

**Agenda for Quarterly Meeting on MDUFA III (FY 2013-2017) Performance**  
**May 8, 2015**  
**2:00 P.M.**

**Welcome.** *Barbara Zimmerman, CDRH-ODE.*

**Guidance Development**

- *Paul Gadiock, CDRH-OCD.*

**FDA MDUFA Performance — Actions through March 31, 2015**

- Report on decisions goals for 2nd Quarter of FY 2015.
  - CDRH: *Barbara Zimmerman, CDRH.*
  - CBER: *Sheryl Kochman, CBER.*

**Qualitative Update on Finances – 2<sup>nd</sup> Quarter of FY 2015**

- User fee receipts through the 2nd Quarter of FY 2015 – *Maurille Beheton and David Miller, FDA-OFM.*

**CDRH Registration and Listing**

- Report on registration and listing- *Dave Gartner, CDRH-OC.*

**Independent Assessment**

- Progress and update- *Raphaela (Madonna) Simon, FDA-OC.*
- RTA – *Michael Bailey, CDRH-ODE*
- eCopy – Top 3 eCopy issues

**CDRH Staff Training Update**

- *Jacqueline Woodard, CDRH-OCE.*

**Set date for next meeting, following close of Q3 FY 2015 -Target Date: July 30, 2015 from**  
10:00 am - Noon

## Medical Device Guidance Documents

(Issued in FY 2015)

(January 1, 2015 through March 31, 2015) (Quarter 2)

26. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling—Guidance for Industry and Food and Drug Administration Staff (3/17/15)  
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm253010.pdf>
25. Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices – Draft Guidance for Industry and Food and Drug Administration Staff (2/25/15)  
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm435355.pdf>
24. Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors – Guidance for Industry and Food and Drug Administration Staff (2/18/15) <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm434502.pdf>
23. Safety Considerations To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications – Guidance for Industry and Food and Drug Administration Staff (2/11/15) <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313385.pdf>
22. Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices – Draft Guidance for Industry and Food and Drug Administration Staff (2/11/15)  
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm433165.pdf>
21. Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices - Guidance for Industry and Food and Drug Administration Staff (2/9/15) <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm401996.pdf>
20. Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff (2/9/15)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>
19. Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails – Draft Guidance for Industry and Food and Drug Administration Staff (1/27/15) <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm431312.pdf>
18. General Wellness: Policy for Low Risk Devices – Draft Guidance for Industry and Food and Drug Administration Staff (1/20/15) <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429674.pdf>

17. Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types – Draft Guidance for Industry and Food and Drug Administration Staff (1/20/15)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf>
16. Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes – Draft Guidance for Industry and Food and Drug Administration Staff (1/20/15) <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm430550.pdf>

**(October 1, 2014 thru December 31, 2014) (Quarter 1)**

15. Radiation Biodosimetry Devices - Draft Guidance for Industry and Food and Drug Administration Staff (12/30/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM427866.pdf>
14. Transfer of a Premarket Notification (510(k)) Clearance: Questions and Answers - Draft Guidance for Industry and Food and Drug Administration Staff (12/22/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM427385.pdf>
13. Minimizing Risk for Children’s Toy Laser Products - Guidance for Industry and Food and Drug Administration Staff (12/19/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM363731.pdf>
12. Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff (12/11/14) (L2)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM107708.pdf>
11. Infusion Pumps Total Product Life Cycle - Guidance for Industry and Food and Drug Administration Staff (12/02/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209337.pdf>
10. Recommendations for Labeling Medical Products To Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex - Guidance for Industry and Food and Drug Administration Staff (12/02/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM342872.pdf>

9. Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators - Guidance for Industry and Food and Drug Administration Staff (11/25/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf>
8. Design Considerations for Devices Intended for Home Use – Guidance for Industry and Food and Drug Administration Staff (11/24/14) (L2)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM331681.pdf>
7. Combined Functionality for Molecular Diagnostic Instruments – Guidance for Industry and Food and Drug Administration Staff (11/12/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM346553.pdf>
6. Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex and Genetic Mutations Associated with Antibiotic Resistance in Respiratory Specimens – Guideline for Industry and Food and Drug Administration Staff (10/22/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM419468.pdf>
5. Distinguishing Medical Device Recalls From Medical Device Enhancements - Guidance for Industry and Food and Drug Administration Staff (10/15/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM418469.pdf>
4. Flow Cytometric Devices – Draft Guidance for Industry and Food and Drug Administration Staff (10/14/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM418205.pdf>
3. Food and Drug Administration Notification and Medical Device Reporting for Laboratory Developed Tests – Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories (10/03/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416684.pdf>
2. Framework for Regulatory Oversight of Laboratory Developed Tests - Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories (10/03/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416685.pdf>
1. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff (10/02/14)  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf>

**Quarterly Update on  
Medical Device Performance Goals  
----MDUFA III CDRH Performance Data ----  
Action through 31 March 2015**

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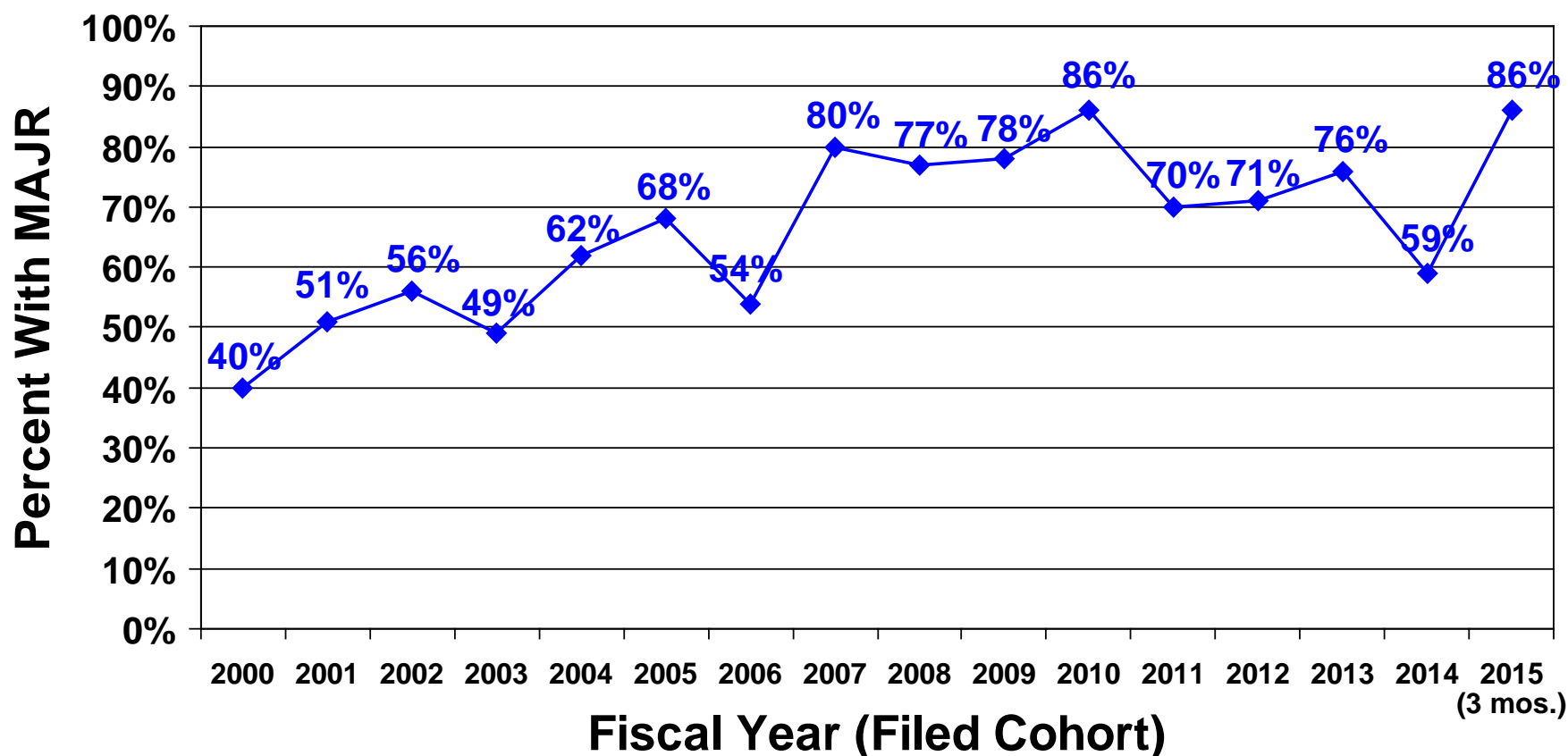
## Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Act
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology Devices
DIHD	Division of Immunology and Hematology Devices
DMD	Division of Microbiology Devices
DMGP	Division of Molecular Genetics and Pathology
DNPM	Division of Neurological and Physical Medicine Devices
DOD	Division of Orthopedic Devices
DOED	Division of Ophthalmic and Ear, Nose and Throat Devices
DRGUD	Division of Reproductive, Gastro-Renal, and Urological Devices
DRH	Division of Radiological Health
DSD	Division of Surgical Devices
IDE	Investigational Device Exemption
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
ODE	Office of Device Evaluation
OIR	Office of In Vitro Diagnostics and Radiological Health
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

**Note: Data may change in subsequent quarterly and annual reports.**

# PMA's

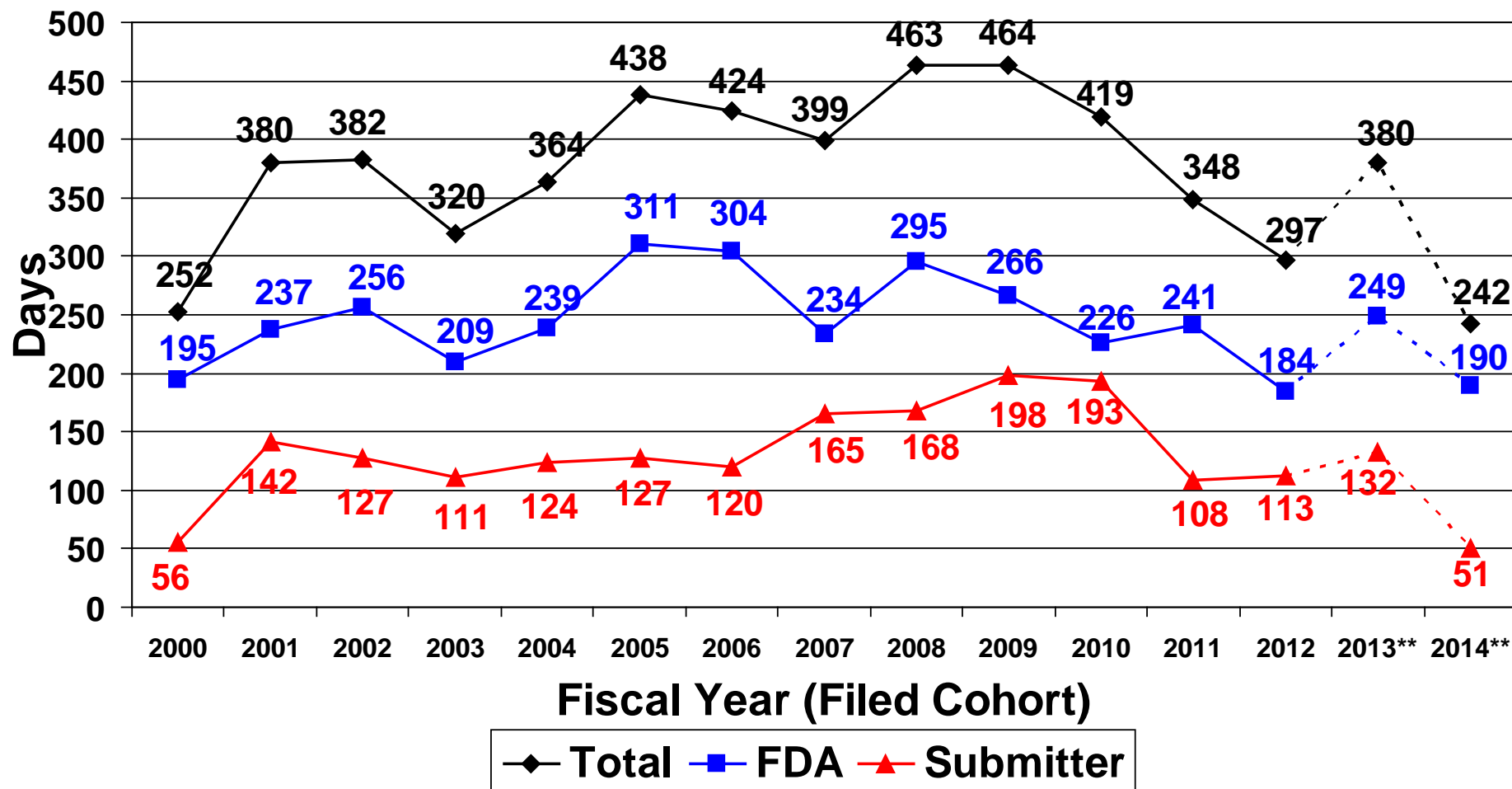
# Percent of PMAs With Major Deficiency Letter (MAJR) on 1<sup>st</sup> FDA Review Cycle\*



\*Includes original PMAs only; FY 2013 - FY 2015 are receipt cohorts including PMAs filed as of 12/31/2014, prior cohorts are filed cohorts; FY 2015 is based on 6 PMAs only and excludes 2 PMAs for which the 1<sup>st</sup> cycle was incomplete as of 03/31/2015, data for FY 2015 will change

# Average Time to MDUFA Decision: PMAs\*

(As of March 31, 2015)

