AMDM

Meeting

Office of *In Vitro* Diagnostic Device
Evaluation and Safety (OIVD)
Center for Devices and Radiological Health

http://www.fda.gov/MedicalDevices/default.htm

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FDA U.S. Food and Drug Administration

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Medical Devices

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Home > Medical Devices

Home Use Devices
Learn about FDA's Medical Device Home Use Initiative.

CDRH Transparency
A window into CDRH's decisions and the data behind them.

Hearing Aids
Learn about hearing loss and the benefits and safety of hearing aids.

Spotlight

- CDRH FY 2010 Strategic Priorities
- CDRH Ombudsman Annual Report - Calendar Year 2009
- LASIK
- Personal Protective Equipment
- Radiation-Emitting Products

Products and Medical Procedures
Approvals & Clearances, Home Use, Surgical, Implants & Prosthetics, In Vitro Diagnostics, more...

Medical Device Safety
Alerts & Notices, Recalls, Report a Problem, MedSun, Emergency Situations

Science and Research (Medical Devices)
Chemistry & Materials Science, Solid & Fluid Mechanics, Imaging & Applied Mathematics, Electrical & Software Engineering, more...

News & Events (Medical Devices)
Medical Device News, Videos, Workshops & Meetings

Recalls & Alerts

- Information About STERIS System 1
- List of Device Recalls
- Recalls Database
- Public Health Notifications
- How to Report a Problem

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Centers & Offices

About the Center for Devices and Radiological Health

CDRH Strategic Planning

CDRH FY 2010 Strategic Priorities

CDRH FY 2010 Strategic Priorities

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Strengthen Premarket Review

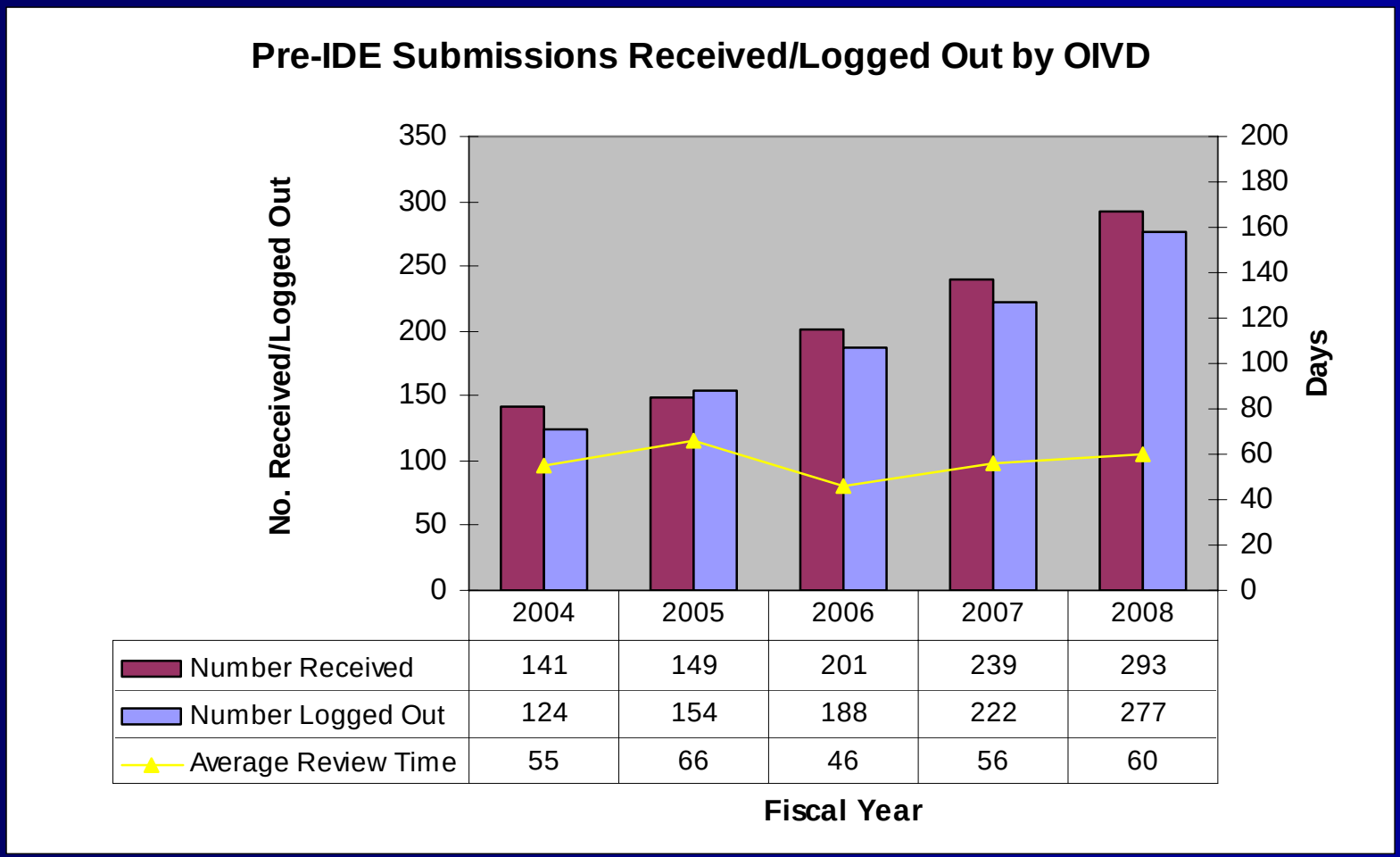
Goal 1.1.1.1. By September 30, 2010, CDRH will begin to implement the recommendations of the 510(k) Working Group.

