	Number	% of Actions
Original PMA	1	1	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	1	1	100.0%	0	0.0%

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total Actions	≤ 30 days		> 30 days	
		Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Expedited PMAs

Filed	Complete 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	--

Complete First Action = "Major Deficiency" Letter							
Total Actions	≤ 120 days			> 120 days			
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions	
0	0	--	--	0	--	--	--

Complete All Other First Actions							Total Applications with a First Action	
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
0	0	--	--	0	--	--	0	--

Complete Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Complete Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

180-day Supplements

Complete 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%

Complete First Action = "Not Approvable" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
2	1	33.3%	50.0%	1	33.3%	50.0%

Complete All Other First Actions							Total 180-day Supplements with a First Action	
Total Actions	≤ 180 days			> 180 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
1	1	33.3%	100.0%	0	0.0%	0.0%	3	100.0%

Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
59	57	24	13	11	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	
33	33	55.9%	57.9%	100.0%	0	0.0%	0.0%	0.0%	

First Action = "Additional Information" Letter									
Total First Action = AI	≤ 75 days				> 75 days				
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI	
23	21	35.6%	36.8%	91.3%	2	3.4%	3.5%	8.7%	

Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
9	10	10	100.0%	0	0.0%

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	43	0	0	0	--	0	0	--	43	100.0%
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.	% 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	25	21	21	84.0%	100.0%	0	0.0%	0.0%	4	16.0%

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.	% of Actions	Number	% of Rcvd.	% of Actions	Number	% of Rcvd.
Class 1	0	0	0	--	--	0	--	--	0	--
Class 2	4	3	3	75.0%	100.0%	0	0.0%	0.0%	1	25.0%

Quarterly Update on Progress Towards Meeting
MDUFMA Performance Goals

— CDRH Performance Data —

Actions through September 30, 2006

PMAs and Panel-Track Supplements

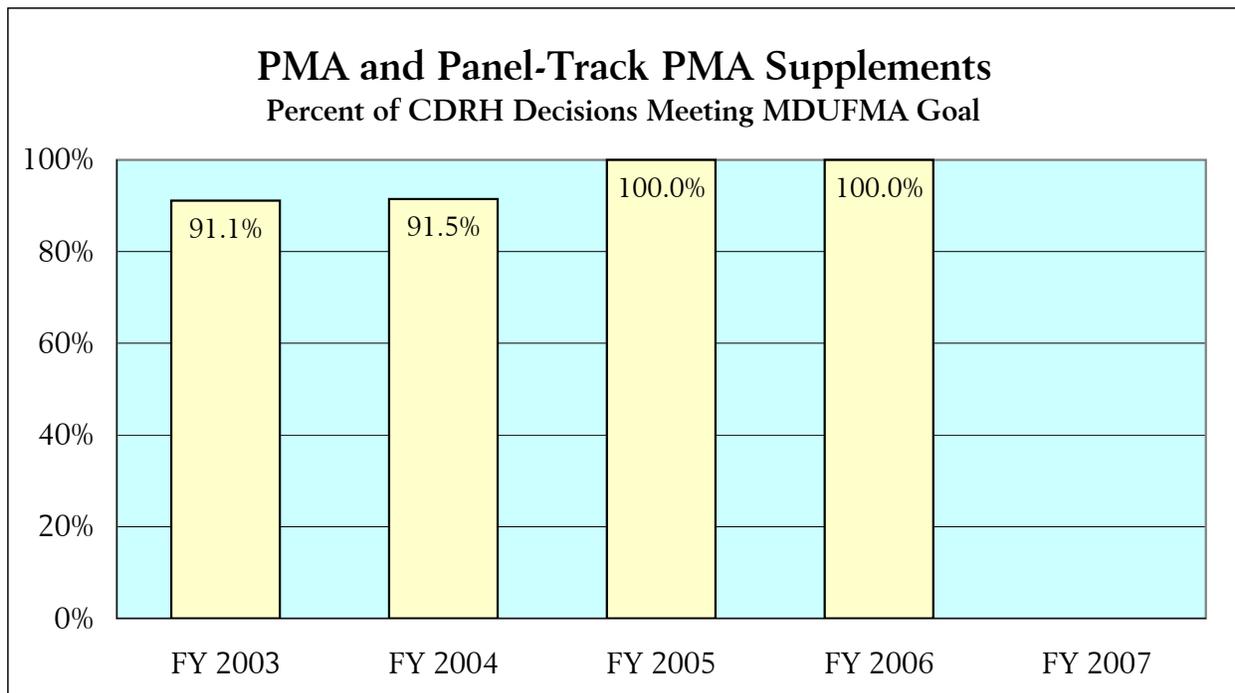
CDRH Actions through September 30, 2006

Workload (Applications Filed to Date)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
PMAs	40	39	41	34	—
Panel-Track Supplements	7	8	12	14	—
Total Workload	47	47	53	48	—

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	45	47	41	18	—
Goal – <i>Percent within 320 days</i>	—	—	—	80%	90%
Percent of decisions within goal	91.1%	91.5%	100.0%	100.0%	—
Applications without a decision	2	0	12	30	—
Cohort status	Open	<i>Complete</i>	Open	Open	—



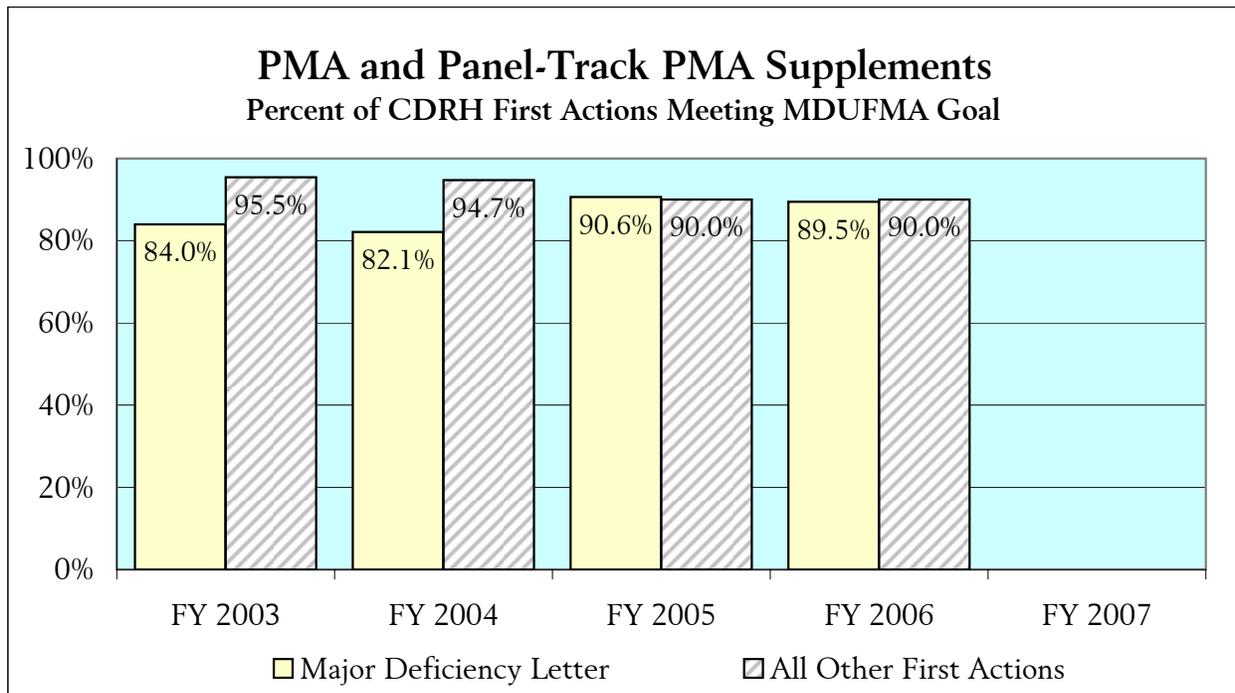
- Progress to date indicates CDRH will likely meet the goal for FY 2006.
- The FY 2004 cohort is complete. All other cohorts remain open.