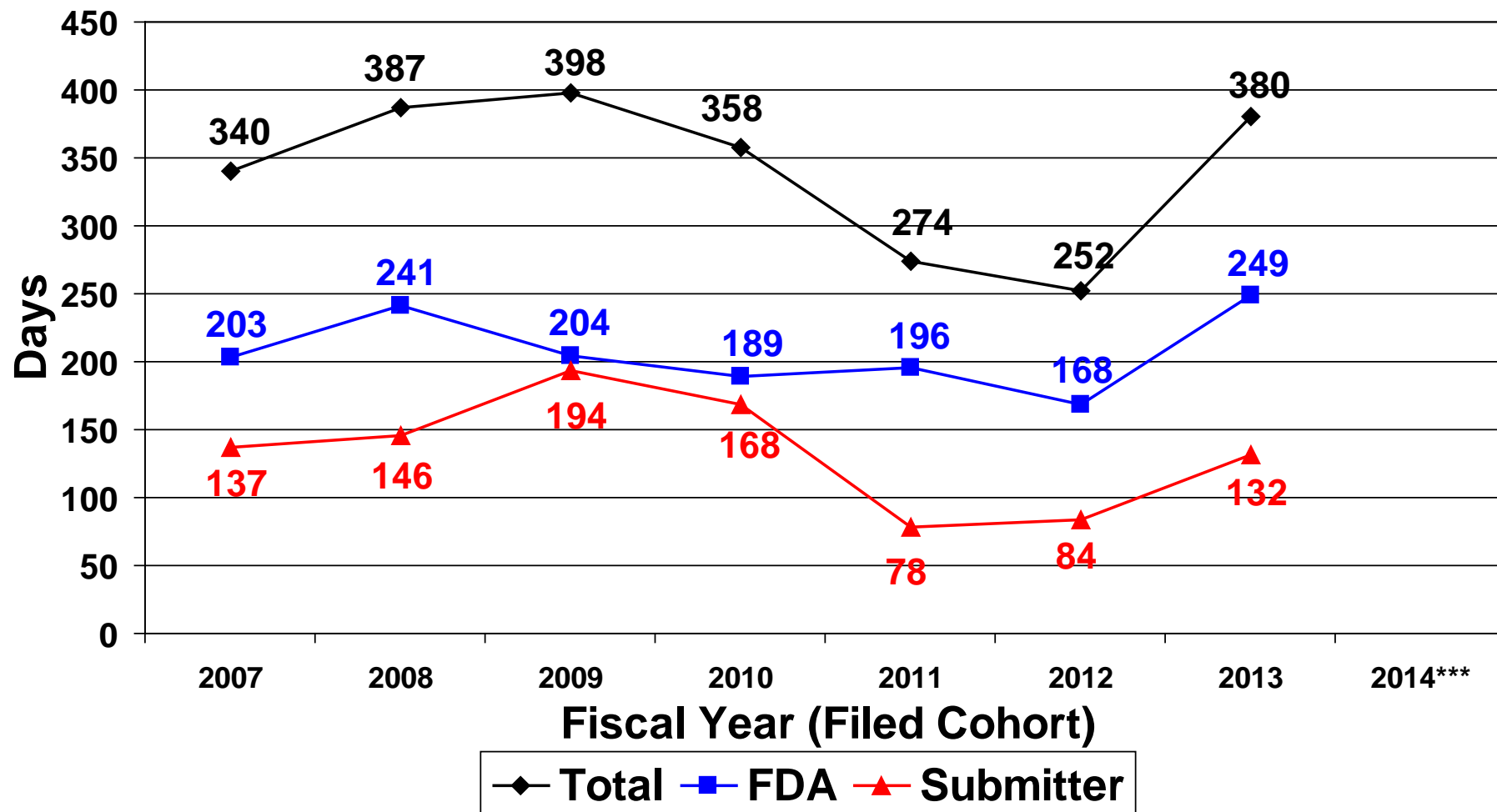


\*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 03/31/2015, prior cohorts are filed cohorts; times may not add to total due to rounding

\*\* Cohort still open, average times will increase; percent of cohort with MDUFA decision:  
FY13 = 83% (24/29); FY14 = 64% (18/28)

# Average Time to MDUFA Decision: PMAs\*

- Comparison of Filed Cohorts When Approx. 83% Closed\*\* -



\*Includes original PMAs only; times may not add to total due to rounding

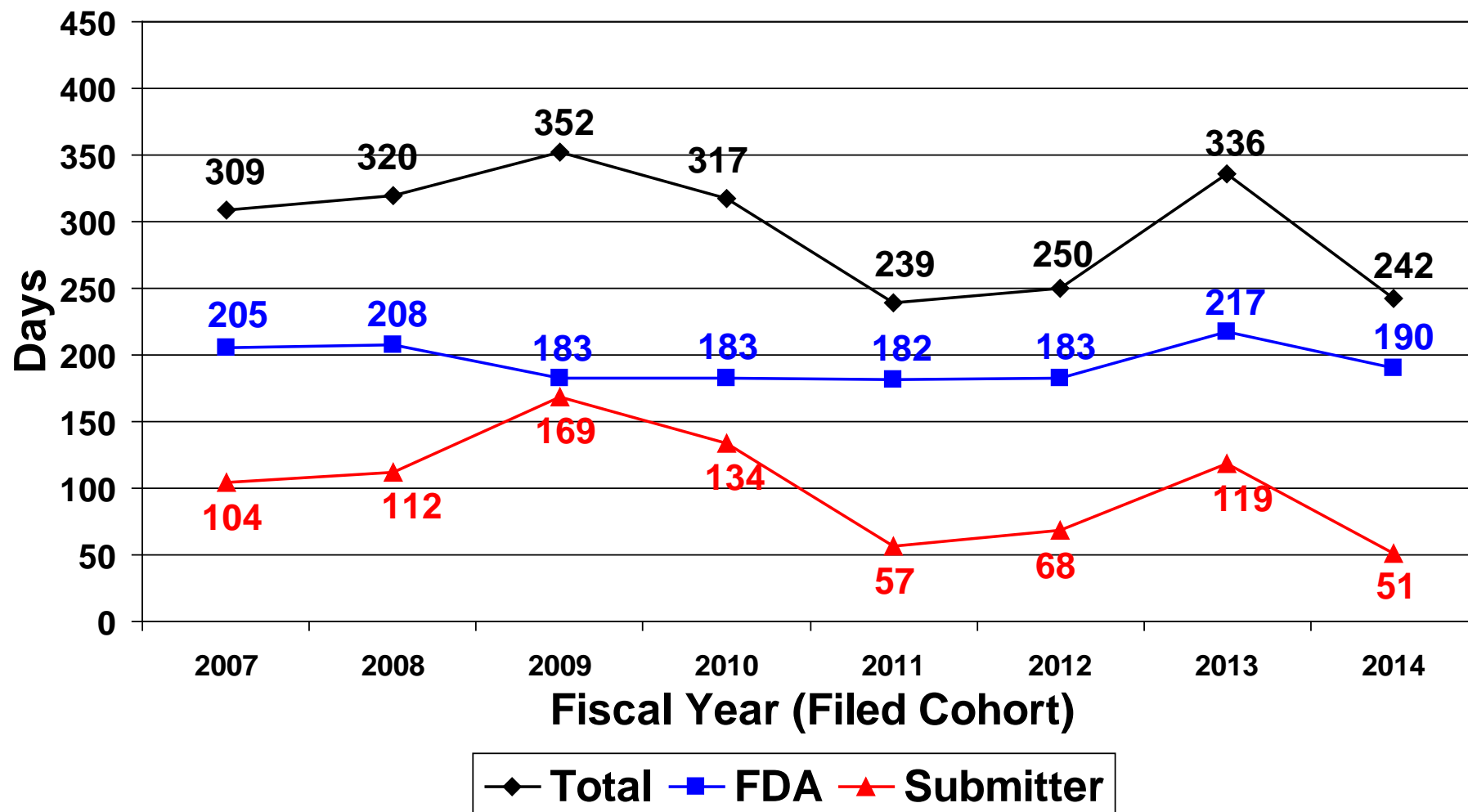
\*\*Proportion of cohort closed (MDUFA decision) in this comparison:

FY07 = 29/35; FY08 = 25/30; FY09 = 27/32; FY10 = 36/43; FY11 = 36/43; FY12 = 20/24; FY13 = 24/29

\*\*\*FY14 cohort is not yet 83% closed (as of 03/31/2015)

# Average Time to MDUFA Decision: PMAs\*

- Comparison of Filed Cohorts When Approx. 64% Closed\*\* -



\*Includes original PMAs only; times may not add to total due to rounding

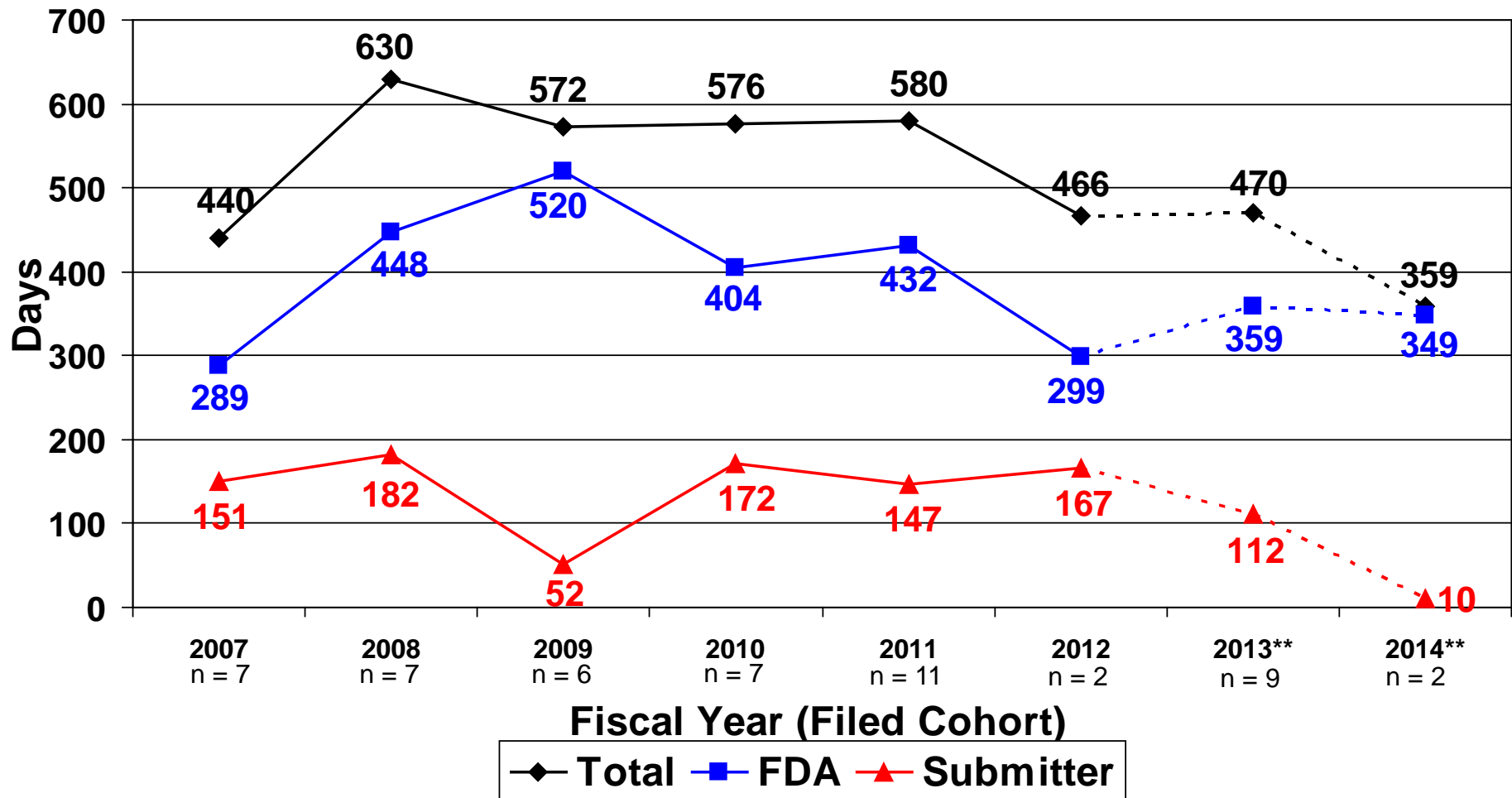
\*\*Proportion of cohort closed (MDUFA decision) in this comparison:

FY07 = 23/35; FY08 = 20/30; FY09 = 21/32; FY10 = 28/43; FY11 = 28/43; FY12 = 16/24;

FY13 = 19/29; FY14 = 18/28

# Average Time to MDUFA Decision: PMAs With Panel Review\*

(As of March 31, 2015)

