

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

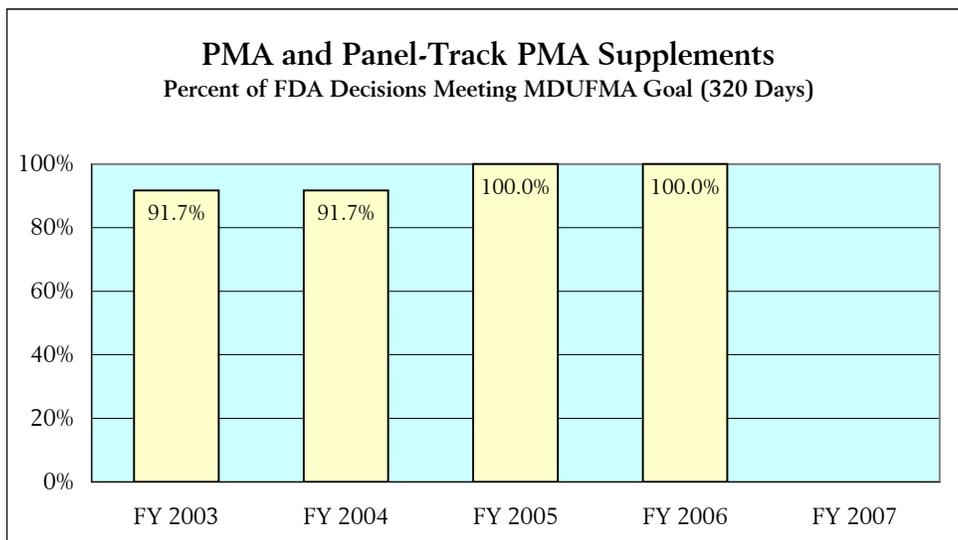
FDA Actions through September 30, 2006

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	—



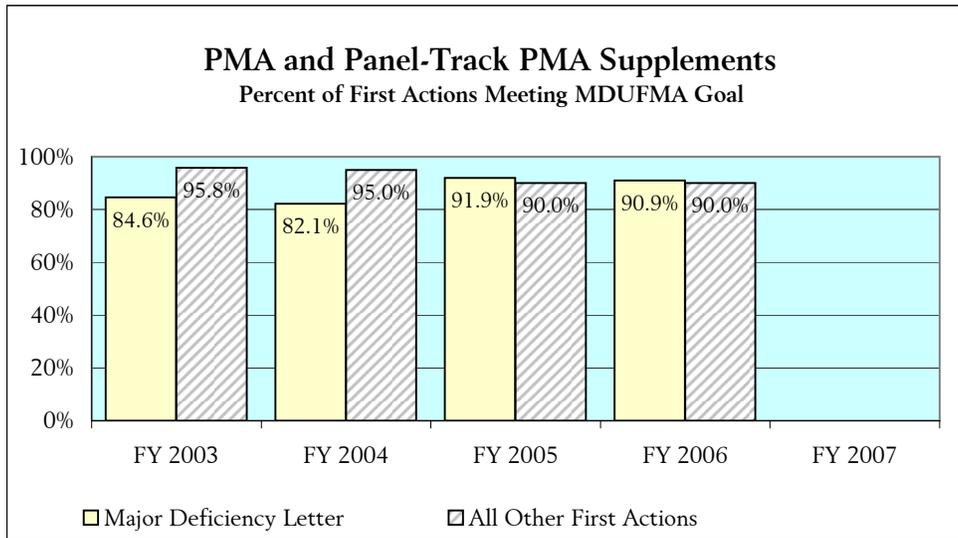
- Progress to date indicates FDA will likely meet the goal for FY 2006.
- FY 2004 cohort is complete. All other cohorts remain open.