PMAs and Panel-Track Supplements

CDRH Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "major deficiency"	25	28	32	19	—
Goal – Percent within 150 days	—	—	75%	80%	90%
Percent of actions within goal	84.0%	82.1%	90.6%	89.5%	—
All other first actions	22	19	20	20	—
Goal – Percent within 180 days	—	—	75%	80%	90%
Percent of actions within goal	95.5%	94.7%	90.0%	90.0%	—
Total applications with a first action	47	47	52	39	—
Applications without a first action	0	0	1	9	—
Cohort status	Complete	Complete	Open	Open	—



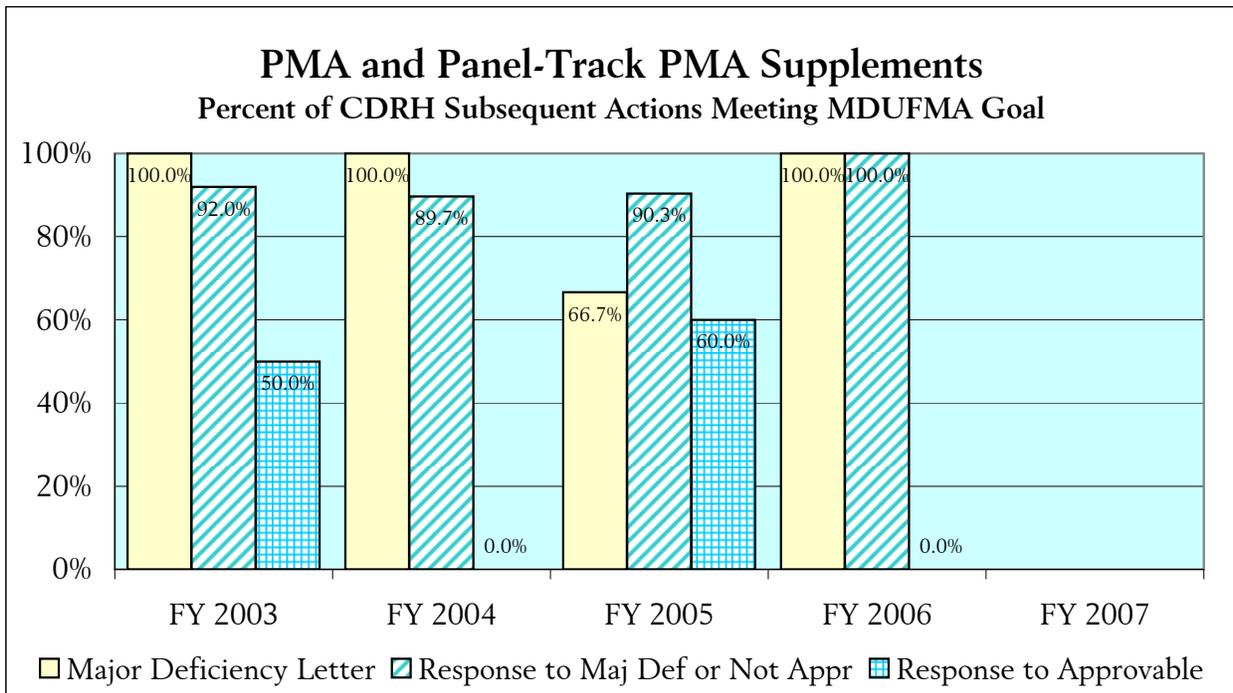
- All FY 2003 and FY 2004 applications have had a first action.
- Only one applications in the FY 2005 receipt cohort has not had a first action.

PMAs and Panel-Track Supplements

CDRH Actions through September 30, 2006

Subsequent Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later action = "major deficiency" letter	2	4	15	3	—
Goal – <i>Percent within 120 days</i>	—	—	75%	80%	90%
Percent of actions within goal	100.0%	100.0%	66.7%	100.0%	—
Cohort status	Open	Open	Open	Open	—
<hr/>					
Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	25	29	31	3	—
Goal – <i>Percent within 180 days</i>	—	—	75%	80%	90%
Percent of actions within goal	92.0%	89.7%	90.3%	100.0%	—
Cohort status	Open	Open	Open	Open	—
<hr/>					
Action on an amendment containing a complete response to an "approvable" letter	2	2	5	0	—
Goal – <i>Percent within 30 days</i>	90%	90%	90%	90%	90%
Percent of actions within goal	50.0%	0.0%	60.0%	--	—
Cohort status	Open	Open	Open	Open	—



- Subsequent action cohorts will remain open longer than decision and first action cohorts.