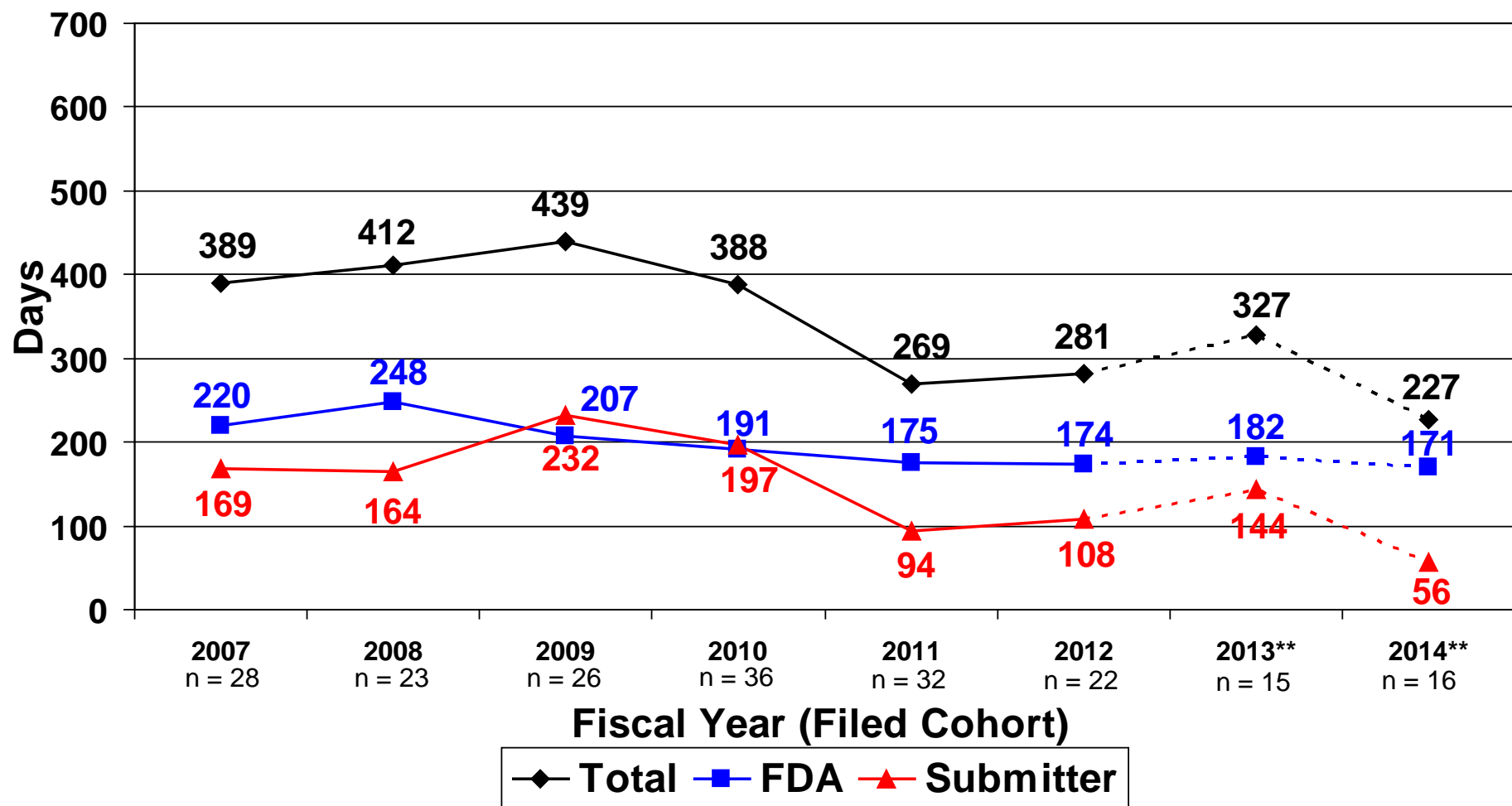


\*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 03/31/2015, prior cohorts are filed cohorts; times may not add to total due to rounding

\*\* Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY13 = 90% (9/10); FY14 = 67% (2/3)

# Average Time to MDUFA Decision: PMAs Without Panel Review\*

(As of March 31, 2015)

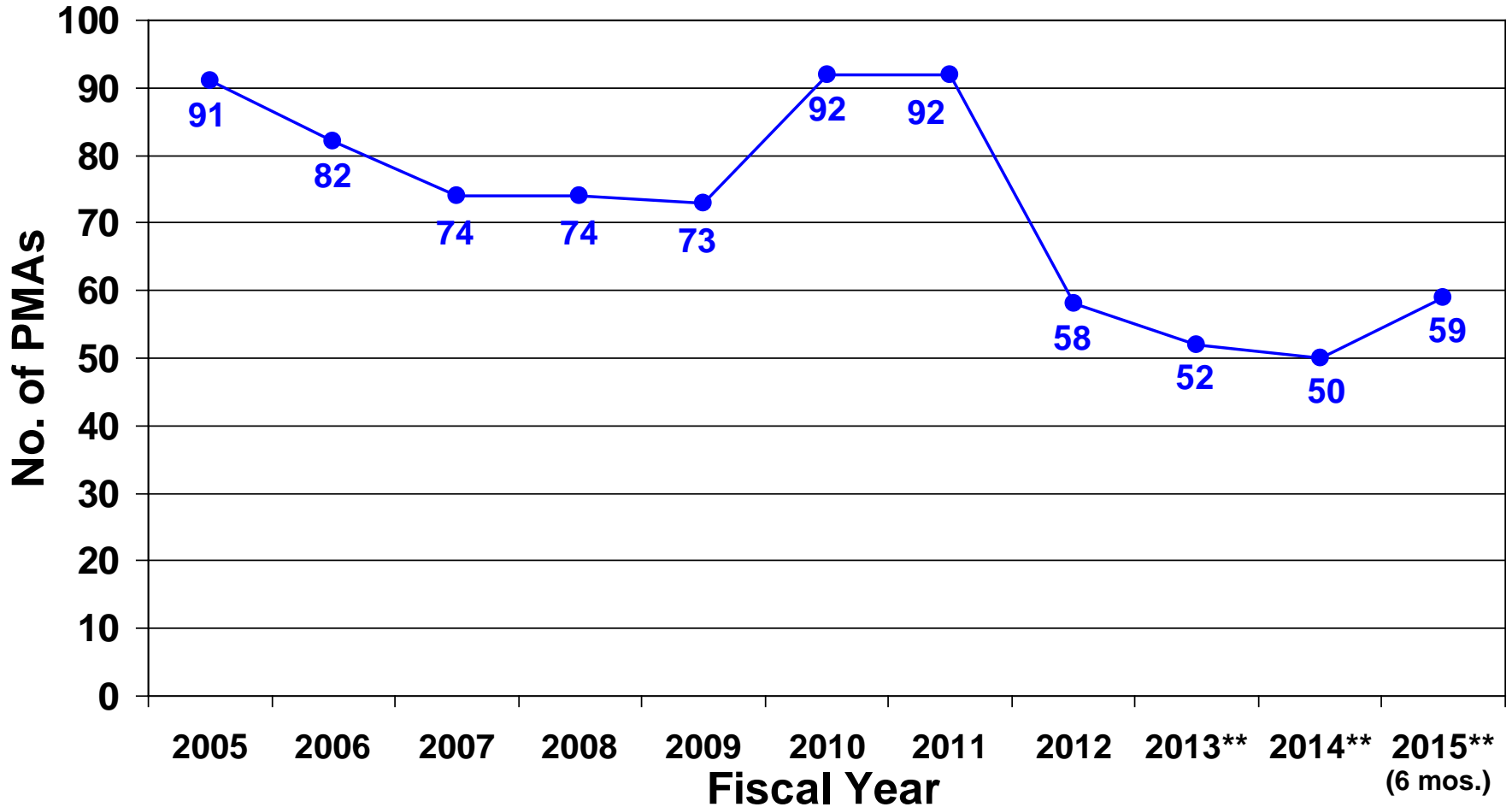


\*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 03/31/2015, prior cohorts are filed cohorts; times may not add to total due to rounding

\*\*Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY13 = 79% (15/19); FY14 = 64% (16/25)



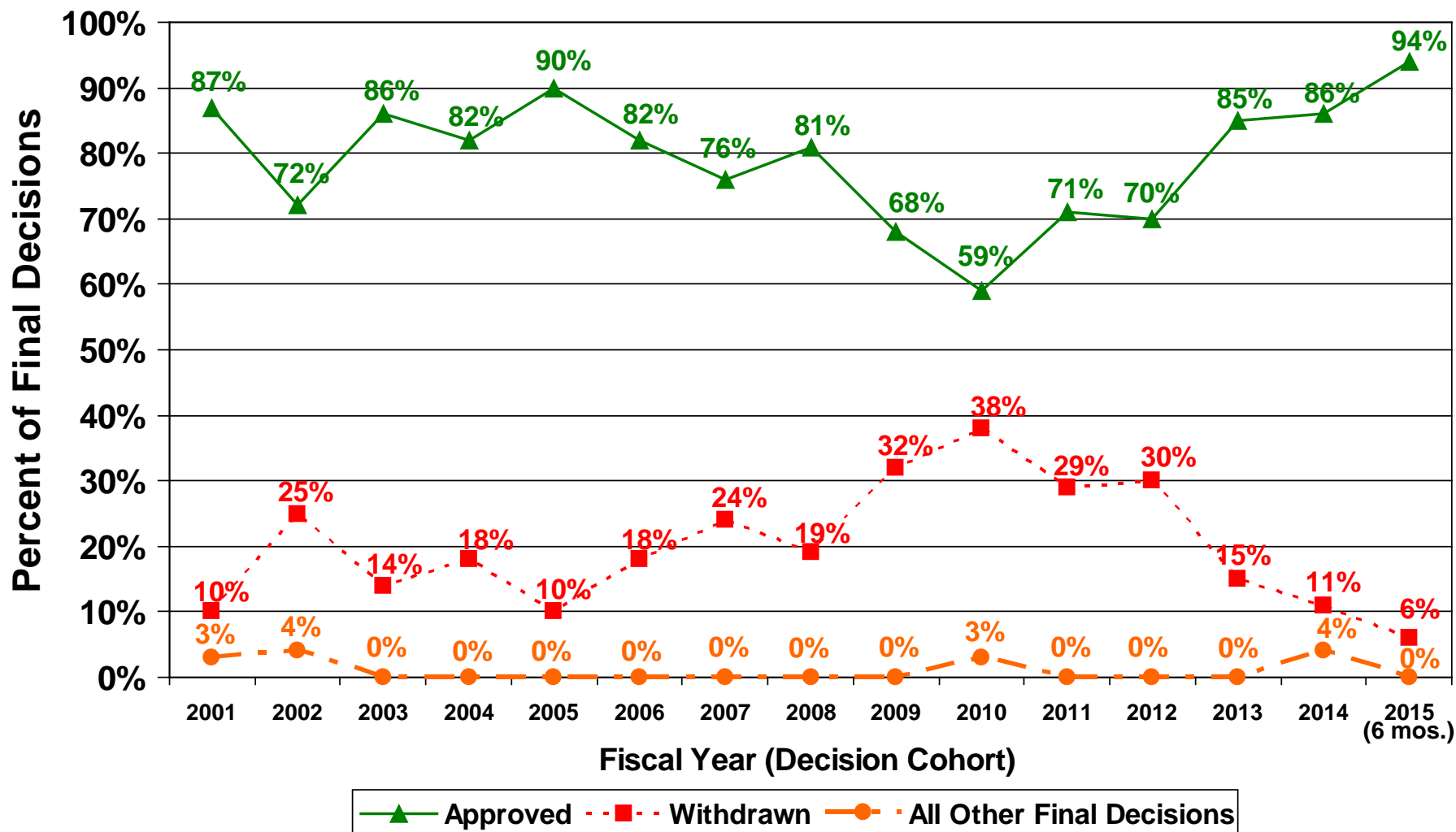
# PMAs Pending\* at End of Year



\*Original PMAs under review or on hold; FY 2015 is as of 03/31/2015

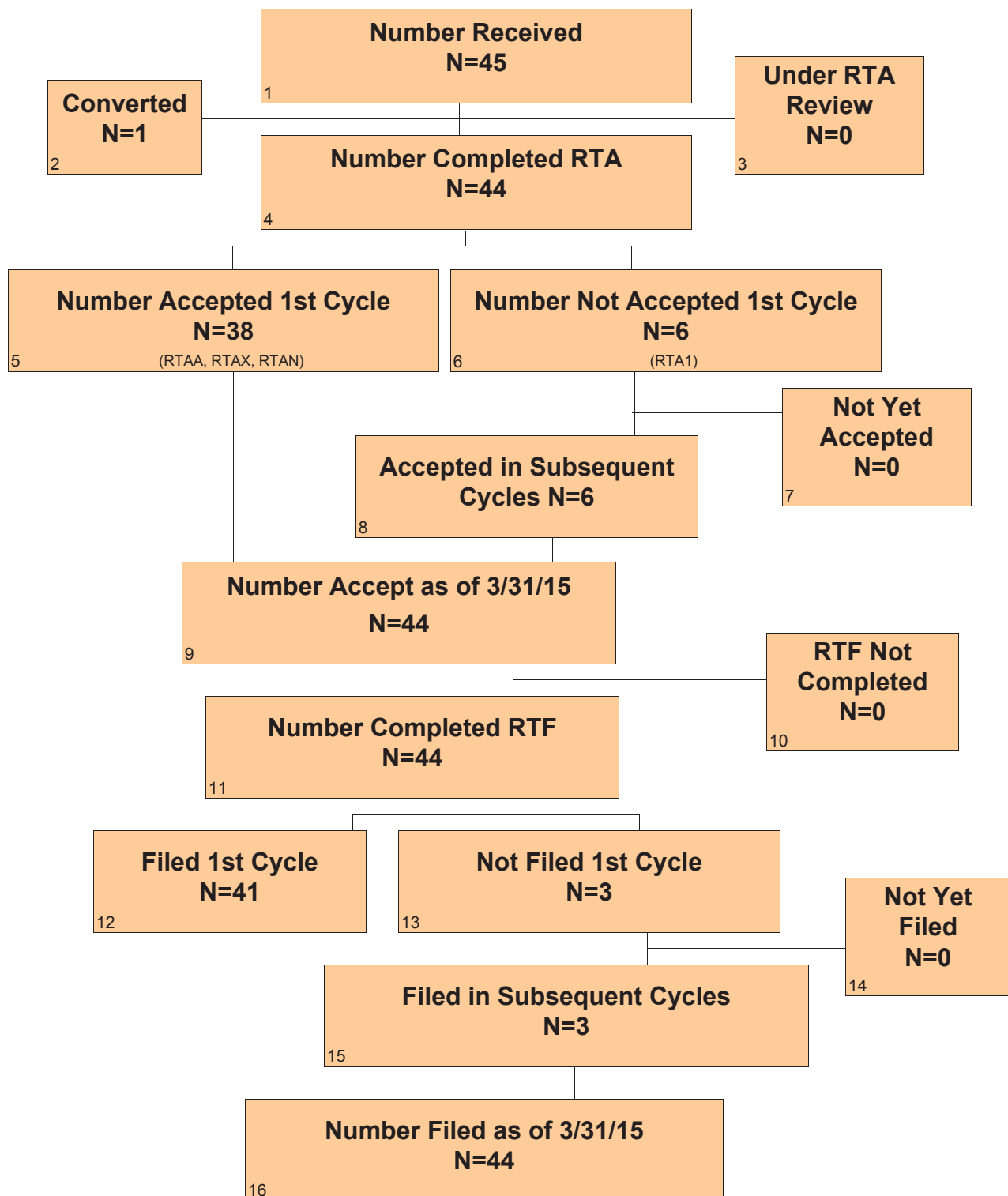
\*\*Excludes FY 2013 - FY 2015 receipts that were not accepted for review at year's end; FY 2015 increase reflects increase in filed PMAs (44 PMA annual rate compared to 24, 29, and 28 for FY 2012 – FY 2014, respectively)