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	—



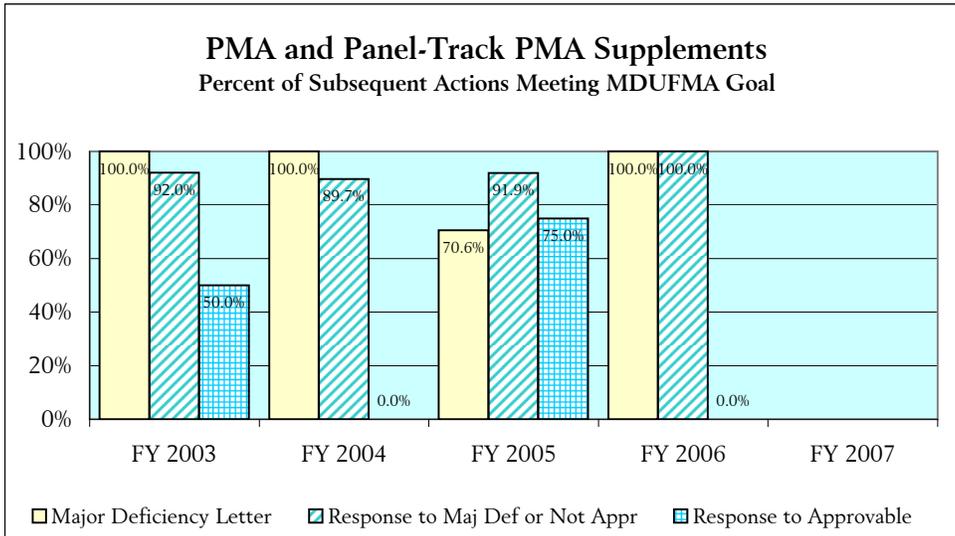
- All FY 2003 and FY 2004 applications have had a first action; these cohorts are complete.
- Progress to date indicates FDA will likely meet both first-action goals for FY 2005 and FY 2006.

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

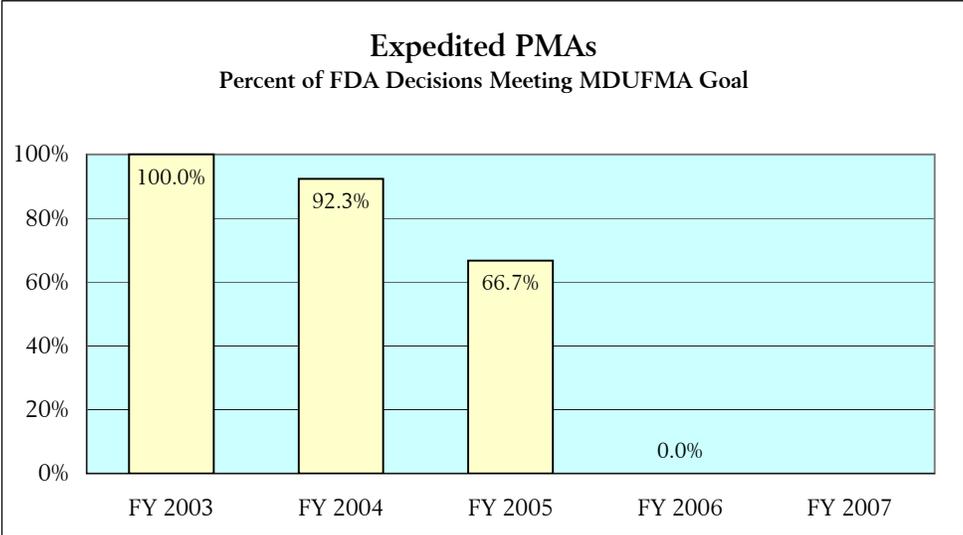
FDA Actions through September 30, 2006

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	—



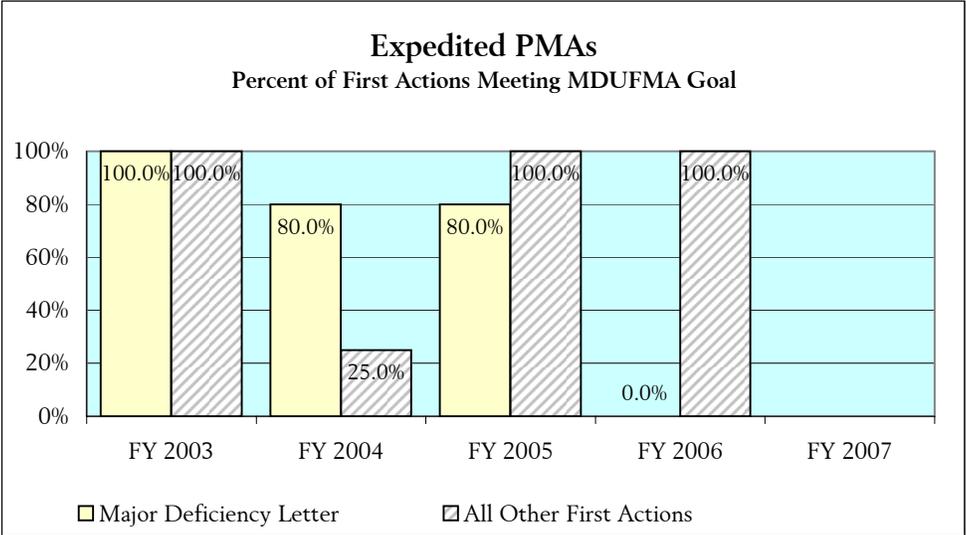
- FY 2003 cohort is complete. All other cohorts remain open.
- Because of the small number of Expedited PMAs, a single action may significantly affect performance measures.
- To date, no CBER PMA has qualified for Expedited status.