Expedited PMAs

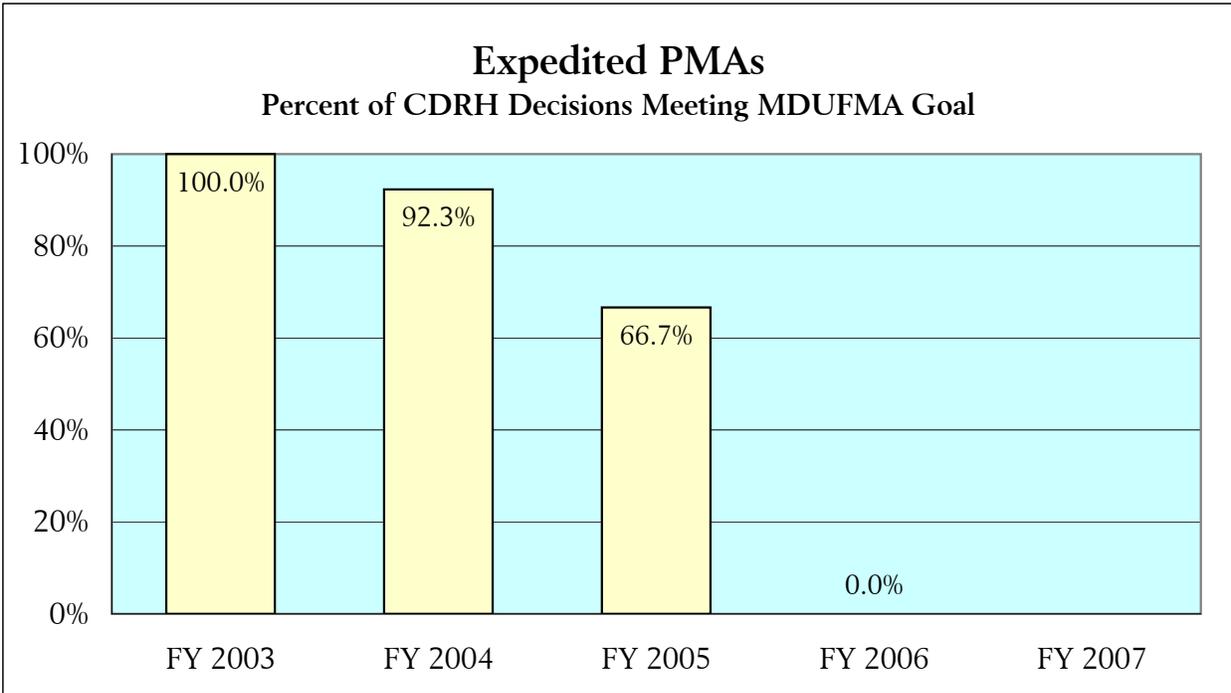
CDRH Actions through September 30, 2006

Workload (Applications Filed to Date)

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

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	3	13	3	0	—
Goal – Percent within 300 days	—	—	70%	80%	90%
Percent of decisions within goal	100.0%	92.3%	66.7%	--	—
Applications without a decision	0	1	3	2	—
Cohort status	Complete	Open	Open	Open	—



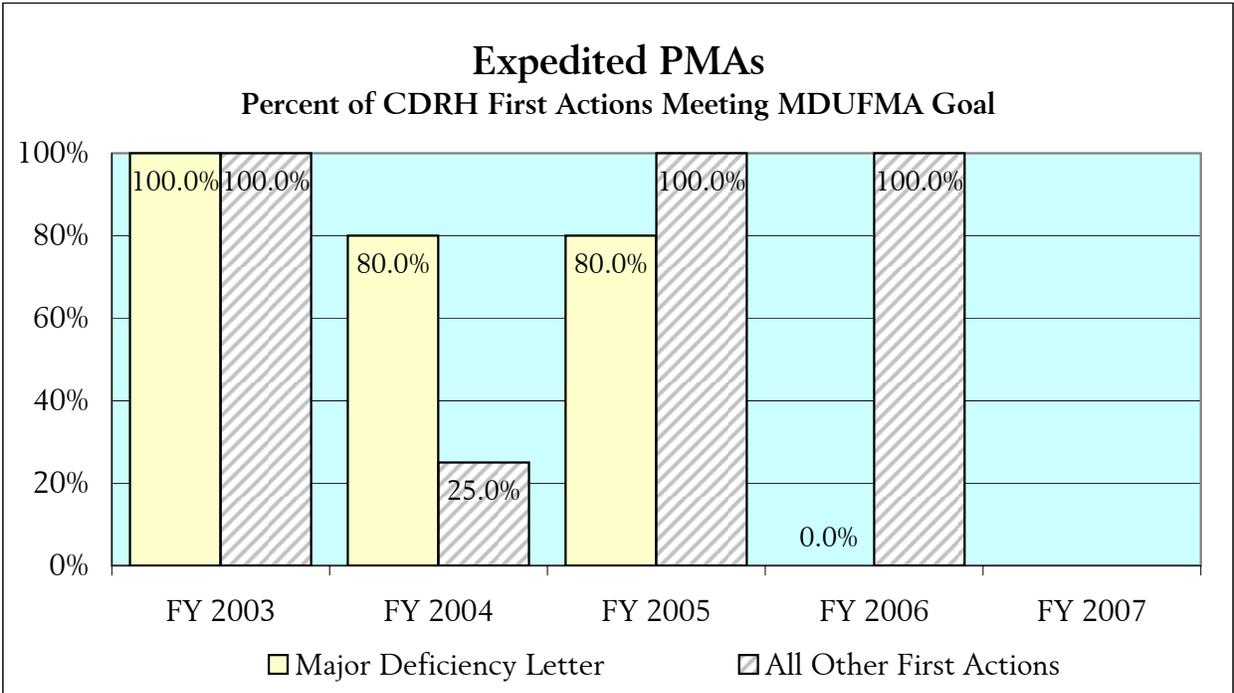
- FY 2003 cohort is complete.
- Because of the small number of Expedited PMAs, a single action may significantly affect performance measures.

Expedited PMAs

CDRH Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "major deficiency"	2	10	5	0	—
Goal – Percent within 120 days	—	—	70%	80%	90%
Percent of actions within goal	100.0%	80.0%	80.0%	--	—
All other first actions	1	4	1	1	—
Goal – Percent within 170 days	—	—	70%	80%	90%
Percent of actions within goal	100.0%	25.0%	100.0%	100.0%	—
Total applications with a first action	3	14	6	1	—
Applications without a first action	0	0	0	1	—
Cohort status	Complete	Complete	Complete	Open	—



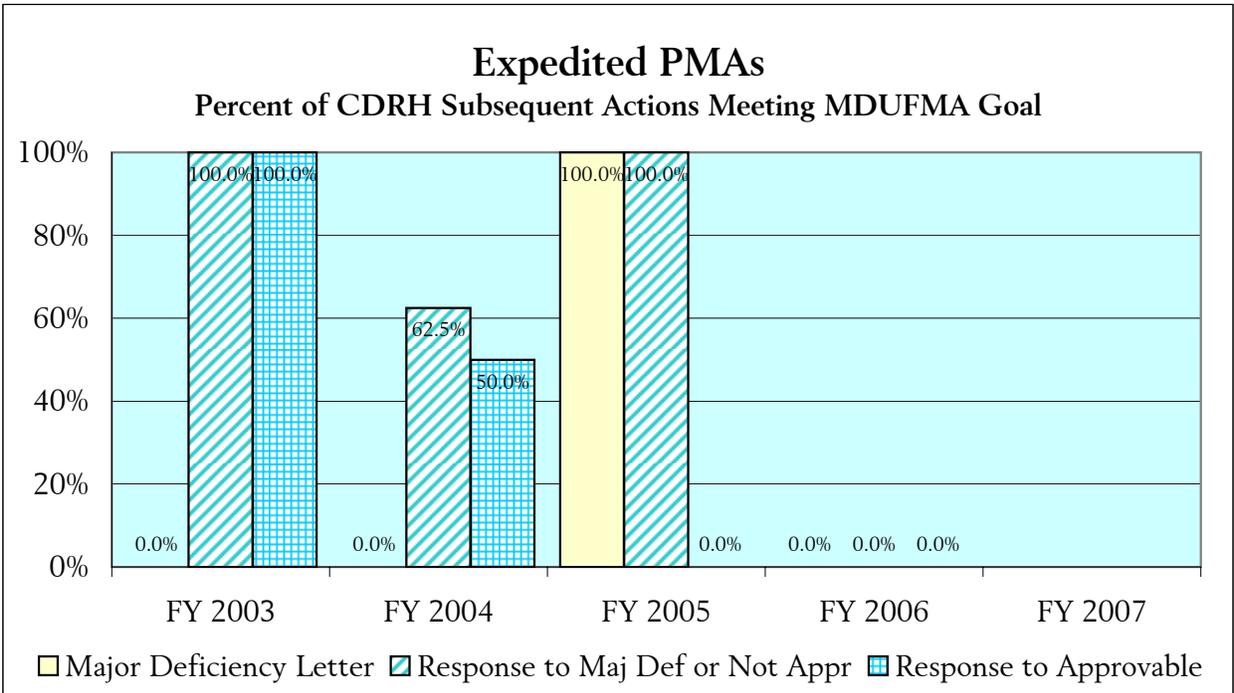
- All FY 2003, FY 2004, and FY 2005 Expedited PMAs have had a first action.
- Because of the small number of Expedited PMAs, a single action may significantly affect performance measures.