- By February 28, 2010, collect input from external constituencies through a public docket and a public meeting.
- By March 31, 2010, hold an all-hands meeting to collect additional input from CDRH employees.
- By March 31, 2010, develop and implement changes to the 510(k) Quarterly Quality Review Program that will allow CDRH to assess the impact of changes to the 510(k) program.
- By May 31, 2010, submit to the Center Director the recommendations of the 510(k) Working Group.
- By July 31, 2010, develop an implementation plan.
- By September 30, 2010, begin to implement the recommendations of the 510(k) Working Group.

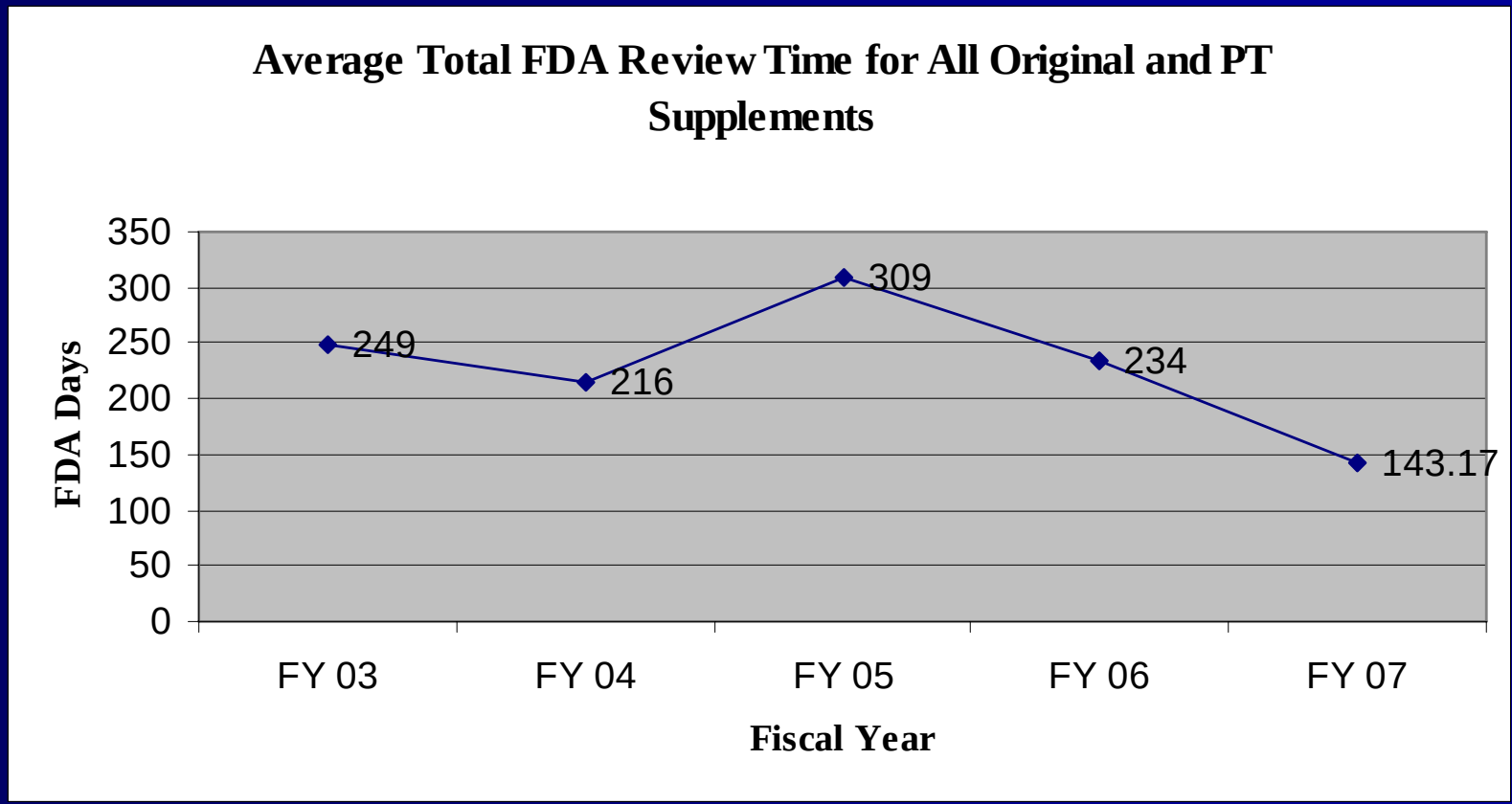
Major Submissions Completed FY 04 – FY 08

Type of Submission	2004	2005	2006	2007	2008
Original PMAs	9	6	10	4	6
PMA Supplements	42	28	44	35	53
Original IDEs	4	6	9	16	4
IDE Amendments	0	0	5	3	2
IDE Supplements	14	23	35	30	24
510(k)s	541	520	613	472	472
Original HDE	1	0	0	1	0
HDE Supplements	1	0	0	1	0
Total	612	583	716	562	561