# Percent of PMAs Approved\*

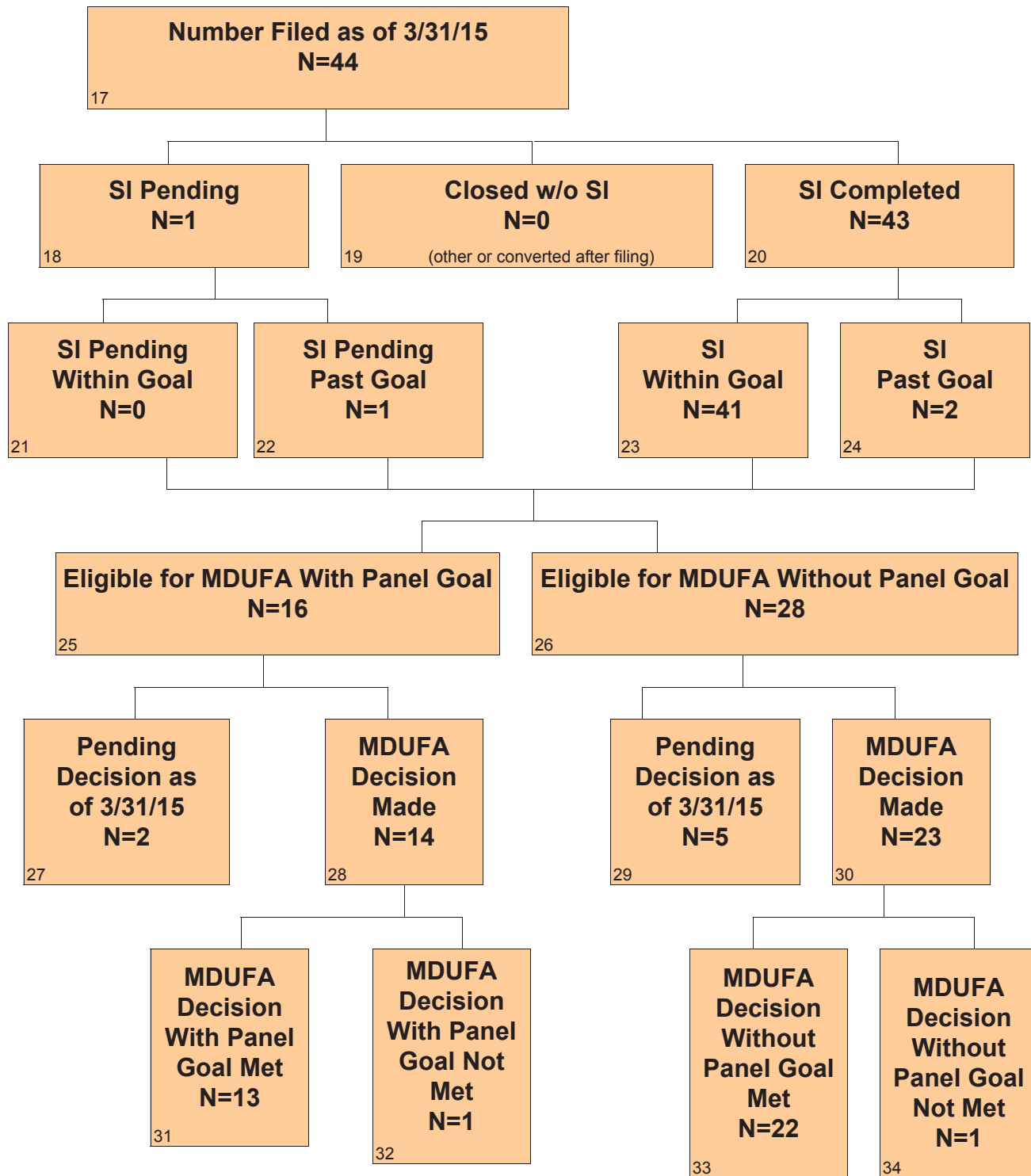


\*Based on original PMAs that were accepted for filing as of 03/31/2015; percentages may not add to 100% due to rounding

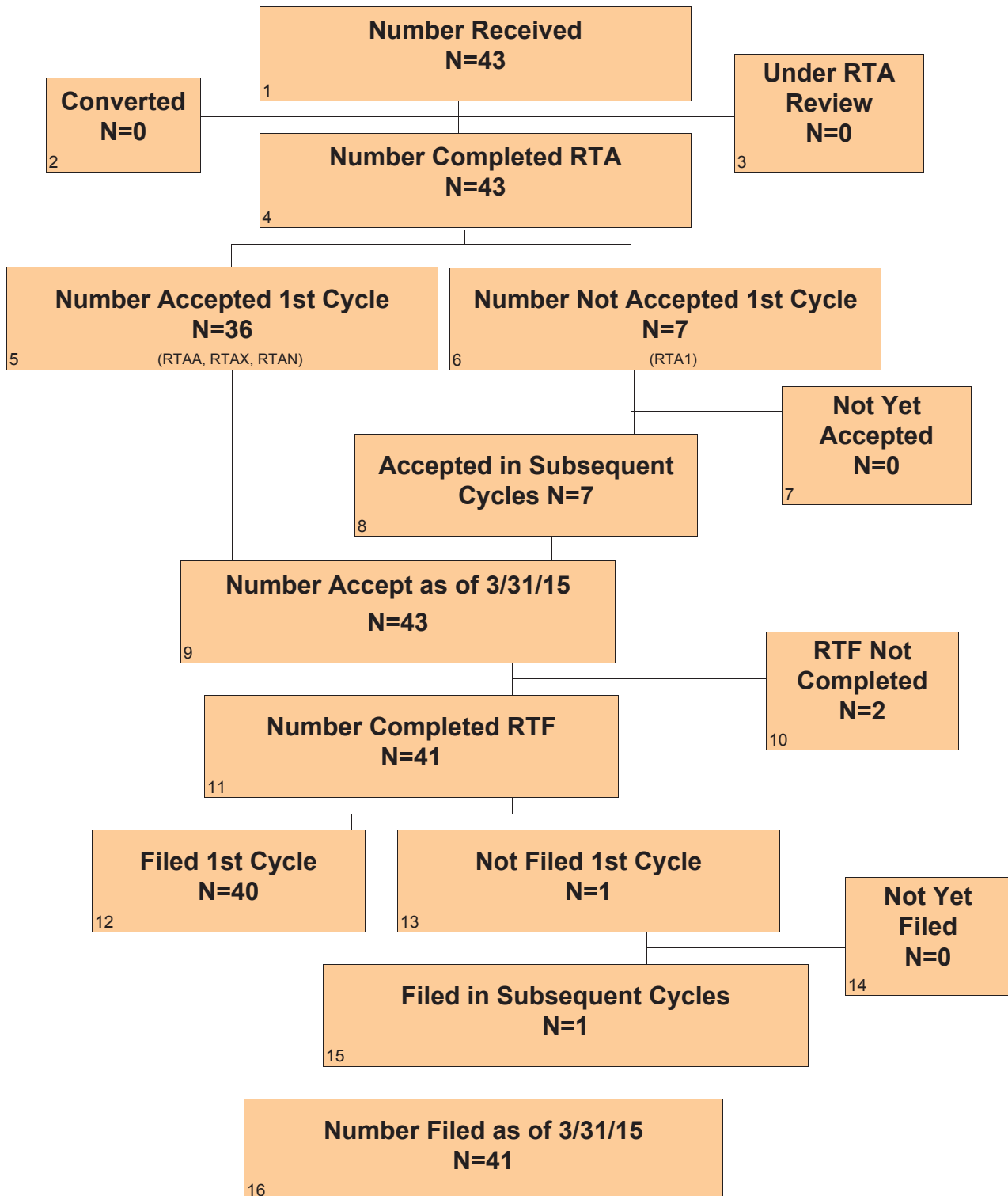
# CDRH PMA Original and Panel Track Supplements - FY 2013 As of 3/31/15



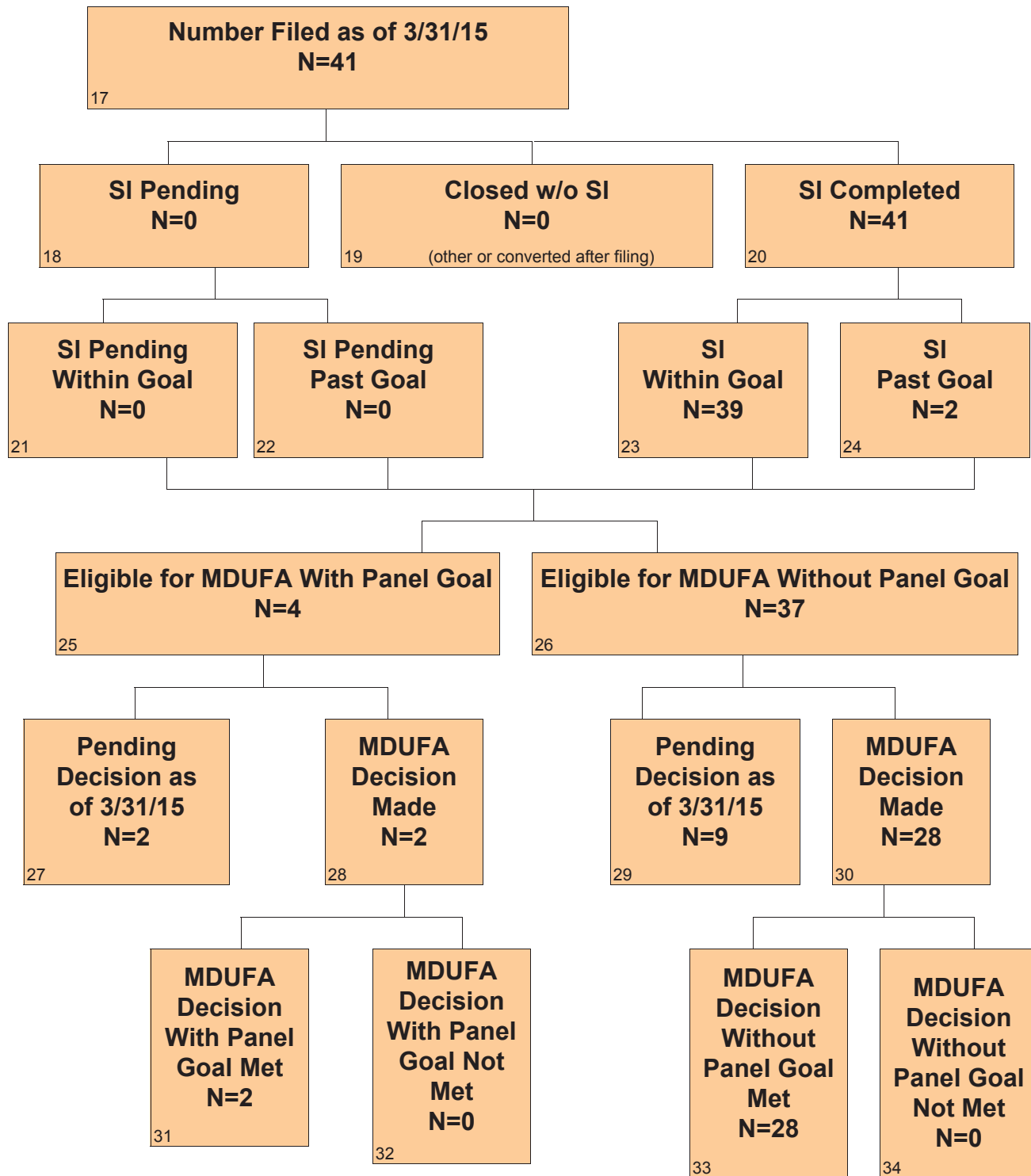
# CDRH PMA Original and Panel Track Supplements - FY 2013 As of 3/31/15 Continued