Expedited PMAs

CDRH Actions through September 30, 2006

Subsequent (Second or Later) Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later action =					
"major deficiency" letter	0	1	2	0	—
<i>Goal – Percent within 100 days</i>	—	—	70%	80%	90%
Percent of actions within goal	--	0.0%	100.0%	--	—
Cohort status	<i>Complete</i>	Open	Open	Open	—
<hr/>					
Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	2	8	5	0	—
<i>Goal – Percent within 170 days</i>	—	—	70%	80%	90%
Percent of actions within goal	100.0%	62.5%	100.0%	--	—
Cohort status	<i>Complete</i>	Open	Open	Open	—
<hr/>					
Action on an amendment containing a complete response to an "approvable" letter	1	2	0	0	—
<i>Goal – Percent within 30 days</i>	90%	90%	90%	90%	90%
Percent of actions within goal	100.0%	50.0%	--	--	—
Cohort status	<i>Complete</i>	Open	Open	Open	—



- Because of the small number of Expedited PMAs, a single action may significantly affect performance measures.

180-day PMA Supplements

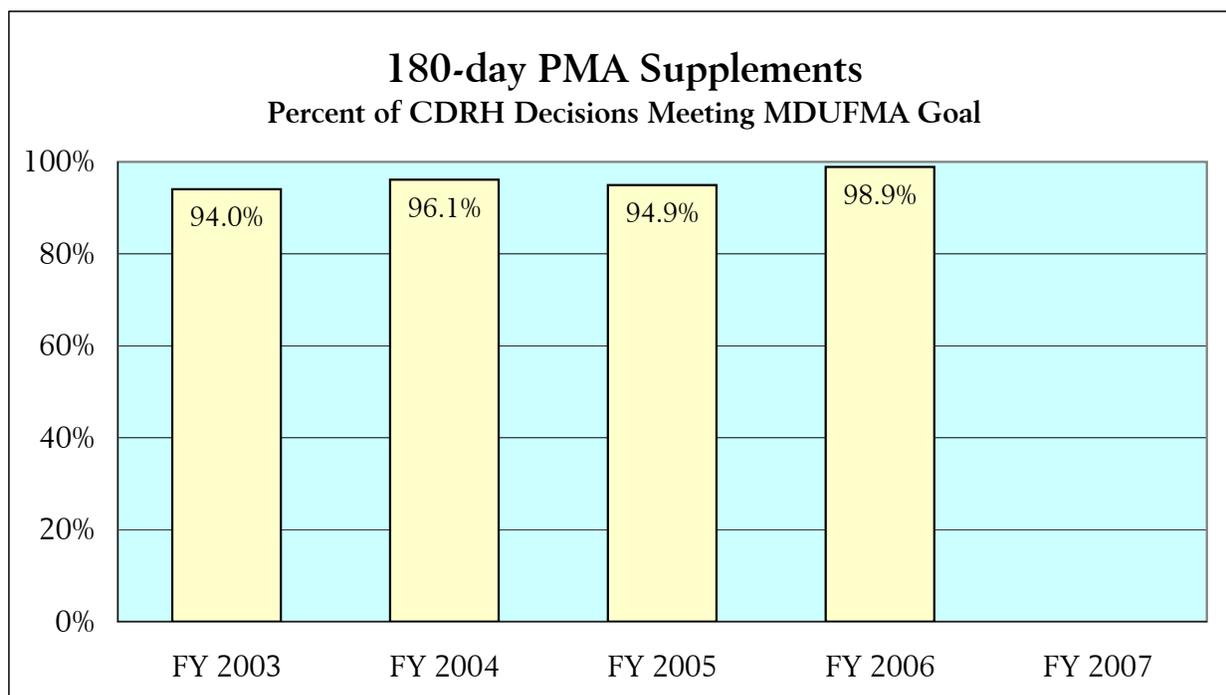
CDRH Actions through September 30, 2006

Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
180-day PMA Supplements	201	103	99	128	—

FDA Decisions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions	201	103	99	92	—
Goal – Percent within 180 days	—	—	80%	80%	90%
Percent of decisions within goal	94.0%	96.1%	94.9%	98.9%	—
Applications without a decision	0	0	0	36	—
Cohort status	Complete	Complete	Complete	Open	—