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	—



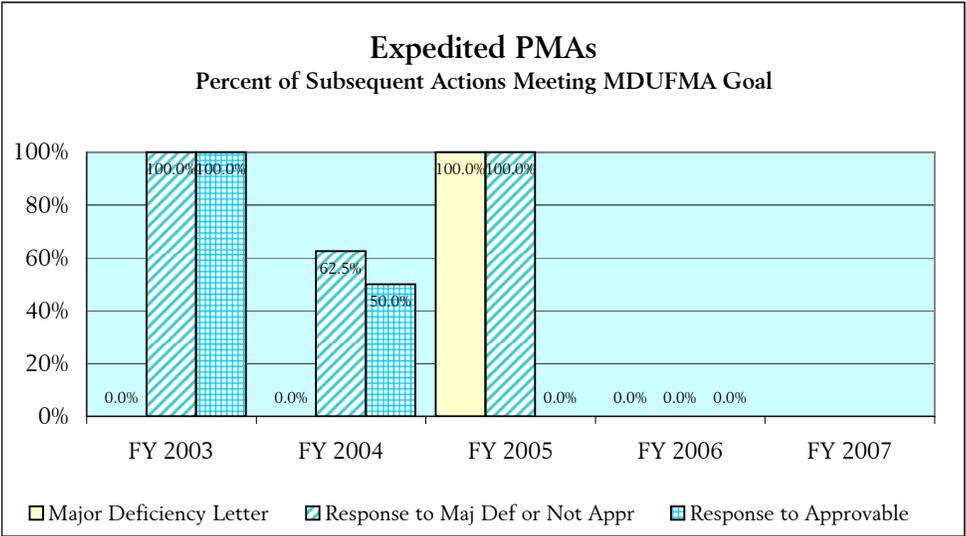
- All FY 2003, FY 2004, and FY 2005 applications have had a first action; these cohorts are complete.

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	—
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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	—
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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