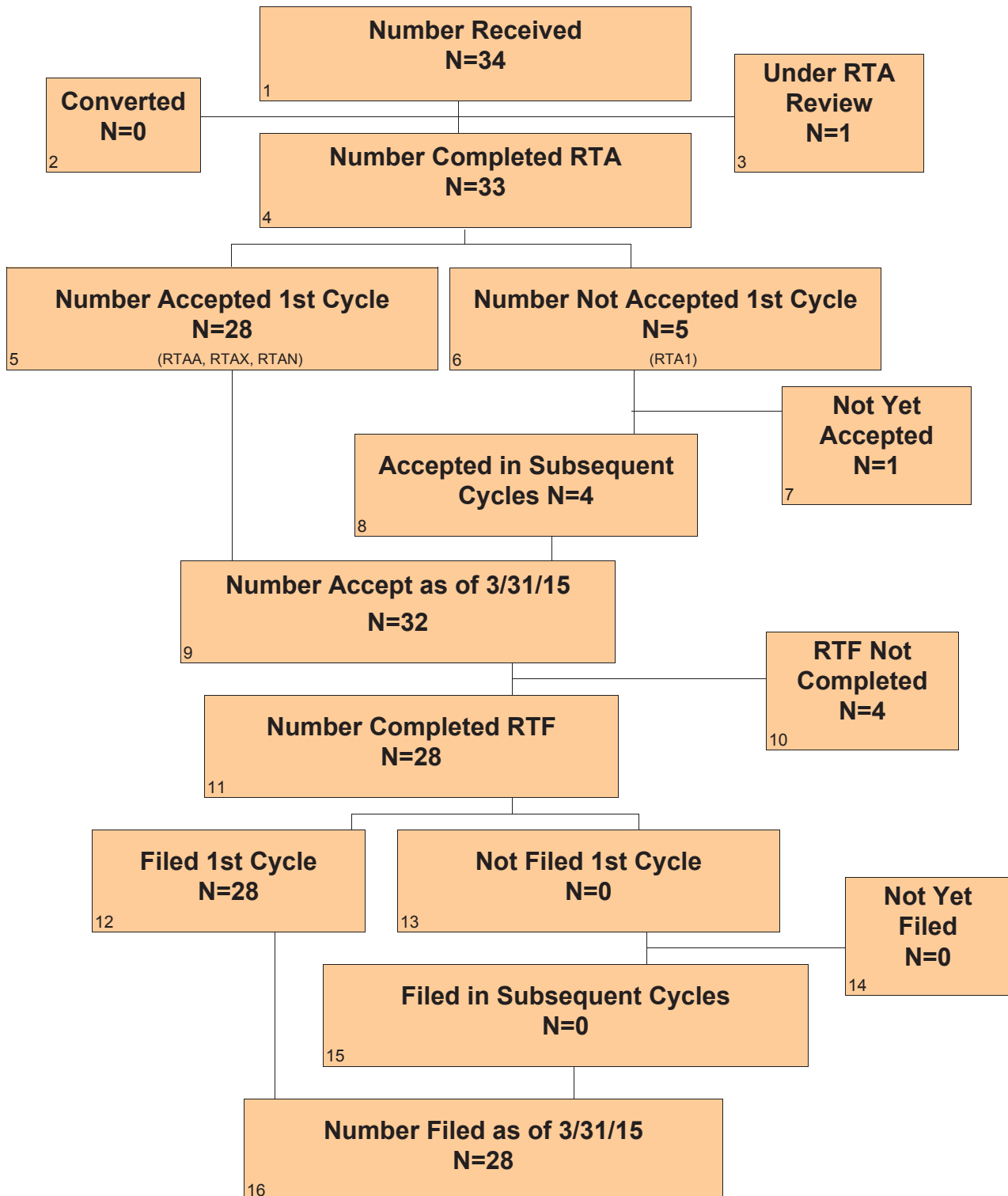
# CDRH PMA Original and Panel Track Supplements - FY 2014 As of 3/31/15



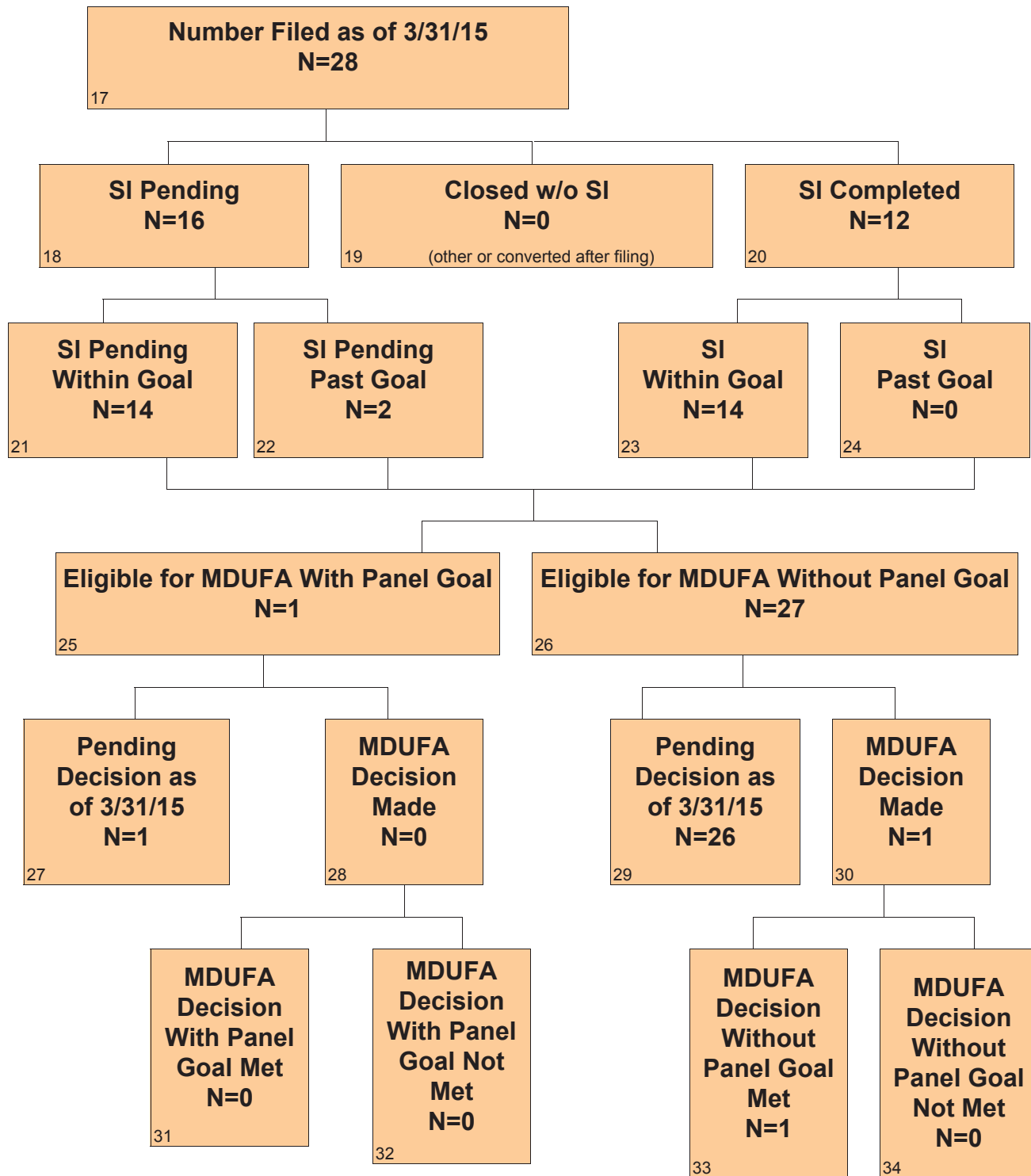
# CDRH PMA Original and Panel Track Supplements - FY 2014 As of 3/31/15 Continued



# CDRH PMA Original and Panel Track Supplements - FY 2015 As of 3/31/15



# CDRH PMA Original and Panel Track Supplements - FY 2015 As of 3/31/15 Continued





## Section 1 PMA Original and Panel Track Supplements - Center Level

**Table 1.1. CDRH – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	35	43	34		
Closed before RTA action	1	0	0		
Number with accepted RTA review	27	35	26		
Number without a RTA Review and > 15 Days since Date Received	1	1	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	1		
Number Not Accepted for Filing Review	6	7	5		
Rate of submissions not accepted for filing review	17.6%	16.3%	15.2%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2 CDRH – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	45	43	34		
Number Accepted	38	36	28		
Completed RTF	44	41	28		
Number Not Filed	3	1	0		
Rate of submissions Not Filed	6.8%	2.4%	0%		

**Table 1.3 CDRH – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	44	41	28		
SI Goal Met	41	39	12		
SI Goal Not Met	2	2	0		
SI Pending Within Goal	0	0	16		
SI Pending Past Goal	1	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	93.2%	95.1%	100%		

**Table 1.4 CDRH – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	43	41	12		
Average number of FDA days to Substantive Interaction	88.3	90.0	84		
20th Percentile FDA days to Substantive Interaction	86	87	83		
40th Percentile FDA days to Substantive Interaction	88	88	86		
60th Percentile FDA days to Substantive Interaction	90	89	87		
80th Percentile FDA days to Substantive Interaction	90	90	88		
Maximum FDA days to Substantive Interaction	117	136	90		

**Table 1.5 CDRH – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of PMAs filed	28	37	27		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	23	28	1		
MDUFA III Decisions Goal Met	22	28	1		
PMAs pending MDUFA III Decision	5	9	26		
PMAs pending MDUFA III Decision Past Goal	1	0	0		
Current Performance Percent Goal Met	91.7%	100%	100%		

**Table 1.6 CDRH – PMA Originals & Panel-Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of PMAs filed	16	4	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	14	2	0		
MDUFA III Decisions Goal Met	13	2	0		
PMAs pending MDUFA III Decision	2	2	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	92.9%	100%	0%		

**Table 1.7 CDRH – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	23	28	1		
<b>Average FDA days to MDUFA III decision</b>	176.8	170.9	104		
20th Percentile FDA days to MDUFA III decision	174	174	104		
40th Percentile FDA days to MDUFA III decision	177	178	104		
60th Percentile FDA days to MDUFA III decision	180	179	104		
80th Percentile FDA days to MDUFA III decision	180	180	104		
Maximum FDA days to MDUFA III decision	291	190	104		
<b>Average Industry days to MDUFA III decision</b>	121.4	41.8	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	78	0	0		
60th Percentile Industry days to MDUFA III decision	108	31	0		
80th Percentile Industry days to MDUFA III decision	208	84	0		
Maximum Industry days to MDUFA III decision	400	168	0		
<b>Average Total days to MDUFA III decision</b>	298.3	212.7	104		
20th Percentile Total days to MDUFA III decision	180	179	104		
40th Percentile Total days to MDUFA III decision	242	180	104		
60th Percentile Total days to MDUFA III decision	284	211	104		
80th Percentile Total days to MDUFA III decision	401	261	104		
Maximum Total days to MDUFA III decision	579	358	104		

**Table 1.8 CDRH – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	14	2	0		
<b>Average FDA days to MDUFA III decision</b>	327.3	348.5	0		
20th Percentile FDA days to MDUFA III decision	262	330	0		
40th Percentile FDA days to MDUFA III decision	313	342	0		
60th Percentile FDA days to MDUFA III decision	316	355	0		
80th Percentile FDA days to MDUFA III decision	322	367	0		
Maximum FDA days to MDUFA III decision	668	379	0		
<b>Average Industry days to MDUFA III decision</b>	85	10.0	0.00		
20th Percentile Industry days to MDUFA III decision	0	4	0		
40th Percentile Industry days to MDUFA III decision	6	8	0		
60th Percentile Industry days to MDUFA III decision	98	12	0		
80th Percentile Industry days to MDUFA III decision	181	16	0		
Maximum Industry days to MDUFA III decision	295	20	0		
<b>Average Total days to MDUFA III decision</b>	412.3	358.5	0.00		
20th Percentile Total days to MDUFA III decision	308	334	0		
40th Percentile Total days to MDUFA III decision	328	350	0		
60th Percentile Total days to MDUFA III decision	425	367	0		
80th Percentile Total days to MDUFA III decision	530	383	0		
Maximum Total days to MDUFA III decision	668	399	0		

**Table 1.9 CDRH – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	28	37	27		
Number with MDUFA decision	23	28	1		
Number of Withdrawals	1	0	0		
Number of Not Approvable	4	1	0		
Rate of Withdrawals	4.3%	0%	N/A		
Rate of Not Approvable	17.4%	4%	N/A		

**Table 1.10 CDRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	16	4	1		
Number with MDUFA decision	14	2	0		
Number of Withdrawals	1	0	0		
Number of Not Approvable	3	0	0		
Rate of Withdrawals	7.1%	0%	0%		
Rate of Not Approvable	21.4%	0%	0%		

**Table 1.11 CDRH – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0		
Mean FDA days for submissions that missed goal	538	0	0		
Mean industry days for submissions that missed goal	57	0	0		

**Table 1.12 CDRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0		
Mean FDA days for submissions that missed goal	668	0	0		
Mean industry days for submissions that missed goal	0	0	0		

## Section 1 PMA Original and Panel Track Supplements - Office Level Metrics

**Table 1.1.ODE - CDRH – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	28	37	28		
Closed before RTA action	1	0	0		
Number with accepted RTA review	20	30	20		
Number without a RTA Review and > 15 Days since Date Received	1	1	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	1		
Number Not Accepted for Filing Review	6	6	5		
Rate of submissions not accepted for filing review	22.2%	16.2%	18.5%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.ODE - CDRH – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	35	37	28		
Number Accepted	28	31	22		
Completed RTF	34	35	22		
Number Not Filed	3	1	0		
Rate of submissions Not Filed	8.8%	2.9%	N/A		

**Table 1.3.ODE - CDRH – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	34	35	22		
SI Goal Met	31	33	7		
SI Goal Not Met	2	2	0		
SI Pending Within Goal	0	0	15		
SI Pending Past Goal	1	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	91.2%	94.3%	100%		

**Table 1.4 ODE - CDRH – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	33	35	7		
Average number of FDA days to Substantive Interaction	88.2	90.7	85		
20th Percentile FDA days to Substantive Interaction	86	87	83		
40th Percentile FDA days to Substantive Interaction	88	88	85		
60th Percentile FDA days to Substantive Interaction	89	89	86		
80th Percentile FDA days to Substantive Interaction	90	90	87		
Maximum FDA days to Substantive Interaction	117	136	88		