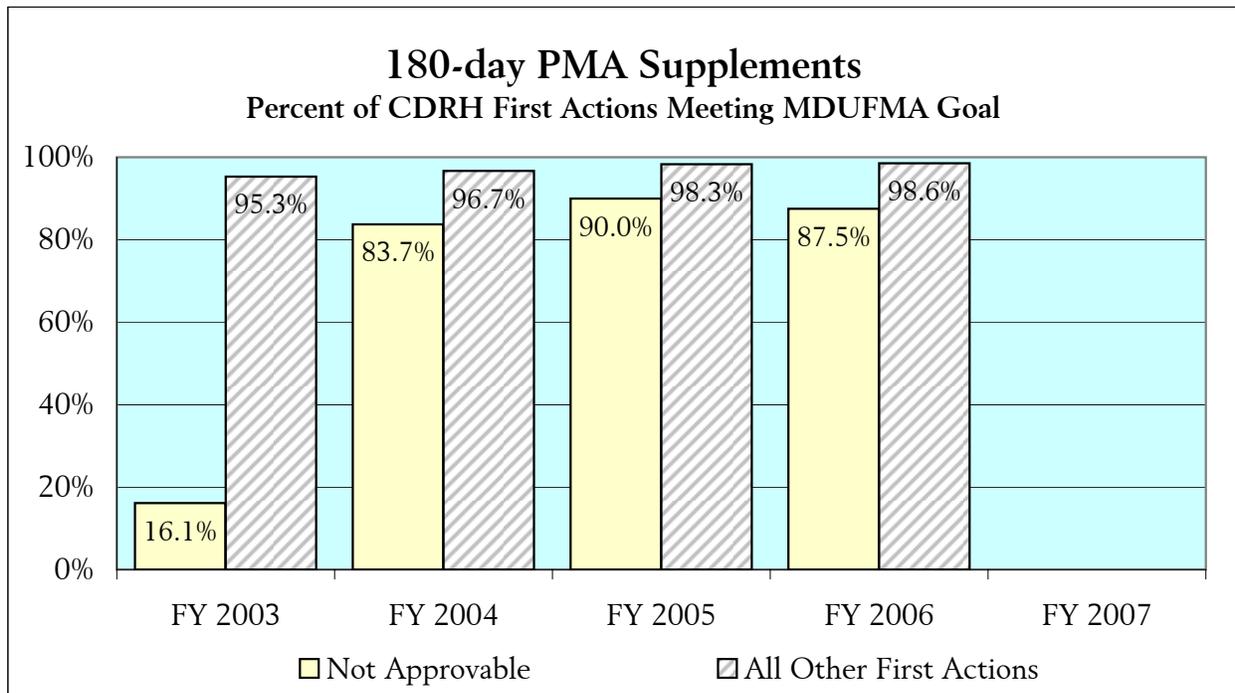
- FY 2003, FY 2004, and FY 2005 cohorts are complete.

180-day PMA Supplements

CDRH Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action = "not approvable"	31	43	40	24	—
Goal – Percent within 120 days	—	—	80%	85%	90%
Percent of actions within goal	16.1%	83.7%	90.0%	87.5%	—
All other first actions	170	60	59	70	—
Goal – Percent within 180 days	—	—	80%	85%	90%
Percent of actions within goal	95.3%	96.7%	98.3%	98.6%	—
Total applications with a first action	201	103	99	94	—
Applications without a first action	0	0	0	34	—
Cohort status	Complete	Complete	Complete	Open	—



- All FY 2003, FY 2004, and FY 2005 applications have had a first action.
- Significant improvement since FY 2003 against MDUFMA goal for first action = "not approvable."

510(k) Premarket Notifications

CDRH Actions through September 30, 2006

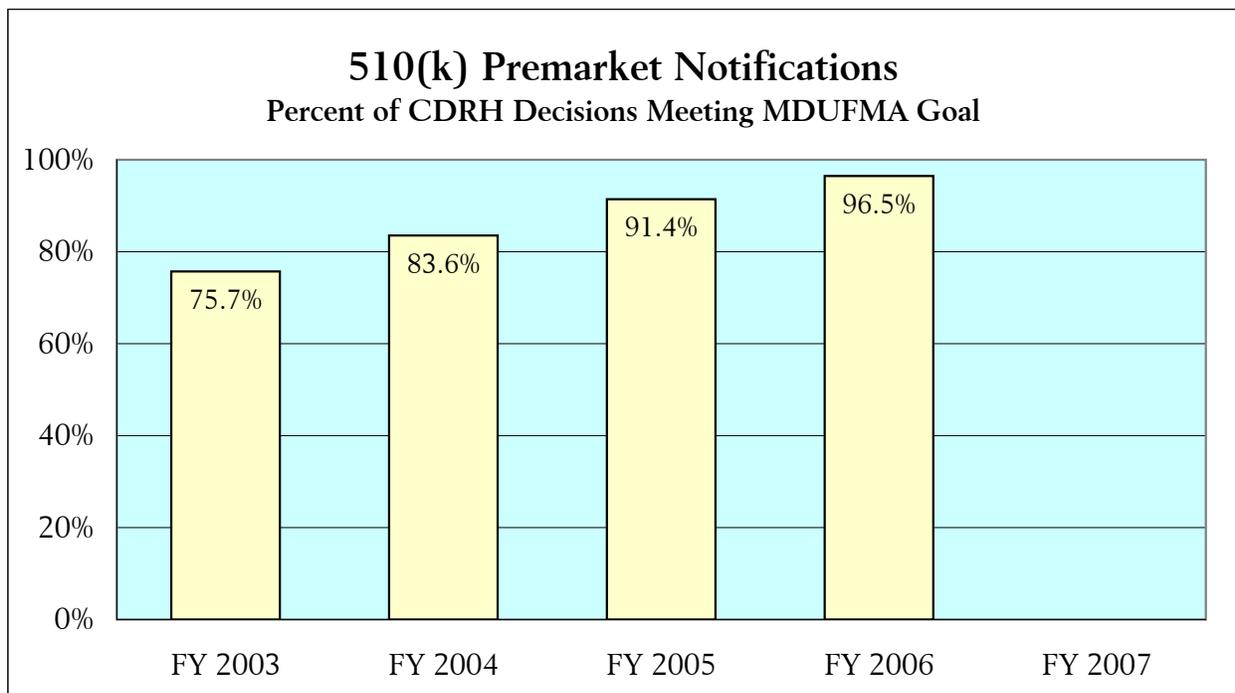
Workload

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Received	4,225	3,632	3,650	3,854	—
MDUFMA Cohort ¹	3,741	3,311	3,356	3,675	—

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)	3,741	3,309	3,321	2,470	—
Goal – Percent within 90 days	—	—	75%	75%	80%
Percent of decisions within goal	75.7%	83.6%	91.4%	96.5%	—
Cohort status	Complete	Open	Open	Open	—