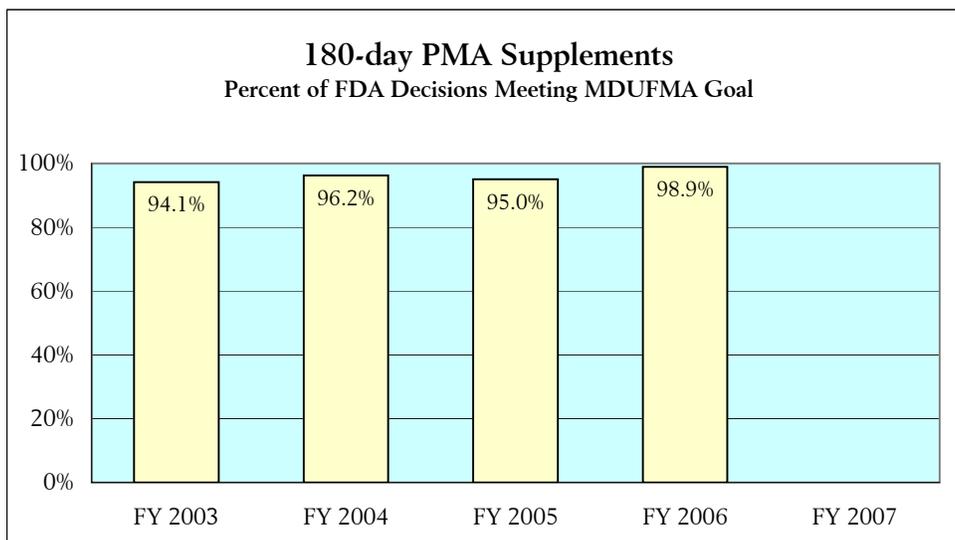
FDA Actions through September 30, 2006

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	—



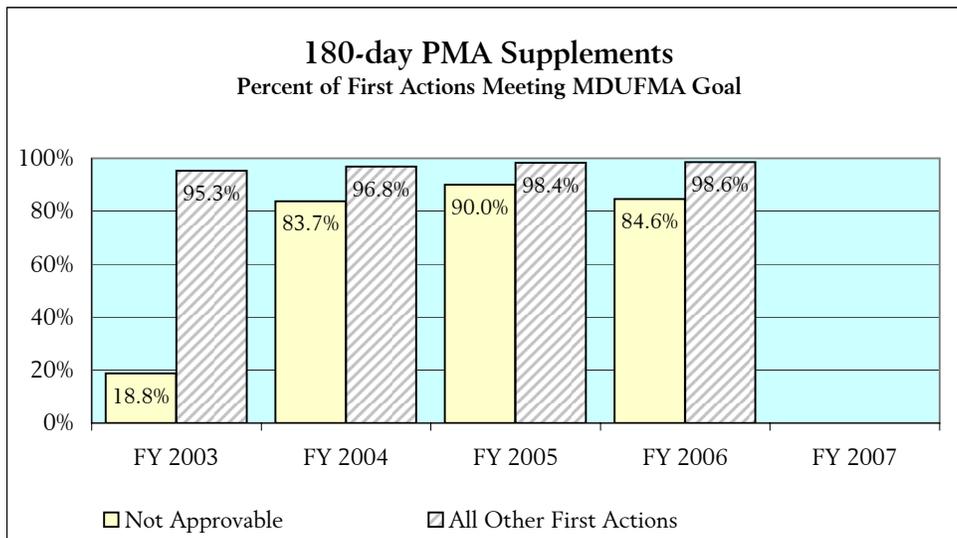
- FDA has made a decision on all 180-day PMA supplements received from FY 2003 through FY 2005. These cohorts are complete.

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	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Open</i>	—