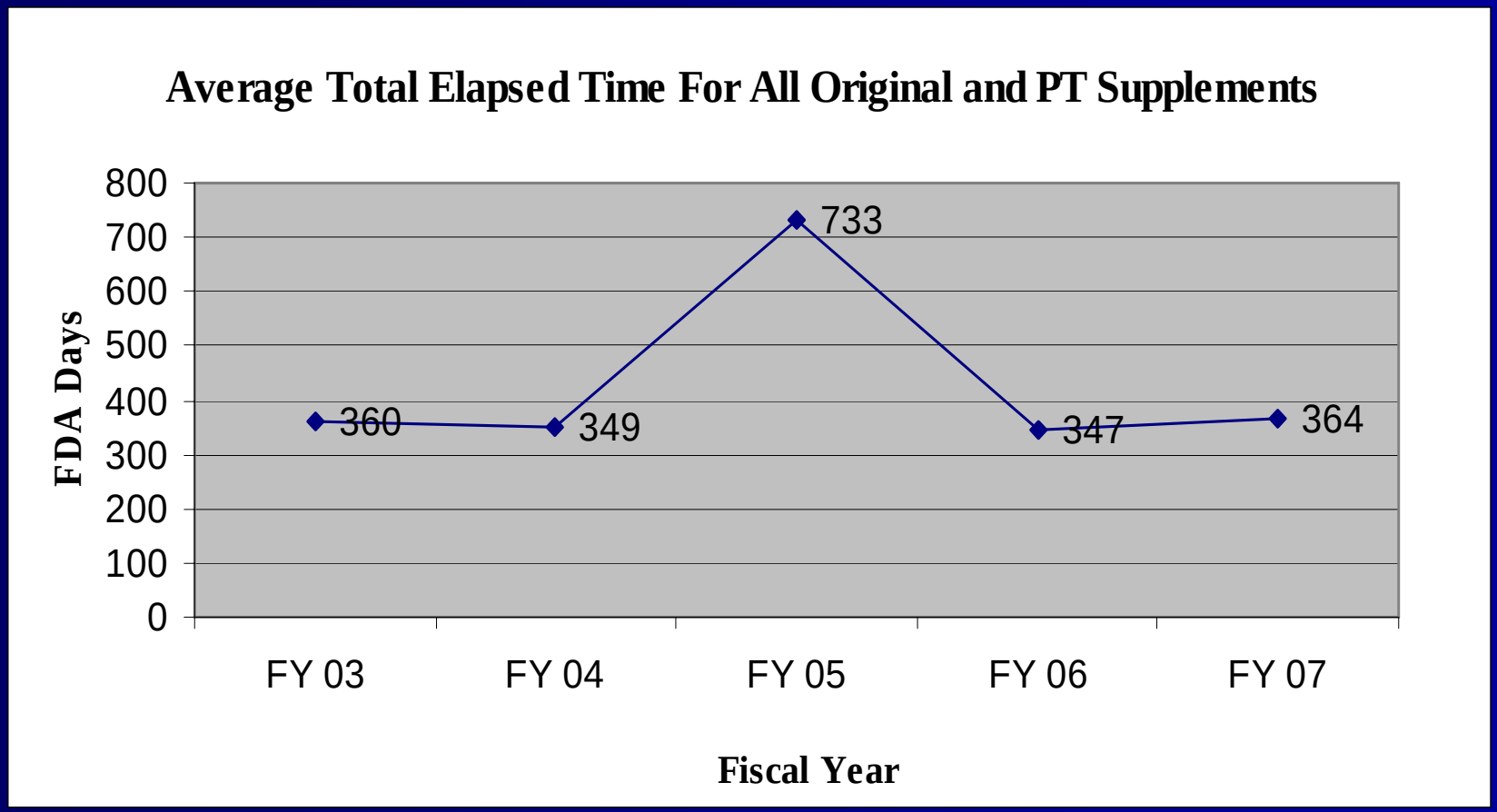
Pre-IDEs


Pre-IDE Submissions Received/Logged Out by OIVD
No. Received/Logged Out
Days
350
300
250
200
150
100
50
0
200
180
160
140
120
100
80
60
40
20
0
2004
2005
2006
2007
2008
Number Received
141
149
201
239
293
Number Logged Out
124
154
188
222
277
Average Review Time
55
66
46
56
60
Fiscal Year