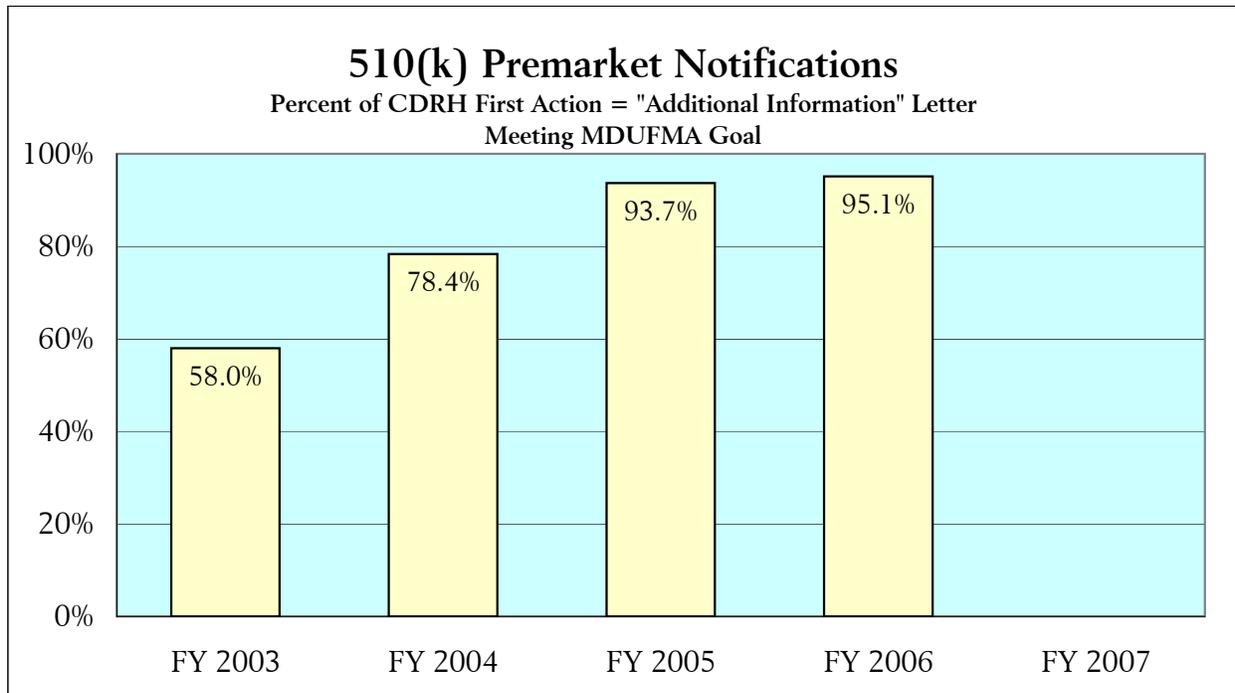
- FY 2003 cohort is complete; only two 510(k)s remain open in the FY 2004 cohort.
- Steady improvement against MDUFMA goal.

510(k) Premarket Notifications

CDRH Actions through September 30, 2006

First Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
First action =					
"additional information" letter	1,701	1,590	1,816	1,791	—
Goal – Percent within 75 days	—	—	70%	80%	90%
Percent of actions within goal	58.0%	78.4%	93.7%	95.1%	—
Cohort status	<i>Complete</i>	Open	Open	Open	—



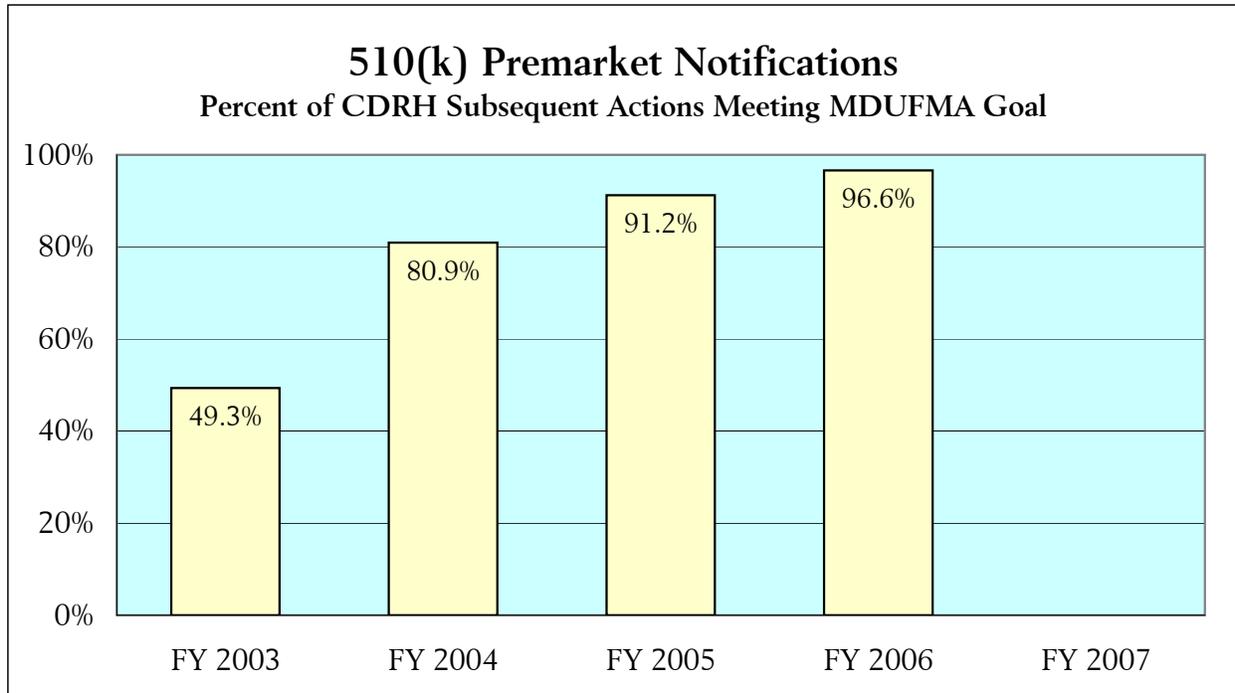
- FY 2003 cohort is complete.
- Steady improvement against MDUMFA goal.

510(k) Premarket Notifications

CDRH Actions through September 30, 2006

Subsequent (Second or Later) Actions

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Second or later actions	592	555	638	439	—
Goal – <i>Percent within 60 days</i>	—	—	70%	80%	90%
Percent of actions within goal	49.3%	80.9%	91.2%	96.6%	—
Cohort status	<i>Complete</i>	Open	Open	Open	—



- FY 2003 cohort is complete.
- Steady improvement against MDUMFA goal.

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

FY 2003 Receipt Cohort

Actions through September 30, 2006

Data for CDRH

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

PMA and Panel-Track Supplements

Type of Application	Filed	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	40	39	36	90.0%	92.3%	3	7.5%	7.7%	1	2.5%
Panel-track Supplement	7	6	5	71.4%	83.3%	1	14.3%	16.7%	1	14.3%
Total	47	45	41	87.2%	91.1%	4	8.5%	8.9%	2	4.3%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Type of Application	Total Actions	<i>Complete</i> First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	20	16	40.0%	80.0%	4	10.0%	20.0%
Panel-track Supplement	5	5	71.4%	100.0%	0	0.0%	0.0%
Total	25	21	44.7%	84.0%	4	8.5%	16.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Type of Application	Total Actions	<i>Complete</i> All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	20	19	47.5%	95.0%	1	2.5%	5.0%	40	100.0%
Panel-track Supplement	2	2	28.6%	100.0%	0	0.0%	0.0%	7	100.0%
Total	22	21	44.7%	95.5%	1	2.1%	4.5%	47	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total	≤ 120 days		> 120 days	
		Number	% of Actions	Number	% of Actions
Original PMA	2	2	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	2	2	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total	≤ 180 days		> 180 days	
		Number	% of Actions	Number	% of Actions
Original PMA	20	19	95.0%	1	5.0%
Panel-track Supplement	5	4	80.0%	1	20.0%
Total	25	23	92.0%	2	8.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total	≤ 30 days		> 30 days	
		Number	% of Actions	Number	% of Actions
Original PMA	2	1	50.0%	1	50.0%
Panel-track Supplement	0	0	--	0	--
Total	2	1	50.0%	1	50.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Expedited PMAs