**Table 1.5 ODE - CDRH – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	22	31	21		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	17	24	1		
MDUFA III Decisions Goal Met	16	24	1		
PMAs pending MDUFA III Decision	5	7	20		
PMAs pending MDUFA III Decision Past Goal	1	0	0		
Current Performance Percent Goal Met	88.9%	100%	100%		

**Table 1.6 ODE - CDRH – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	12	4	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	10	2	0		
MDUFA III Decisions Goal Met	9	2	0		
PMAs pending MDUFA III Decision	2	2	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	90.0%	100%	N/A		

**Table 1.7 ODE - CDRH – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	17	24	1		
<b>Average FDA days to MDUFA III decision</b>	185.6	173.5	104		
20th Percentile FDA days to MDUFA III decision	176	175	104		
40th Percentile FDA days to MDUFA III decision	180	178	104		
60th Percentile FDA days to MDUFA III decision	180	179	104		
80th Percentile FDA days to MDUFA III decision	180	180	104		
Maximum FDA days to MDUFA III decision	291	190	104		
<b>Average Industry days to MDUFA III decision</b>	110.8	44.4	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	48	0	0		
60th Percentile Industry days to MDUFA III decision	101	41	0		
80th Percentile Industry days to MDUFA III decision	212	83	0		
Maximum Industry days to MDUFA III decision	360	168	0		
<b>Average Total days to MDUFA III decision</b>	296.4	217.9	104		
20th Percentile Total days to MDUFA III decision	179	179	104		
40th Percentile Total days to MDUFA III decision	228	180	104		
60th Percentile Total days to MDUFA III decision	283	218	104		
80th Percentile Total days to MDUFA III decision	403	260	104		
Maximum Total days to MDUFA III decision	540	358	104		

**Table 1.8 ODE - CDRH – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	10	2	0		
<b>Average FDA days to MDUFA III decision</b>	343.9	348.5	0.00		
20th Percentile FDA days to MDUFA III decision	276	330	0		
40th Percentile FDA days to MDUFA III decision	314	342	0		
60th Percentile FDA days to MDUFA III decision	316	355	0		
80th Percentile FDA days to MDUFA III decision	356	367	0		
Maximum FDA days to MDUFA III decision	668	379	0		
<b>Average Industry days to MDUFA III decision</b>	89.6	10.0	0.00		
20th Percentile Industry days to MDUFA III decision	0	4	0		
40th Percentile Industry days to MDUFA III decision	17	8	0		
60th Percentile Industry days to MDUFA III decision	97	12	0		
80th Percentile Industry days to MDUFA III decision	180	16	0		
Maximum Industry days to MDUFA III decision	295	20	0		
<b>Average Total days to MDUFA III decision</b>	433.5	358.5	0.00		
20th Percentile Total days to MDUFA III decision	316	334	0		
40th Percentile Total days to MDUFA III decision	338	350	0		
60th Percentile Total days to MDUFA III decision	439	367	0		
80th Percentile Total days to MDUFA III decision	577	383	0		
Maximum Total days to MDUFA III decision	668	399	0		

**Table 1.9 ODE - CDRH – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	22	31	22		
Number with MDUFA decision	17	24	1		
Number of Withdrawals	1	0	0		
Number of Not Approvable	3	1	0		
Rate of Withdrawals	5.9%	0%	N/A		
Rate of Not Approvable	17.6%	4%	N/A		

**Table 1.10 ODE - CDRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	12	4	1		
Number with MDUFA decision	10	2	0		
Number of Withdrawals	1	0	0		
Number of Not Approvable	2	0	0		
Rate of Withdrawals	10.0%	0%	N/A		
Rate of Not Approvable	20.0%	0%	N/A		

**Table 1.11 ODE - CDRH – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0		
Mean FDA days for submissions that missed goal	538	0	0		
Mean industry days for submissions that missed goal	57	0	0		

**Table 1.12 ODE - CDRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0		
Mean FDA days for submissions that missed goal	668	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.OIR - CDRH – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	6	6		
Closed before RTA action	0	0	0		
Number with accepted RTA review	7	5	6		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	1	0		
Rate of submissions not accepted for filing review	0%	16.7%	0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.OIR - CDRH – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	6	6		
Number Accepted	10	5	6		
Completed RTF	10	6	6		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

**Table 1.3.OIR - CDRH – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	10	6	6		
SI Goal Met	10	6	5		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 1.4 OIR - CDRH – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	10	6	5		
Average number of FDA days to Substantive Interaction	88.8	86.3	82		
20th Percentile FDA days to Substantive Interaction	86	85	80		
40th Percentile FDA days to Substantive Interaction	90	86	87		
60th Percentile FDA days to Substantive Interaction	90	87	88		
80th Percentile FDA days to Substantive Interaction	90	88	90		
Maximum FDA days to Substantive Interaction	112	89	90		

**Table 1.5 OIR - CDRH – PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	6	6	6		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	6	4	0		
MDUFA III Decisions Goal Met	6	4	0		
PMAs pending MDUFA III Decision	0	2	6		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	0%		

**Table 1.6 OIR - CDRH – PMA Originals & Panel-Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	4	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	4	0	0		
MDUFA III Decisions Goal Met	4	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	N/A		

**Table 1.7 OIR - CDRH – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	6	4	0		
<b>Average FDA days to MDUFA III decision</b>	152.0	155.3	0		
20th Percentile FDA days to MDUFA III decision	116	141	0		
40th Percentile FDA days to MDUFA III decision	167	177	0		
60th Percentile FDA days to MDUFA III decision	174	179	0		
80th Percentile FDA days to MDUFA III decision	177	179	0		
Maximum FDA days to MDUFA III decision	179	179	0		
<b>Average Industry days to MDUFA III decision</b>	151.7	26.5	0		
20th Percentile Industry days to MDUFA III decision	81	0	0		
40th Percentile Industry days to MDUFA III decision	107	0	0		
60th Percentile Industry days to MDUFA III decision	118	0	0		
80th Percentile Industry days to MDUFA III decision	133	42	0		
Maximum Industry days to MDUFA III decision	400	106	0		
<b>Average Total days to MDUFA III decision</b>	303.7	181.8	0		
20th Percentile Total days to MDUFA III decision	217	142	0		
40th Percentile Total days to MDUFA III decision	248	179	0		
60th Percentile Total days to MDUFA III decision	284	179	0		
80th Percentile Total days to MDUFA III decision	307	221	0		
Maximum Total days to MDUFA III decision	579	283	0		



**Table 1.8 OIR - CDRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	4	0	0		
<b>Average FDA days to MDUFA III decision</b>	285.8	0	0		
20th Percentile FDA days to MDUFA III decision	261	0	0		
40th Percentile FDA days to MDUFA III decision	301	0	0		
60th Percentile FDA days to MDUFA III decision	311	0	0		
80th Percentile FDA days to MDUFA III decision	319	0	0		
Maximum FDA days to MDUFA III decision	325	0	0		
<b>Average Industry days to MDUFA III decision</b>	359	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	21	0	0		
60th Percentile Industry days to MDUFA III decision	84	0	0		
80th Percentile Industry days to MDUFA III decision	139	0	0		
Maximum Industry days to MDUFA III decision	189	0	0		
<b>Average Total days to MDUFA III decision</b>	359.3	0	0		
20th Percentile Total days to MDUFA III decision	261	0	0		
40th Percentile Total days to MDUFA III decision	324	0	0		
60th Percentile Total days to MDUFA III decision	403	0	0		
80th Percentile Total days to MDUFA III decision	460	0	0		
Maximum Total days to MDUFA III decision	504	0	0		

**Table 1.9 OIR - CDRH – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	6	6	6		
Number with MDUFA decision	6	4	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	1	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	16.67%	0%	N/A		

**Table 1.10 OIR - CDRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4	0	0		
Number with MDUFA decision	4	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	1	0	0		
Rate of Withdrawals	0%	N/A	N/A		
Rate of Not Approvable	25.0%	N/A	N/A		

**Table 1.11 OIR - CDRH – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12 OIR - CDRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

## Section 1 PMA Original and Panel Track Supplements - Division Level Metrics

**Table 1.1.DAGRID - ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	1	1		
Closed before RTA action	0	0	0		
Number with accepted RTA review	0	1	1		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	1	0	0		
Rate of submissions not accepted for filing review	100%	0%	0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DAGRID - ODE – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1	1		
Number Accepted	1	1	1		
Completed RTF	2	1	1		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

**Table 1.3.DAGRID - ODE – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	2	1	1		
SI Goal Met	2	1	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	N/A		

**Table 1.4.DAGRID - ODE – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	1	0		
Average number of FDA days to Substantive Interaction	85.0	87.0	0		
20th Percentile FDA days to Substantive Interaction	84	87	0		
40th Percentile FDA days to Substantive Interaction	85	87	0		
60th Percentile FDA days to Substantive Interaction	85	87	0		
80th Percentile FDA days to Substantive Interaction	86	87	0		
Maximum FDA days to Substantive Interaction	87	87	0		

**Table 1.5.DAGRID - ODE – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	1	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	1	0		
MDUFA III Decisions Goal Met	1	1	0		
PMAs pending MDUFA III Decision	0	0	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	0%		

**Table 1.6.DAGRID - ODE – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	0	0		
MDUFA III Decisions Goal Met	1	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	N/A		

**Table 1.7.DAGRID - ODE – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	1	0		
<b>Average FDA days to MDUFA III decision</b>	180.0	179	0		
20th Percentile FDA days to MDUFA III decision	180	179	0		
40th Percentile FDA days to MDUFA III decision	180	179	0		
60th Percentile FDA days to MDUFA III decision	180	179	0		
80th Percentile FDA days to MDUFA III decision	180	179	0		
Maximum FDA days to MDUFA III decision	180	179	0		
<b>Average Industry days to MDUFA III decision</b>	360.0	0	0		
20th Percentile Industry days to MDUFA III decision	360	0	0		
40th Percentile Industry days to MDUFA III decision	360	0	0		
60th Percentile Industry days to MDUFA III decision	360	0	0		
80th Percentile Industry days to MDUFA III decision	360	0	0		
Maximum Industry days to MDUFA III decision	360	0	0		
<b>Average Total days to MDUFA III decision</b>	540.0	179	0		
20th Percentile Total days to MDUFA III decision	540	179	0		
40th Percentile Total days to MDUFA III decision	540	179	0		
60th Percentile Total days to MDUFA III decision	540	179	0		
80th Percentile Total days to MDUFA III decision	540	179	0		
Maximum Total days to MDUFA III decision	540	179	0		

**Table 1.8.DAGRID - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	0	0		
<b>Average FDA days to MDUFA III decision</b>	320.0	0	0		
20th Percentile FDA days to MDUFA III decision	320	0	0		
40th Percentile FDA days to MDUFA III decision	320	0	0		
60th Percentile FDA days to MDUFA III decision	320	0	0		
80th Percentile FDA days to MDUFA III decision	320	0	0		
Maximum FDA days to MDUFA III decision	320	0	0		
<b>Average Industry days to MDUFA III decision</b>	28.0	0	0		
20th Percentile Industry days to MDUFA III decision	28	0	0		
40th Percentile Industry days to MDUFA III decision	28	0	0		
60th Percentile Industry days to MDUFA III decision	28	0	0		
80th Percentile Industry days to MDUFA III decision	28	0	0		
Maximum Industry days to MDUFA III decision	28	0	0		
<b>Average Total days to MDUFA III decision</b>	348.0	0	0		
20th Percentile Total days to MDUFA III decision	348	0	0		
40th Percentile Total days to MDUFA III decision	348	0	0		
60th Percentile Total days to MDUFA III decision	348	0	0		
80th Percentile Total days to MDUFA III decision	348	0	0		
Maximum Total days to MDUFA III decision	348	0	0		

**Table 1.9.DAGRID - ODE – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1	1		
Number with MDUFA decision	1	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	0%	0%	N/A		

**Table 1.10.DAGRID - ODE – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0	0		
Number with MDUFA decision	1	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	N/A	N/A		
Rate of Not Approvable	0%	N/A	N/A		

**Table 1.11.DAGRID - ODE – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DAGRID - ODE – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		



**Table 1.1.DCD - ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	17	17	15		
Closed before RTA action	1	0	0		
Number with accepted RTA review	15	15	12		
Number without a RTA Review and > 15 Days since Date Received	1	1	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	1		
Number Not Accepted for Filing Review	0	1	2		
Rate of submissions not accepted for filing review	0%	5.9%	14.3%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DCD - ODE – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	20	17	15		
Number Accepted	19	16	12		
Completed RTF	19	16	12		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

**Table 1.3.DCD - ODE – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	19	16	12		
SI Goal Met	17	15	5		
SI Goal Not Met	1	1	0		
SI Pending Within Goal	0	0	7		
SI Pending Past Goal	1	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	89.5%	93.8%	100%		

**Table 1.4.DCD - ODE – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	18	16	5		
Average number of FDA days to Substantive Interaction	88.3	87.6	85.8		
20th Percentile FDA days to Substantive Interaction	84	87	85		
40th Percentile FDA days to Substantive Interaction	88	88	86		
60th Percentile FDA days to Substantive Interaction	90	89	86		
80th Percentile FDA days to Substantive Interaction	90	90	87		
Maximum FDA days to Substantive Interaction	117	91	88		

**Table 1.5.DCD - ODE – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	16	15	12		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	11	14	1		
MDUFA III Decisions Goal Met	10	14	1		
PMAs pending MDUFA III Decision	5	1	11		
PMAs pending MDUFA III Decision Past Goal	1	0	0		
Current Performance Percent Goal Met	83.3%	100%	100%		