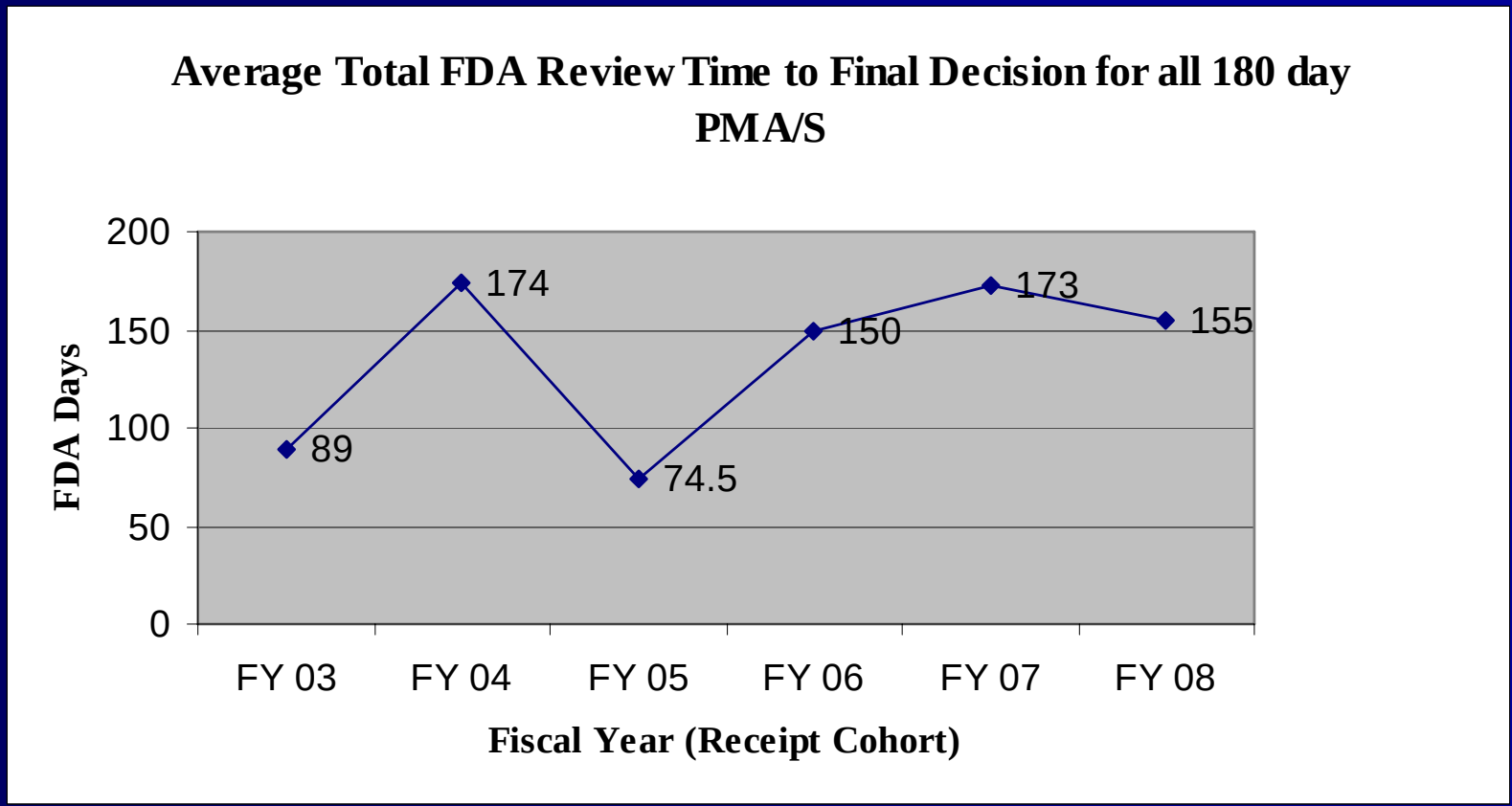
PMAs
Originals and Panel Track



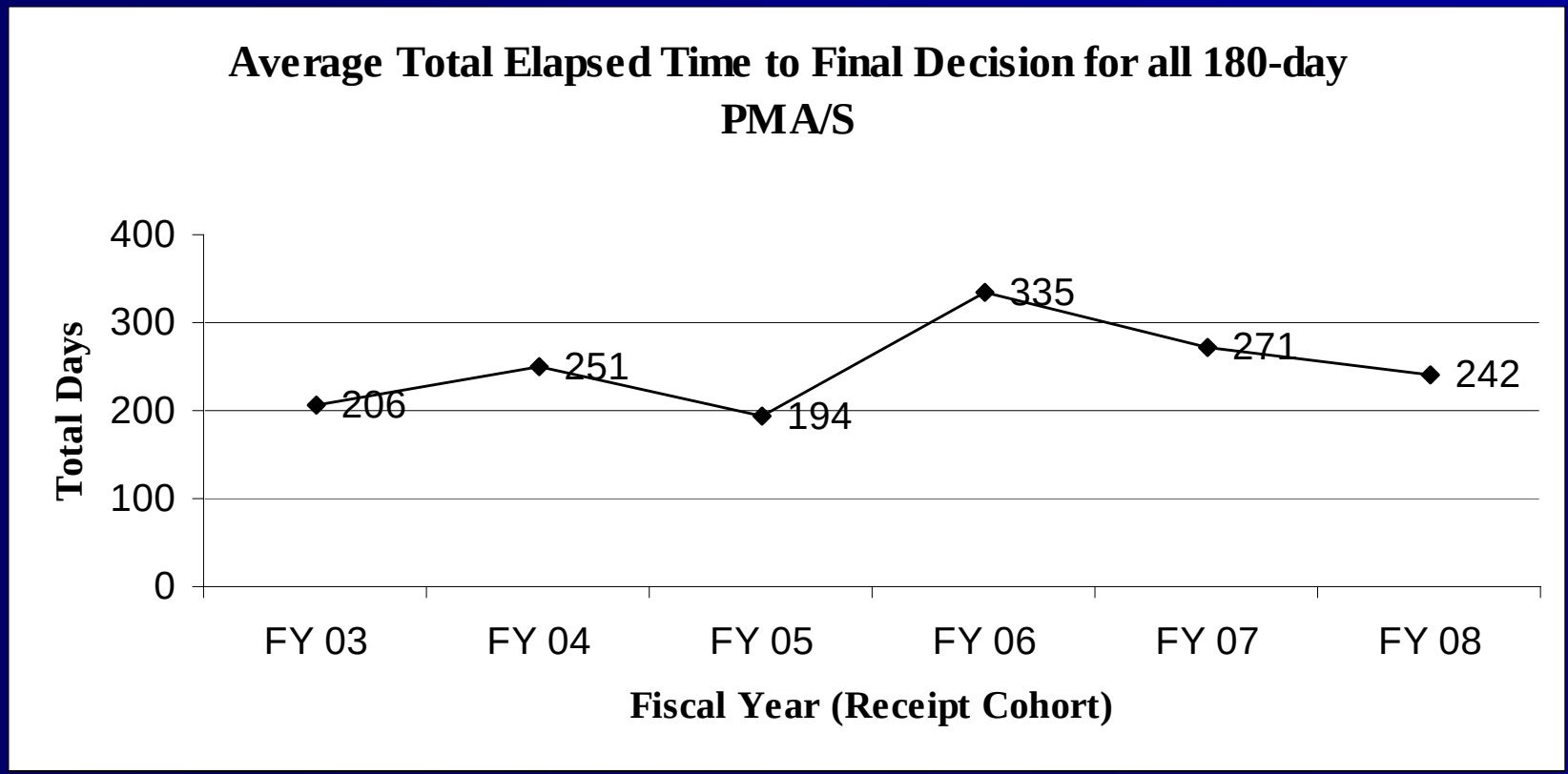
PMAs
Originals and Panel Track



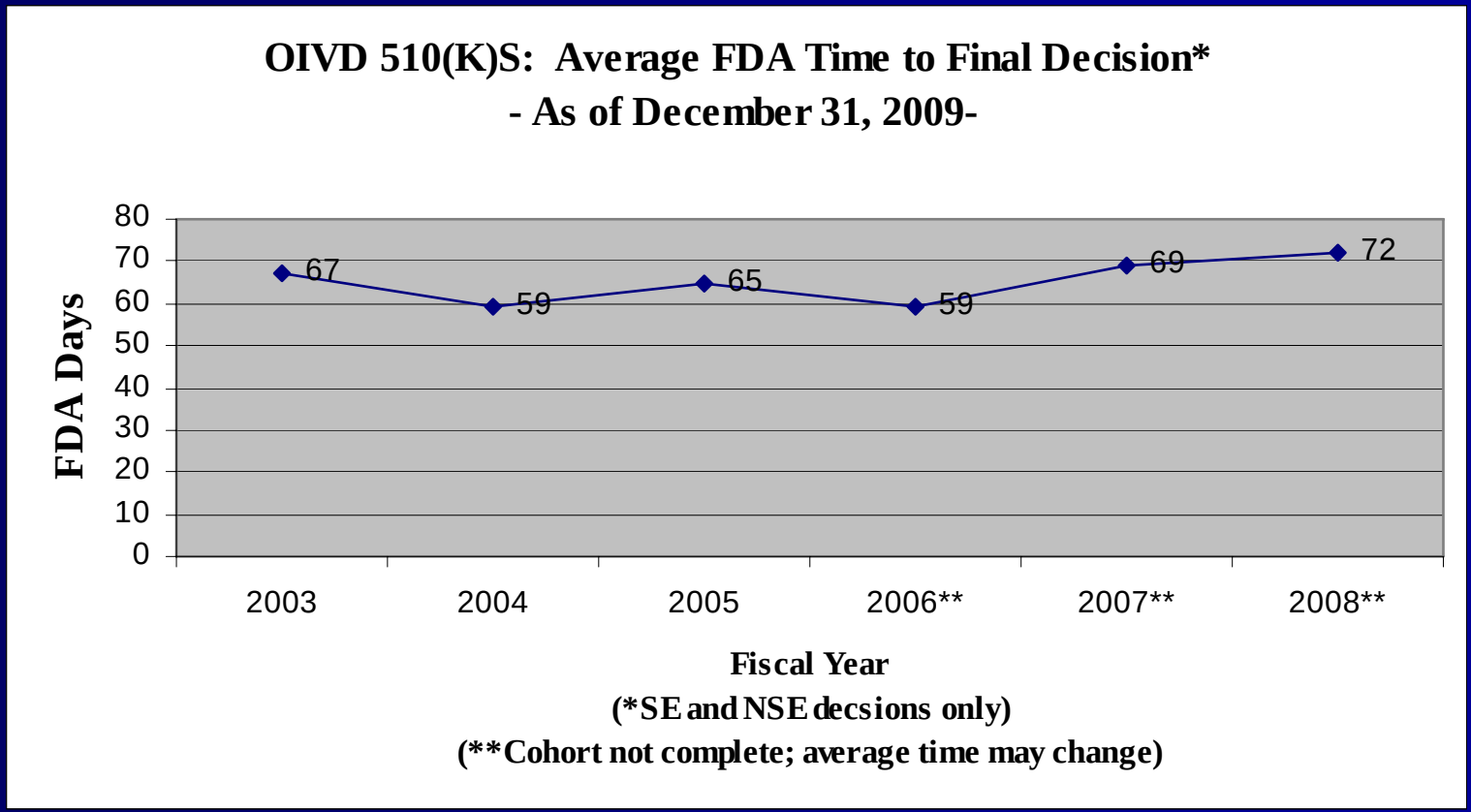