Filed	Complete 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		
3	3	3	100.0%	100.0%	0	0.0%	0.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Complete First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
2	2	66.7%	100.0%	0	0.0%	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Complete All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
1	1	33.3%	100.0%	0	0.0%	0.0%	3	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Complete Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Complete Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
2	2	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Complete Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
1	1	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

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		
201	201	189	94.0%	94.0%	12	6.0%	6.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

<i>Complete</i>		First Action = "Not Approvable" Letter					
Total Actions	Number	≤ 120 days		> 120 days			
		% of Filed	% of Actions	Number	% of Filed	% of Actions	
31	5	2.5%	16.1%	26	12.9%	83.9%	

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

<i>Complete</i>		All Other First Actions					Total 180-day Supplements with a First Action	
Total Actions	Number	≤ 180 days		> 180 days			Number	% of Filed
		% of Filed	% of Actions	Number	% of Filed	% of Actions		
170	162	80.6%	95.3%	8	4.0%	4.7%	201	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

<i>Complete</i>		Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter			
Total Actions	Number	≤ 160 days		> 160 days	
		% of Actions	Number	% of Actions	
22	21	95.5%	1	4.5%	

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
4,225	3,741	-	-	-	-

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. *Source:* PMN Summary Reports; Report Name: USER FEE - DECISION GOALS.

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
3,741	2,833	67.1%	75.7%	75.7%	908	21.5%	24.3%	24.3%

Source: PMN Summary Reports; Report Name: USER FEE - DECISION GOALS

Complete First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
1,701	986	23.3%	26.4%	58.0%	715	16.9%	19.1%	42.0%

Source: PMN Summary Reports; Report Name: USER FEE - FIRST ACTION ADDITIONAL INFORMATION LETTER

Complete Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
479	592	292	49.3%	300	50.7%

Source: PMN Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION LETTER

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

FY 2004 Receipt Cohort

Actions through September 30, 2006

Data for CDRH

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

PMA 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	39	39	35	89.7%	89.7%	4	10.3%	10.3%	0	0.0%
Panel-track Supplement	8	8	8	100.0%	100.0%	0	0.0%	0.0%	0	0.0%
Total	47	47	43	91.5%	91.5%	4	8.5%	8.5%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Type of Application	Total Actions	<i>Complete</i> First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	24	20	51.3%	83.3%	4	10.3%	16.7%
Panel-track Supplement	4	3	37.5%	75.0%	1	12.5%	25.0%
Total	28	23	48.9%	82.1%	5	10.6%	17.9%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Type of Application	Total Actions	<i>Complete</i> All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	15	14	35.9%	93.3%	1	2.6%	6.7%	39	100.0%
Panel-track Supplement	4	4	50.0%	100.0%	0	0.0%	0.0%	8	100.0%
Total	19	18	38.3%	94.7%	1	2.1%	5.3%	47	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total Actions	≤ 120 days		> 120 days	
		Number	% of Actions	Number	% of Actions
Original PMA	4	4	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	4	4	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total	≤ 180 days		> 180 days	
		Number	% of Actions	Number	% of Actions
Original PMA	24	21	87.5%	3	12.5%
Panel-track Supplement	5	5	100.0%	0	0.0%
Total	29	26	89.7%	3	10.3%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total	≤ 30 days		> 30 days	
		Number	% of Actions	Number	% of Actions
Original PMA	1	0	0.0%	1	100.0%
Panel-track Supplement	1	0	0.0%	1	100.0%
Total	2	0	0.0%	2	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Expedited PMAs

Filed	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		
14	13	12	85.7%	92.3%	1	7.1%	7.7%	1	7.1%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Complete First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
10	8	57.1%	80.0%	2	14.3%	20.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Complete All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
4	1	7.1%	25.0%	3	21.4%	75.0%	14	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
1	0	0.0%	1	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
8	5	62.5%	3	37.5%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
2	1	50.0%	1	50.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

180-day Supplements

Complete 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		
103	103	99	96.1%	96.1%	4	3.9%	3.9%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Complete First Action = "Not Approvable" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
43	36	35.0%	83.7%	7	6.8%	16.3%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Complete All Other First Actions							Total 180-day Supplements with a First Action	
Total Actions	≤ 180 days			> 180 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
60	58	56.3%	96.7%	2	1.9%	3.3%	103	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total Actions	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
42	41	97.6%	1	2.4%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
3,632	3,311	2	1	1	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. *Source:* PMN Summary Reports; Report Name: USER FEE - DECISION GOALS.

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
3,309	2,765	76.1%	83.5%	83.6%	544	15.0%	16.4%	16.4%

Source: PMN Summary Reports; Report Name: USER FEE - DECISION GOALS

First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
1,590	1,246	34.3%	37.6%	78.4%	344	9.5%	10.4%	21.6%

Source: PMN Summary Reports; Report Name: USER FEE - FIRST ACTION ADDITIONAL INFORMATION LETTER

Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
485	555	449	80.9%	106	19.1%

Source: PMN Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION LETTER

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

FY 2005 Receipt Cohort

Actions through September 30, 2006

Data for CDRH

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

PMA and Panel-Track Supplements

Type of Application	Filed	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	41	32	32	78.0%	100.0%	0	0.0%	0.0%	9	22.0%
Panel-track Supplement	12	9	9	75.0%	100.0%	0	0.0%	0.0%	3	25.0%
Total	53	41	41	77.4%	100.0%	0	0.0%	0.0%	12	22.6%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Type of Application	Total Actions	First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	27	25	61.0%	92.6%	2	4.9%	7.4%
Panel-track Supplement	5	4	33.3%	80.0%	1	8.3%	20.0%
Total	32	29	54.7%	90.6%	3	5.7%	9.4%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Type of Application	Total Actions	All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	14	12	29.3%	85.7%	2	4.9%	14.3%	41	100.0%
Panel-track Supplement	6	6	50.0%	100.0%	0	0.0%	0.0%	11	91.7%
Total	20	18	34.0%	90.0%	2	3.8%	10.0%	52	98.1%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total Actions	≤ 120 days		> 120 days	
		Number	% of Actions	Number	% of Actions
Original PMA	14	9	64.3%	5	35.7%
Panel-track Supplement	1	1	100.0%	0	0.0%
Total	15	10	66.7%	5	33.3%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total	≤ 180 days		> 180 days	
		Number	% of Actions	Number	% of Actions
Original PMA	29	26	89.7%	3	10.3%
Panel-track Supplement	2	2	100.0%	0	0.0%
Total	31	28	90.3%	3	9.7%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total	≤ 30 days		> 30 days	
		Number	% of Actions	Number	% of Actions
Original PMA	4	3	75.0%	1	25.0%
Panel-track Supplement	1	0	0.0%	1	100.0%
Total	5	3	60.0%	2	40.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Expedited PMAs

Filed	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		
6	3	2	33.3%	66.7%	1	16.7%	33.3%	3	50.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Complete First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
5	4	66.7%	80.0%	1	16.7%	20.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Complete All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
1	1	16.7%	100.0%	0	0.0%	0.0%	6	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
2	2	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
5	5	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

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		
99	99	94	94.9%	94.9%	5	5.1%	5.1%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

<i>Complete</i>		First Action = "Not Approvable" Letter				
Total Actions	Number	≤ 120 days		> 120 days		
		% of Filed	% of Actions	Number	% of Filed	% of Actions
40	36	36.4%	90.0%	4	4.0%	10.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

<i>Complete</i>		All Other First Actions				Total 180-day Supplements with a First Action		
Total Actions	Number	≤ 180 days		> 180 days		Number	% of Filed	
		% of Filed	% of Actions	Number	% of Filed			% of Actions
59	58	58.6%	98.3%	1	1.0%	1.7%	99	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total Actions	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
30	27	25.0%	10	22.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
3,650	3,356	35	25	10	22

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. *Source:* PMN Summary Reports; Report Name: USER FEE - DECISION GOALS.