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

510(k) Premarket Notifications

FDA Actions through September 30, 2006

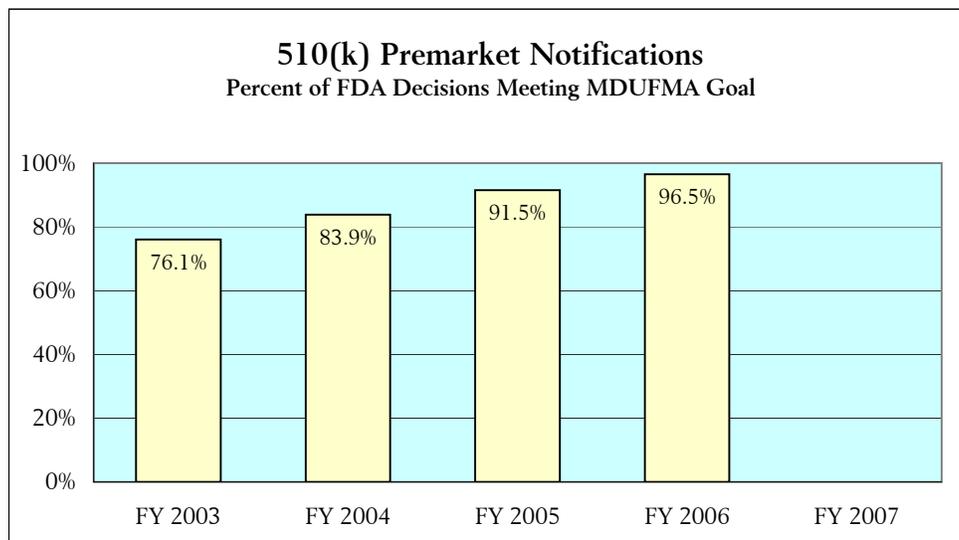
Workload

	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	—



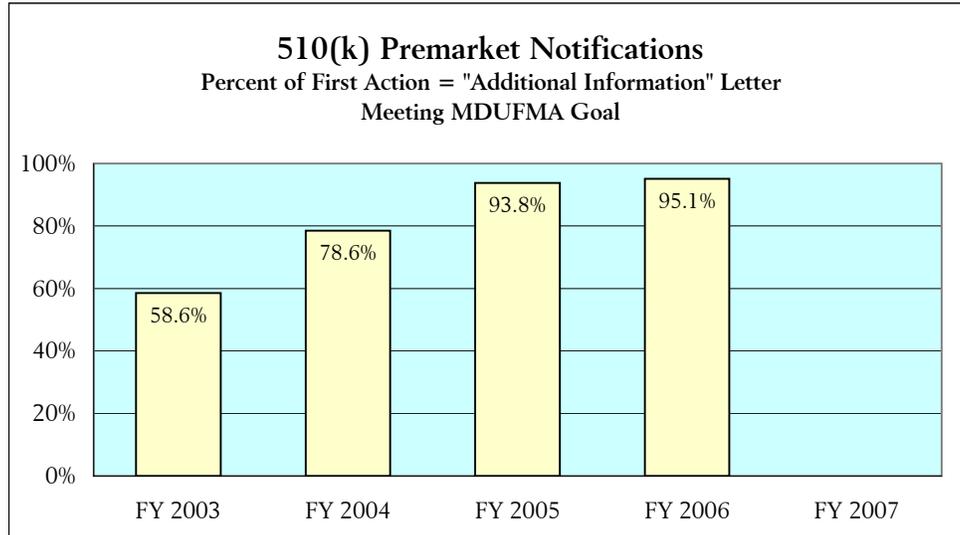
- FY 2003 cohort is complete.

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	—



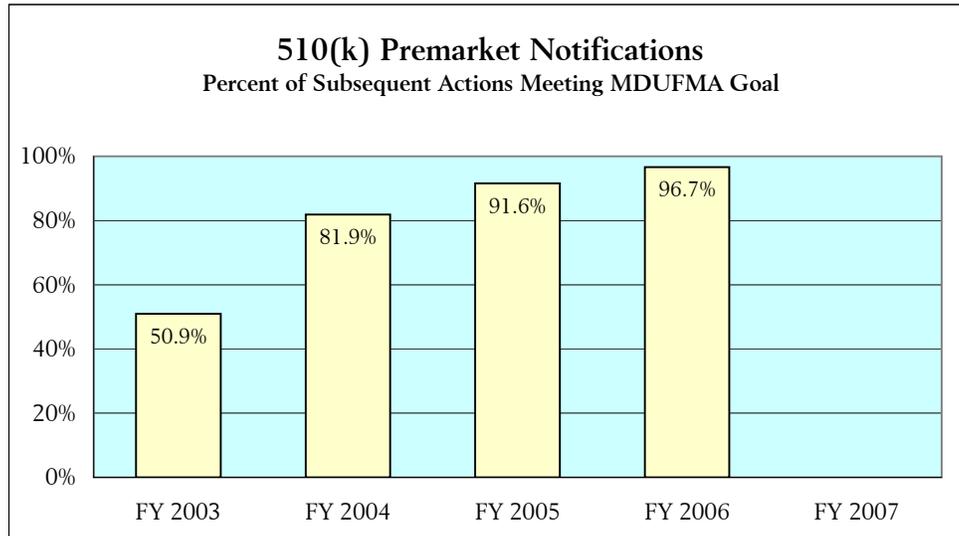
- FY 2003 cohort is complete.

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	Complete	Open	Open	Open	—



- FY 2003 cohort is complete.

Biologics Licensing Applications

FDA Actions through September 30, 2006

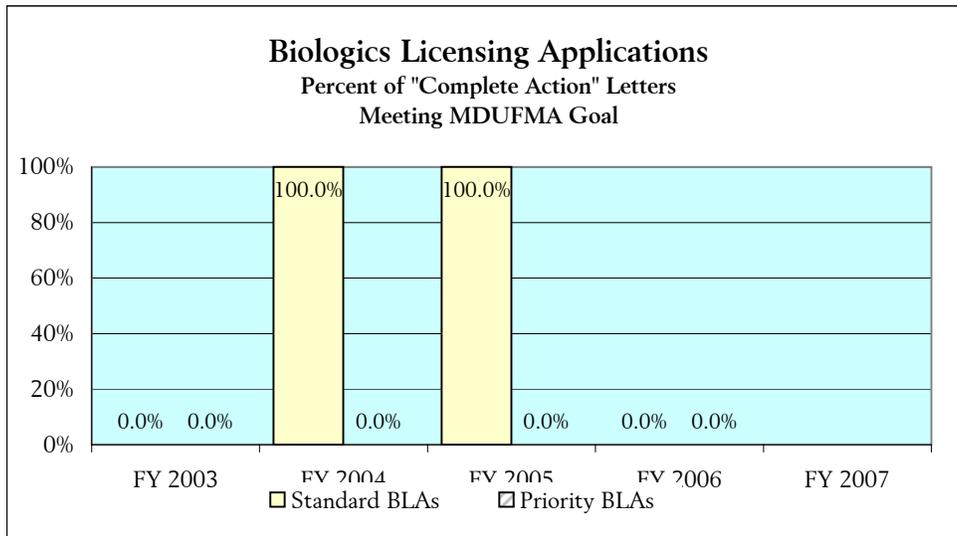
Workload (Applications Filed to Date)