**Table 1.6.DCD - ODE – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	3	1	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	3	1	0		
MDUFA III Decisions Goal Met	2	1	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	66.7%	100%	N/A		

**Table 1.7.DCD - ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	11	14	1		
<b>Average FDA days to MDUFA III decision</b>	189.4	172	104		
20th Percentile FDA days to MDUFA III decision	176	177	104		
40th Percentile FDA days to MDUFA III decision	180	178	104		
60th Percentile FDA days to MDUFA III decision	180	179	104		
80th Percentile FDA days to MDUFA III decision	180	180	104		
Maximum FDA days to MDUFA III decision	291	180	104		
<b>Average Industry days to MDUFA III decision</b>	62.7	30.4	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	35	0	0		
60th Percentile Industry days to MDUFA III decision	80	0	0		
80th Percentile Industry days to MDUFA III decision	105	46	0		
Maximum Industry days to MDUFA III decision	194	161	0		
<b>Average Total days to MDUFA III decision</b>	252.1	202.4	104		
20th Percentile Total days to MDUFA III decision	179	179	104		
40th Percentile Total days to MDUFA III decision	215	179	104		
60th Percentile Total days to MDUFA III decision	260	180	104		
80th Percentile Total days to MDUFA III decision	285	223	104		
Maximum Total days to MDUFA III decision	404	338	104		

**Table 1.8.DCD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	3	1	0		
<b>Average FDA days to MDUFA III decision</b>	433.3	318	0		
20th Percentile FDA days to MDUFA III decision	316	318	0		
40th Percentile FDA days to MDUFA III decision	316	318	0		
60th Percentile FDA days to MDUFA III decision	386	318	0		
80th Percentile FDA days to MDUFA III decision	527	318	0		
Maximum FDA days to MDUFA III decision	668	318	0		
<b>Average Industry days to MDUFA III decision</b>	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
<b>Average Total days to MDUFA III decision</b>	433.3	318	0		
20th Percentile Total days to MDUFA III decision	316	318	0		
40th Percentile Total days to MDUFA III decision	316	318	0		
60th Percentile Total days to MDUFA III decision	386	318	0		
80th Percentile Total days to MDUFA III decision	527	318	0		
Maximum Total days to MDUFA III decision	668	318	0		

**Table 1.9.DCD - ODE – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	16	15	14		
Number with MDUFA decision	11	14	1		
Number of Withdrawals	1	0	0		
Number of Not Approvable	2	0	0		
Rate of Withdrawals	9.1%	0%	0%		
Rate of Not Approvable	18.2%	0%	0%		

**Table 1.10.DCD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	3	1	0		
Number with MDUFA decision	3	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	0%	0%	N/A		

**Table 1.11.DCD - ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0		
Mean FDA days for submissions that missed goal	538	0	0		
Mean industry days for submissions that missed goal	57	0	0		

**Table 1.12.DCD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0		
Mean FDA days for submissions that missed goal	668	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.DNPMD - ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	3	2		
Closed before RTA action	0	0	0		
Number with accepted RTA review	0	2	2		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	1	1	0		
Rate of submissions not accepted for filing review	100%	33.3%	0.0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DNPMD - ODE – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	3	2		
Number Accepted	0	2	2		
Completed RTF	1	3	2		
Number Not Filed	0	1	0		
Rate of submissions Not Filed	0%	33.3%	0.0%		

**Table 1.3.DNPMD - ODE – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	1	3	2		
SI Goal Met	0	2	0		
SI Goal Not Met	1	1	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	0%	66.7%	N/A		

**Table 1.4.DNPMD - ODE – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	1	3	0		
Average number of FDA days to Substantive Interaction	92.0	90.3	0		
20th Percentile FDA days to Substantive Interaction	92	90	0		
40th Percentile FDA days to Substantive Interaction	92	90	0		
60th Percentile FDA days to Substantive Interaction	92	90	0		
80th Percentile FDA days to Substantive Interaction	92	91	0		
Maximum FDA days to Substantive Interaction	92	91	0		



**Table 1.5.DNPMD - ODE – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	3	2		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	3	0		
MDUFA III Decisions Goal Met	1	3	0		
PMAs pending MDUFA III Decision	0	0	2		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	0%		

**Table 1.6.DNPMD - ODE – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	0	0		
MDUFA III Decisions Goal Met	0	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

**Table 1.7.DNPMD - ODE – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	3	0		
<b>Average FDA days to MDUFA III decision</b>	180.0	182.3	0		
20th Percentile FDA days to MDUFA III decision	180	178	0		
40th Percentile FDA days to MDUFA III decision	180	179	0		
60th Percentile FDA days to MDUFA III decision	180	182	0		
80th Percentile FDA days to MDUFA III decision	180	186	0		
Maximum FDA days to MDUFA III decision	180	190	0		
<b>Average Industry days to MDUFA III decision</b>	0	92	0		
20th Percentile Industry days to MDUFA III decision	0	48	0		
40th Percentile Industry days to MDUFA III decision	0	69	0		
60th Percentile Industry days to MDUFA III decision	0	97	0		
80th Percentile Industry days to MDUFA III decision	0	132	0		
Maximum Industry days to MDUFA III decision	0	168	0		
<b>Average Total days to MDUFA III decision</b>	180.0	274.0	0		
20th Percentile Total days to MDUFA III decision	180	227	0		
40th Percentile Total days to MDUFA III decision	180	246	0		
60th Percentile Total days to MDUFA III decision	180	276	0		
80th Percentile Total days to MDUFA III decision	180	317	0		
Maximum Total days to MDUFA III decision	180	358	0		

**Table 1.8.DNPMD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	0	0		
<b>Average FDA days to MDUFA III decision</b>	0	0	0		
20th Percentile FDA days to MDUFA III decision	0	0	0		
40th Percentile FDA days to MDUFA III decision	0	0	0		
60th Percentile FDA days to MDUFA III decision	0	0	0		
80th Percentile FDA days to MDUFA III decision	0	0	0		
Maximum FDA days to MDUFA III decision	0	0	0		
<b>Average Industry days to MDUFA III decision</b>	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
<b>Average Total days to MDUFA III decision</b>	0	0	0		
20th Percentile Total days to MDUFA III decision	0	0	0		
40th Percentile Total days to MDUFA III decision	0	0	0		
60th Percentile Total days to MDUFA III decision	0	0	0		
80th Percentile Total days to MDUFA III decision	0	0	0		
Maximum Total days to MDUFA III decision	0	0	0		

**Table 1.9.DNPMD - ODE – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	3	2		
Number with MDUFA decision	1	3	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	0%	0%	N/A		

**Table 1.10.DNPMD - ODE – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0	0		
Number with MDUFA decision	0	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11.DNPMD - ODE – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DNPMD - ODE – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.DOD - ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	4	3		
Closed before RTA action	0	0	0		
Number with accepted RTA review	0	4	1		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	2		
Rate of submissions not accepted for filing review	N/A	0%	67%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DOD - ODE – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	4	3		
Number Accepted	2	4	1		
Completed RTF	2	4	2		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

**Table 1.3.DOD - ODE – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	2	4	2		
SI Goal Met	2	4	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	N/A		

**Table 1.4.DOD - ODE – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	4	0		
Average number of FDA days to Substantive Interaction	86.0	100	0		
20th Percentile FDA days to Substantive Interaction	86	89	0		
40th Percentile FDA days to Substantive Interaction	86	89	0		
60th Percentile FDA days to Substantive Interaction	86	90	0		
80th Percentile FDA days to Substantive Interaction	86	107	0		
Maximum FDA days to Substantive Interaction	86	133	0		

**Table 1.5.DOD - ODE – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	3	2		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	1	0		
MDUFA III Decisions Goal Met	1	1	0		
PMAs pending MDUFA III Decision	0	2	2		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	0%		

**Table 1.6.DOD - ODE – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	1	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	0	0		
MDUFA III Decisions Goal Met	1	0	0		
PMAs pending MDUFA III Decision	0	1	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	N/A		

**Table 1.7.DOD - ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	1	0		
<b>Average FDA days to MDUFA III decision</b>	175.0	180.0	0		
20th Percentile FDA days to MDUFA III decision	175	180	0		
40th Percentile FDA days to MDUFA III decision	175	180	0		
60th Percentile FDA days to MDUFA III decision	175	180	0		
80th Percentile FDA days to MDUFA III decision	175	180	0		
Maximum FDA days to MDUFA III decision	175	180	0		
<b>Average Industry days to MDUFA III decision</b>	356.0	77.0	0		
20th Percentile Industry days to MDUFA III decision	356	77	0		
40th Percentile Industry days to MDUFA III decision	356	77	0		
60th Percentile Industry days to MDUFA III decision	356	77	0		
80th Percentile Industry days to MDUFA III decision	356	77	0		
Maximum Industry days to MDUFA III decision	356	77	0		
<b>Average Total days to MDUFA III decision</b>	531.0	257.0	0		
20th Percentile Total days to MDUFA III decision	531	257	0		
40th Percentile Total days to MDUFA III decision	531	257	0		
60th Percentile Total days to MDUFA III decision	531	257	0		
80th Percentile Total days to MDUFA III decision	531	257	0		
Maximum Total days to MDUFA III decision	531	257	0		



**Table 1.8.DOD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	0	0		
<b>Average FDA days to MDUFA III decision</b>	219.0	0	0		
20th Percentile FDA days to MDUFA III decision	219	0	0		
40th Percentile FDA days to MDUFA III decision	219	0	0		
60th Percentile FDA days to MDUFA III decision	219	0	0		
80th Percentile FDA days to MDUFA III decision	219	0	0		
Maximum FDA days to MDUFA III decision	219	0	0		
<b>Average Industry days to MDUFA III decision</b>	186.0	0	0		
20th Percentile Industry days to MDUFA III decision	186	0	0		
40th Percentile Industry days to MDUFA III decision	186	0	0		
60th Percentile Industry days to MDUFA III decision	186	0	0		
80th Percentile Industry days to MDUFA III decision	186	0	0		
Maximum Industry days to MDUFA III decision	186	0	0		
<b>Average Total days to MDUFA III decision</b>	405.0	0	0		
20th Percentile Total days to MDUFA III decision	405	0	0		
40th Percentile Total days to MDUFA III decision	405	0	0		
60th Percentile Total days to MDUFA III decision	405	0	0		
80th Percentile Total days to MDUFA III decision	405	0	0		
Maximum Total days to MDUFA III decision	405	0	0		

**Table 1.9.DOD - ODE – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	3	2		
Number with MDUFA decision	1	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	1	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	100%	0%	N/A		

**Table 1.10.DOD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1	0		
Number with MDUFA decision	1	0	0		
Number of Withdrawals	1	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	100%	N/A	N/A		
Rate of Not Approvable	0%	N/A	N/A		

**Table 1.11.DOD - ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DOD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.DOED - ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1	1		
Closed before RTA action	0	0	0		
Number with accepted RTA review	4	1	1		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	1	0	0		
Rate of submissions not accepted for filing review	20.0%	0%	0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DOED - ODE – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	1	1		
Number Accepted	5	1	1		
Completed RTF	6	1	1		
Number Not Filed	1	0	0		
Rate of submissions Not Filed	16.7%	0%	0%		

**Table 1.3.DOED - ODE – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	6	1	1		
SI Goal Met	6	1	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 1.4.DOED - ODE – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	6	1	1		
Average number of FDA days to Substantive Interaction	88.5	81.0	79		
20th Percentile FDA days to Substantive Interaction	88	81	79		
40th Percentile FDA days to Substantive Interaction	88	81	79		
60th Percentile FDA days to Substantive Interaction	89	81	79		
80th Percentile FDA days to Substantive Interaction	90	81	79		
Maximum FDA days to Substantive Interaction	90	81	79		

**Table 1.5.DOED - ODE – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>70% within 180 FDA days</b>	<b>80% within 180 FDA days</b>	<b>80% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>90% within 180 FDA days</b>
Number of PMAs filed	2	1	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	2	1	0		
MDUFA III Decisions Goal Met	2	1	0		
PMAs pending MDUFA III Decision	0	0	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	0%		

**Table 1.6.DOED - ODE – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>50% within 320 FDA days</b>	<b>70% within 320 FDA days</b>	<b>80% within 320 FDA days</b>	<b>80% within 320 FDA days</b>	<b>90% within 320 FDA days</b>
Number of PMAs filed	4	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	2	0	0		
MDUFA III Decisions Goal Met	2	0	0		
PMAs pending MDUFA III Decision	2	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	N/A		

**Table 1.7.DOED - ODE – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	2	1	0		
<b>Average FDA days to MDUFA III decision</b>	178.5	170.0	0		
20th Percentile FDA days to MDUFA III decision	178	170	0		
40th Percentile FDA days to MDUFA III decision	178	170	0		
60th Percentile FDA days to MDUFA III decision	179	170	0		
80th Percentile FDA days to MDUFA III decision	179	170	0		
Maximum FDA days to MDUFA III decision	180	170	0		
<b>Average Industry days to MDUFA III decision</b>	108.5	0	0		
20th Percentile Industry days to MDUFA III decision	43	0	0		
40th Percentile Industry days to MDUFA III decision	87	0	0		
60th Percentile Industry days to MDUFA III decision	130	0	0		
80th Percentile Industry days to MDUFA III decision	174	0	0		
Maximum Industry days to MDUFA III decision	217	0	0		
<b>Average Total days to MDUFA III decision</b>	287.0	170.0	0		
20th Percentile Total days to MDUFA III decision	221	170	0		
40th Percentile Total days to MDUFA III decision	265	170	0		
60th Percentile Total days to MDUFA III decision	309	170	0		
80th Percentile Total days to MDUFA III decision	353	170	0		
Maximum Total days to MDUFA III decision	397	170	0		