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
3,321	3,035	83.2%	90.4%	91.4%	286	7.8%	8.5%	8.6%

Source: PMN Summary Reports; Report Name: USER FEE - DECISION GOALS

First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
1,816	1,701	46.6%	50.7%	93.7%	115	3.2%	3.4%	6.3%

Source: PMN Summary Reports; Report Name: USER FEE - FIRST ACTION ADDITIONAL INFORMATION LETTER

Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
586	638	582	91.2%	56	8.8%

Source: PMN Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION LETTER

Quarterly Report on Progress Towards Achieving MDUFMA Performance Goals

FY 2006 Receipt Cohort

Actions through September 30, 2006

Data for CDRH

PMA and Panel-Track Supplements

Type of Application	Filed	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	34	13	13	38.2%	100.0%	0	0.0%	0.0%	21	61.8%
Panel-track Supplement	14	5	5	35.7%	100.0%	0	0.0%	0.0%	9	64.3%
Total	48	18	18	37.5%	100.0%	0	0.0%	0.0%	30	62.5%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Type of Application	Total Actions	First Action = "Major Deficiency" Letter					
		≤ 150 days			> 150 days		
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
Original PMA	16	15	44.1%	93.8%	1	2.9%	6.3%
Panel-track Supplement	3	2	14.3%	66.7%	1	7.1%	33.3%
Total	19	17	35.4%	89.5%	2	4.2%	10.5%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Type of Application	Total Actions	All Other First Actions						Total Applications with a First Action	
		≤ 180 days			> 180 days			Number	% of Filed
		Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
Original PMA	14	12	35.3%	85.7%	2	5.9%	14.3%	30	88.2%
Panel-track Supplement	6	6	42.9%	100.0%	0	0.0%	0.0%	9	64.3%
Total	20	18	37.5%	90.0%	2	4.2%	10.0%	39	81.3%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Type of Application	Second or Later Action = "Major Deficiency" Letter				
	Total Actions	≤ 120 days		> 120 days	
		Number	% of Actions	Number	% of Actions
Original PMA	3	3	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	3	3	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Type of Application	Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
	Total	≤ 180 days		> 180 days	
		Number	% of Actions	Number	% of Actions
Original PMA	3	3	100.0%	0	0.0%
Panel-track Supplement	0	0	--	0	--
Total	3	3	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Type of Application	Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
	Total	≤ 30 days		> 30 days	
		Number	% of Actions	Number	% of Actions
Original PMA	0	0	--	0	--
Panel-track Supplement	0	0	--	0	--
Total	0	0	--	0	--

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

Expedited PMAs

Filed	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		
2	0	0	0.0%	--	0	0.0%	--	2	100.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

First Action = "Major Deficiency" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
0	0	0.0%	--	0	0.0%	--

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

All Other First Actions						Total Applications with a First Action		
Total Actions	≤ 170 days			> 170 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
1	1	50.0%	100.0%	0	0.0%	0.0%	1	50.0%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Second or Later Action = "Major Deficiency" Letter				
Total Actions	≤ 100 days		> 100 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Action on an Amendment Containing a Complete Response to a "Major Deficiency" or "Not Approvable" Letter				
Total Actions	≤ 170 days		> 170 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Source: PMA Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION GOALS

Action on an Amendment Containing a Complete Response to an "Approvable" Letter				
Total Actions	≤ 30 days		> 30 days	
	Number	% of Actions	Number	% of Actions
0	0	--	0	--

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

180-day Supplements

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		
128	92	91	71.1%	98.9%	1	0.8%	1.1%	36	28.1%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

First Action = "Not Approvable" Letter						
Total Actions	≤ 120 days			> 120 days		
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions
24	21	16.4%	87.5%	3	2.3%	12.5%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

All Other First Actions						Total 180-day Supplements with a First Action		
Total Actions	≤ 180 days			> 180 days			Number	% of Filed
	Number	% of Filed	% of Actions	Number	% of Filed	% of Actions		
70	69	53.9%	98.6%	1	0.8%	1.4%	94	73.4%

Source: PMA Summary Reports; Report Name: USER FEE - FIRST ACTION GOALS

Action on an Amendment Containing a Complete Response to a "Not Approvable" Letter				
Total Actions	≤ 160 days		> 160 days	
	Number	% of Actions	Number	% of Actions
8	8	100.0%	0	0.0%

Source: PMA Summary Reports; Report Name: USER FEE - DECISION GOALS

510(k)s

Received	MDUFMA Cohort ¹	Awaiting MDUFMA Decision			
		Total Remaining	On Hold	Under Review	Pending > 90 days
3,854	3,675	1,205	474	731	50

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. *Source:* PMN Summary Reports; Report Name: USER FEE - DECISION GOALS.

SE and NSE Decisions								
Total Decisions	≤ 90 days				> 90 days			
	Number	% of Rcvd.	% of Cohort	% of Decisions	Number	% of Rcvd.	% of Cohort	% of Decisions
2,470	2,383	61.8%	64.8%	96.5%	87	2.3%	2.4%	3.5%

Source: PMN Summary Reports; Report Name: USER FEE - DECISION GOALS

First Action = "Additional Information" Letter								
Total First Action = AI	≤ 75 days				> 75 days			
	Number	% of Rcvd.	% of Cohort	% of AI	Number	% of Rcvd.	% of Cohort	% of AI
1,791	1,704	44.2%	46.4%	95.1%	87	2.3%	2.4%	4.9%

Source: PMN Summary Reports; Report Name: USER FEE - FIRST ACTION ADDITIONAL INFORMATION LETTER

Second or Later Action					
510(k)s with Subseq. Ltr.	Total Subseq. Ltrs.	≤ 60 days		> 60 days	
		Number	% of Sub. Ltrs.	Number	% of Sub. Ltrs.
413	439	424	96.6%	15	3.4%

Source: PMN Summary Reports; Report Name: USER FEE - SUBSEQUENT ACTION LETTER