	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

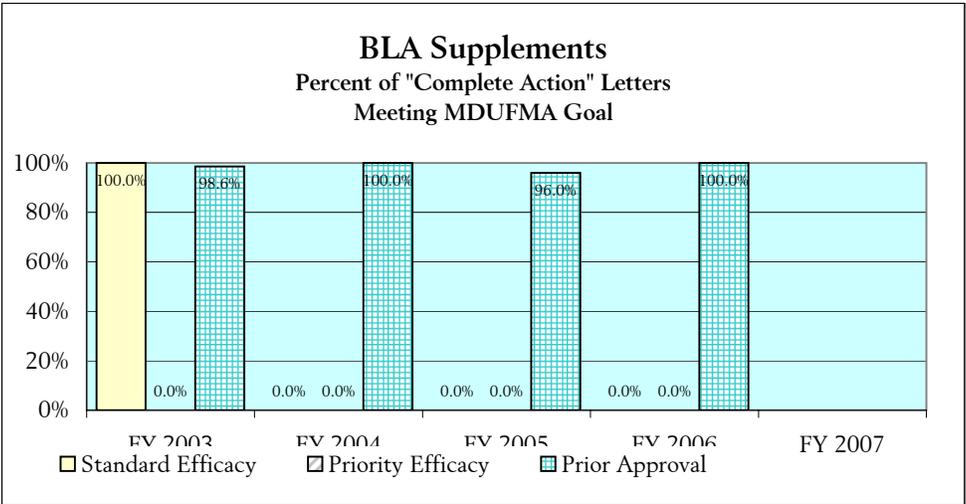
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
"Complete Action" Letter	3	0	0	0	—
Goal – Percent within 10 months	—	—	—	75%	90%
Percent of actions within goal	100.0%	--	--	--	—
Applications without an action	0	0	0	0	—
Cohort status	Complete	Complete	Complete	Open	—

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	—

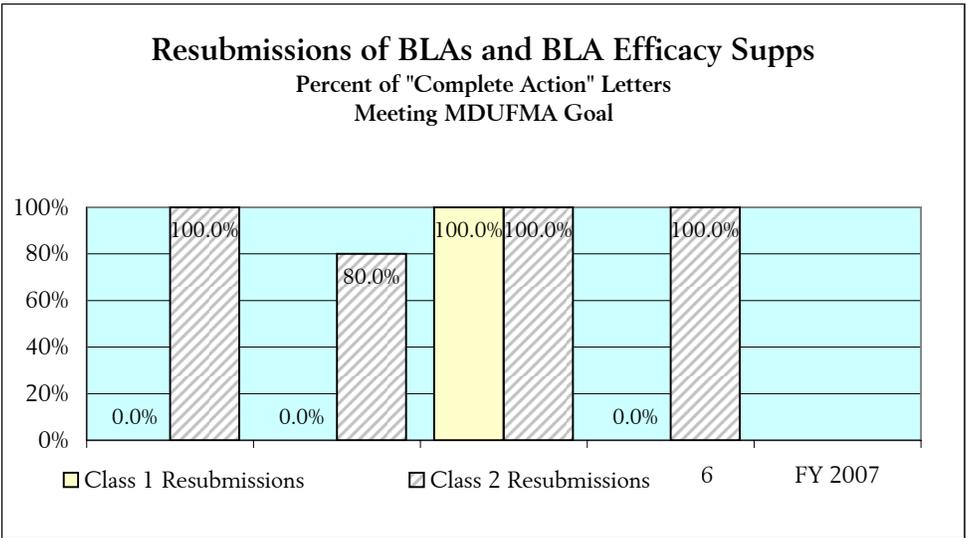
Review and Act on Resubmissions

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	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Open</i>	—

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	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Open</i>	—



- 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.