180 Day PMA Supplements



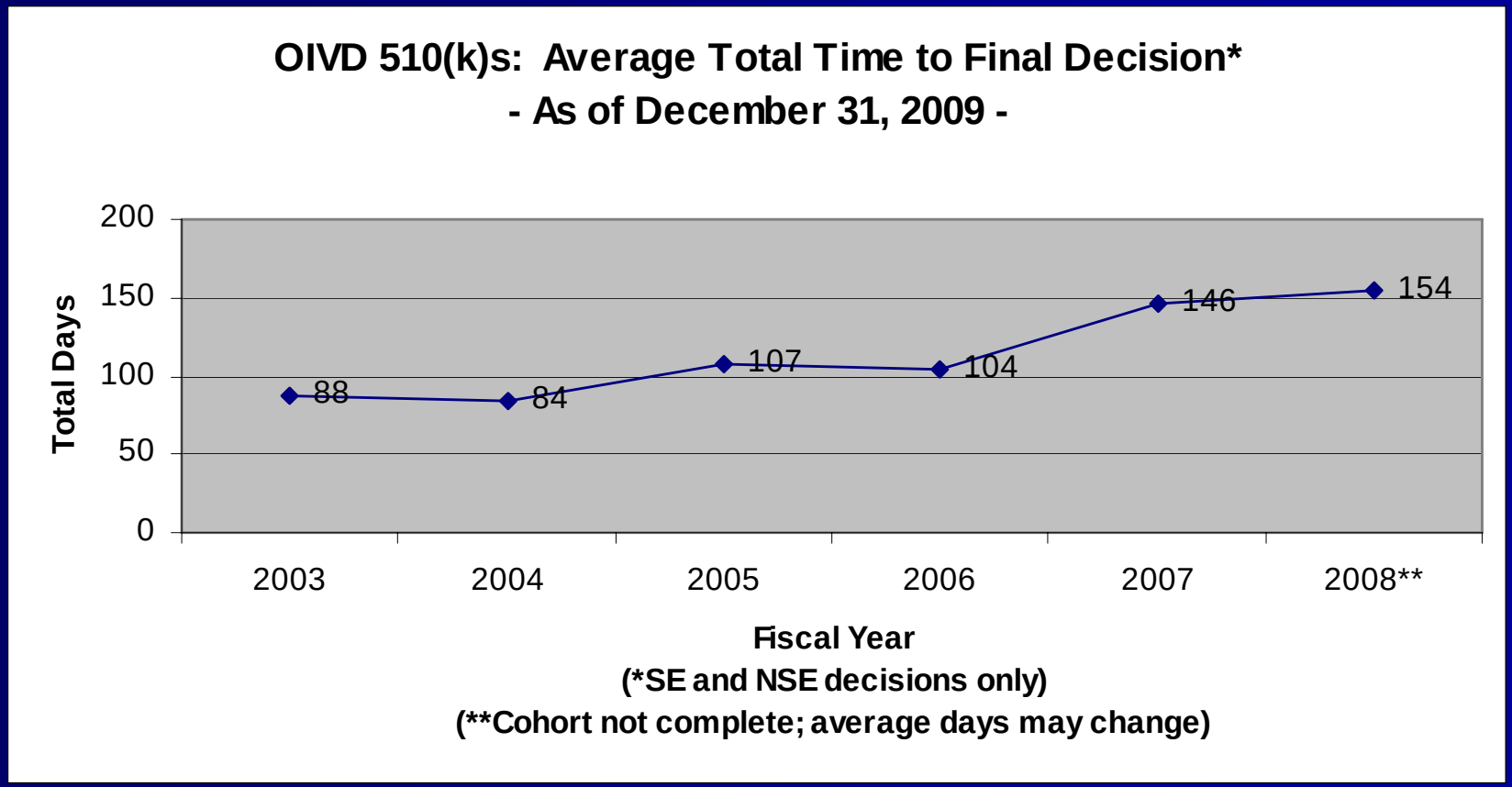
180 Day PMA Supplements



510(k)s


OIVD 510(K)S: Average FDA Time to Final Decision*
- As of December 31, 2009-
FDA Days
80
70
60
50
40
30
20
10
0
67
59
65
59
69
72
2003
2004
2005
2006**
2007**
2008**
Fiscal Year
(*SE and NSE decsions only)
(**Cohort not complete; average time may change)

510(k)s


OIVD 510(k)s: Average Total Time to Final Decision*
- As of December 31, 2009 -
Total Days
200
150
100
50
0
88
84
107
104
146
154
2003
2004
2005
2006
2007
2008**
Fiscal Year
(*SE and NSE decisions only)
(**Cohort not complete; average days may change)