**Table 1.8.DOED - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	2	0	0		
<b>Average FDA days to MDUFA III decision</b>	236.0	0	0		
20th Percentile FDA days to MDUFA III decision	204	0	0		
40th Percentile FDA days to MDUFA III decision	225	0	0		
60th Percentile FDA days to MDUFA III decision	247	0	0		
80th Percentile FDA days to MDUFA III decision	268	0	0		
Maximum FDA days to MDUFA III decision	290	0	0		
<b>Average Industry days to MDUFA III decision</b>	70.5	0	0		
20th Percentile Industry days to MDUFA III decision	28	0	0		
40th Percentile Industry days to MDUFA III decision	56	0	0		
60th Percentile Industry days to MDUFA III decision	85	0	0		
80th Percentile Industry days to MDUFA III decision	113	0	0		
Maximum Industry days to MDUFA III decision	141	0	0		
<b>Average Total days to MDUFA III decision</b>	306.5	0	0		
20th Percentile Total days to MDUFA III decision	297	0	0		
40th Percentile Total days to MDUFA III decision	303	0	0		
60th Percentile Total days to MDUFA III decision	310	0	0		
80th Percentile Total days to MDUFA III decision	316	0	0		
Maximum Total days to MDUFA III decision	323	0	0		

**Table 1.9.DOED - ODE – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	1	1		
Number with MDUFA decision	2	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	0%	0%	N/A		

**Table 1.10.DOED - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4	0	0		
Number with MDUFA decision	2	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	N/A	N/A		
Rate of Not Approvable	0%	N/A	N/A		

**Table 1.11.DOED - ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DOED - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		



**Table 1.1.DRGUD - ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	5	2		
Closed before RTA action	0	0	0		
Number with accepted RTA review	1	3	1		
Number without a RTA Review and > 15 Days since Date Received	0	0	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	3	2	0		
Rate of submissions not accepted for filing review	75.0%	40.0%	0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DRGUD - ODE – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	5	2		
Number Accepted	1	3	2		
Completed RTF	4	5	1		
Number Not Filed	2	0	0		
Rate of submissions Not Filed	50.0%	0%	0%		

**Table 1.3.DRGUD - ODE – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	4	5	1		
SI Goal Met	4	5	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 1.4.DRGUD - ODE – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	4	5	1		
Average number of FDA days to Substantive Interaction	88.5	97.8	86		
20th Percentile FDA days to Substantive Interaction	88	88	86		
40th Percentile FDA days to Substantive Interaction	88	88	86		
60th Percentile FDA days to Substantive Interaction	88	89	86		
80th Percentile FDA days to Substantive Interaction	89	99	86		
Maximum FDA days to Substantive Interaction	90	136	86		

**Table 1.5.DRGUD - ODE – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	5	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	1	0		
MDUFA III Decisions Goal Met	1	1	0		
PMAs pending MDUFA III Decision	0	4	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	N/A		

**Table 1.6.DRGUD - ODE – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	3	0	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	3	0	0		
MDUFA III Decisions Goal Met	3	0	0		
PMAs pending MDUFA III Decision	0	0	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	0%		

**Table 1.7.DRGUD - ODE – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	1	0		
<b>Average FDA days to MDUFA III decision</b>	180	148	0		
20th Percentile FDA days to MDUFA III decision	180	148	0		
40th Percentile FDA days to MDUFA III decision	180	148	0		
60th Percentile FDA days to MDUFA III decision	180	148	0		
80th Percentile FDA days to MDUFA III decision	180	148	0		
Maximum FDA days to MDUFA III decision	180	148	0		
<b>Average Industry days to MDUFA III decision</b>	260	140	0		
20th Percentile Industry days to MDUFA III decision	260	140	0		
40th Percentile Industry days to MDUFA III decision	260	140	0		
60th Percentile Industry days to MDUFA III decision	260	140	0		
80th Percentile Industry days to MDUFA III decision	260	140	0		
Maximum Industry days to MDUFA III decision	260	140	0		
<b>Average Total days to MDUFA III decision</b>	220	144	0		
20th Percentile Total days to MDUFA III decision	220	144	0		
40th Percentile Total days to MDUFA III decision	220	144	0		
60th Percentile Total days to MDUFA III decision	220	144	0		
80th Percentile Total days to MDUFA III decision	220	144	0		
Maximum Total days to MDUFA III decision	220	144	0		

**Table 1.8.DRGUD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	3	0	0		
<b>Average FDA days to MDUFA III decision</b>	376.0	0	0		
20th Percentile FDA days to MDUFA III decision	313	0	0		
40th Percentile FDA days to MDUFA III decision	314	0	0		
60th Percentile FDA days to MDUFA III decision	352	0	0		
80th Percentile FDA days to MDUFA III decision	427	0	0		
Maximum FDA days to MDUFA III decision	501	0	0		
<b>Average Industry days to MDUFA III decision</b>	180.3	0	0		
20th Percentile Industry days to MDUFA III decision	112	0	0		
40th Percentile Industry days to MDUFA III decision	156	0	0		
60th Percentile Industry days to MDUFA III decision	201	0	0		
80th Percentile Industry days to MDUFA III decision	248	0	0		
Maximum Industry days to MDUFA III decision	295	0	0		
<b>Average Total days to MDUFA III decision</b>	556.3	0	0		
20th Percentile Total days to MDUFA III decision	522	0	0		
40th Percentile Total days to MDUFA III decision	553	0	0		
60th Percentile Total days to MDUFA III decision	577	0	0		
80th Percentile Total days to MDUFA III decision	594	0	0		
Maximum Total days to MDUFA III decision	610	0	0		

**Table 1.9.DRGUD - ODE – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	5	1		
Number with MDUFA decision	1	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	1	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	0%	100%	N/A		

**Table 1.10.DRGUD - ODE – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	3	0	1		
Number with MDUFA decision	3	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	2	0	0		
Rate of Withdrawals	0%	N/A	N/A		
Rate of Not Approvable	67%	N/A	N/A		

**Table 1.11.DRGUD - ODE – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DRGUD - ODE – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.DSD - ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	6	4		
Closed before RTA action	0	0	0		
Number with accepted RTA review	0	4	2		
Number without a RTA Review and > 15 Days since Date Received	0	0	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	2	1		
Rate of submissions not accepted for filing review	N/A	33.3%	25.0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DSD - ODE – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	6	4		
Number Accepted	0	4	3		
Completed RTF	0	5	3		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	N/A	0%	0%		

**Table 1.3.DSD - ODE – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	0	5	3		
SI Goal Met	0	5	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	N/A	100%	N/A		

**Table 1.4.DSD - ODE – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	0	5	0		
Average number of FDA days to Substantive Interaction	0	88.8	0		
20th Percentile FDA days to Substantive Interaction	0	88	0		
40th Percentile FDA days to Substantive Interaction	0	90	0		
60th Percentile FDA days to Substantive Interaction	0	90	0		
80th Percentile FDA days to Substantive Interaction	0	90	0		
Maximum FDA days to Substantive Interaction	0	90	0		



**Table 1.5.DSD - ODE – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	0	3	3		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	3	0		
MDUFA III Decisions Goal Met	0	3	0		
PMAs pending MDUFA III Decision	0	0	3		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	100%	0%		

**Table 1.6.DSD - ODE – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	2	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	1	0		
MDUFA III Decisions Goal Met	0	1	0		
PMAs pending MDUFA III Decision	0	1	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	100%	N/A		

**Table 1.7.DSD - ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	3	0		
<b>Average FDA days to MDUFA III decision</b>	0	177.3	0		
20th Percentile FDA days to MDUFA III decision	0	175	0		
40th Percentile FDA days to MDUFA III decision	0	178	0		
60th Percentile FDA days to MDUFA III decision	0	179	0		
80th Percentile FDA days to MDUFA III decision	0	180	0		
Maximum FDA days to MDUFA III decision	0	180	0		
<b>Average Industry days to MDUFA III decision</b>	0	49.0	0		
20th Percentile Industry days to MDUFA III decision	0	46	0		
40th Percentile Industry days to MDUFA III decision	0	47	0		
60th Percentile Industry days to MDUFA III decision	0	49	0		
80th Percentile Industry days to MDUFA III decision	0	52	0		
Maximum Industry days to MDUFA III decision	0	55	0		
<b>Average Total days to MDUFA III decision</b>	0	226.3	0		
20th Percentile Total days to MDUFA III decision	0	222	0		
40th Percentile Total days to MDUFA III decision	0	223	0		
60th Percentile Total days to MDUFA III decision	0	226	0		
80th Percentile Total days to MDUFA III decision	0	230	0		
Maximum Total days to MDUFA III decision	0	234	0		

**Table 1.8.DSD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	1	0		
<b>Average FDA days to MDUFA III decision</b>	0	379	0		
20th Percentile FDA days to MDUFA III decision	0	379	0		
40th Percentile FDA days to MDUFA III decision	0	379	0		
60th Percentile FDA days to MDUFA III decision	0	379	0		
80th Percentile FDA days to MDUFA III decision	0	379	0		
Maximum FDA days to MDUFA III decision	0	379	0		
<b>Average Industry days to MDUFA III decision</b>	0	20	0		
20th Percentile Industry days to MDUFA III decision	0	20	0		
40th Percentile Industry days to MDUFA III decision	0	20	0		
60th Percentile Industry days to MDUFA III decision	0	20	0		
80th Percentile Industry days to MDUFA III decision	0	20	0		
Maximum Industry days to MDUFA III decision	0	20	0		
<b>Average Total days to MDUFA III decision</b>	0	399	0		
20th Percentile Total days to MDUFA III decision	0	399	0		
40th Percentile Total days to MDUFA III decision	0	399	0		
60th Percentile Total days to MDUFA III decision	0	399	0		
80th Percentile Total days to MDUFA III decision	0	399	0		
Maximum Total days to MDUFA III decision	0	399	0		

**Table 1.9.DSD - ODE – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	3	3		
Number with MDUFA decision	0	3	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	N/A	0%	N/A		
Rate of Not Approvable	N/A	0%	N/A		

**Table 1.10.DSD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	2	0		
Number with MDUFA decision	0	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	N/A	0%	N/A		
Rate of Not Approvable	N/A	0%	N/A		

**Table 1.11.DSD - ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DSD - ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.DCTD - OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	2	3		
Closed before RTA action	0	0	0		
Number with accepted RTA review	2	2	3		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of submissions not accepted for filing review	0%	0%	0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DCTD - OIR – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	2	3		
Number Accepted	2	2	3		
Completed RTF	2	2	3		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

**Table 1.3.DCTD - OIR – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	2	2	3		
SI Goal Met	2	2	2		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 1.4.DCTD - OIR – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	2	2		
Average number of FDA days to Substantive Interaction	90.0	88.0	71		
20th Percentile FDA days to Substantive Interaction	90	87	62		
40th Percentile FDA days to Substantive Interaction	90	88	68		
60th Percentile FDA days to Substantive Interaction	90	88	74		
80th Percentile FDA days to Substantive Interaction	90	89	80		
Maximum FDA days to Substantive Interaction	90	89	86		

**Table 1.5.DCTD - OIR – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>70% within 180 FDA days</b>	<b>80% within 180 FDA days</b>	<b>80% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>90% within 180 FDA days</b>
Number of PMAs filed	2	2	3		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	2	1	0		
MDUFA III Decisions Goal Met	2	1	0		
PMAs pending MDUFA III Decision	0	1	3		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	0%		

**Table 1.6.DCTD - OIR – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>50% within 320 FDA days</b>	<b>70% within 320 FDA days</b>	<b>80% within 320 FDA days</b>	<b>80% within 320 FDA days</b>	<b>90% within 320 FDA days</b>
Number of PMAs filed	0	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	0	0		
MDUFA III Decisions Goal Met	0	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

**Table 1.7.DCTD - OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	2	1	0		
<b>Average FDA days to MDUFA III decision</b>	176.5	179	0		
20th Percentile FDA days to MDUFA III decision	175	179	0		
40th Percentile FDA days to MDUFA III decision	176	179	0		
60th Percentile FDA days to MDUFA III decision	177	179	0		
80th Percentile FDA days to MDUFA III decision	178	179	0		
Maximum FDA days to MDUFA III decision	179	179	0		
<b>Average Industry days to MDUFA III decision</b>	266.5	0	0		
20th Percentile Industry days to MDUFA III decision	186	0	0		
40th Percentile Industry days to MDUFA III decision	240	0	0		
60th Percentile Industry days to MDUFA III decision	293	0	0		
80th Percentile Industry days to MDUFA III decision	347	0	0		
Maximum Industry days to MDUFA III decision	400	0	0		
<b>Average Total days to MDUFA III decision</b>	443.0	179	0		
20th Percentile Total days to MDUFA III decision	361	179	0		
40th Percentile Total days to MDUFA III decision	416	179	0		
60th Percentile Total days to MDUFA III decision	470	179	0		
80th Percentile Total days to MDUFA III decision	525	179	0		
Maximum Total days to MDUFA III decision	579	179	0		



**Table 1.8.DCTD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	0	0		
<b>Average FDA days to MDUFA III decision</b>	0	0	0		
20th Percentile FDA days to MDUFA III decision	0	0	0		
40th Percentile FDA days to MDUFA III decision	0	0	0		
60th Percentile FDA days to MDUFA III decision	0	0	0		
80th Percentile FDA days to MDUFA III decision	0	0	0		
Maximum FDA days to MDUFA III decision	0	0	0		
<b>Average Industry days to MDUFA III decision</b>	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
<b>Average Total days to MDUFA III decision</b>	0	0	0		
20th Percentile Total days to MDUFA III decision	0	0	0		
40th Percentile Total days to MDUFA III decision	0	0	0		
60th Percentile Total days to MDUFA III decision	0	0	0		
80th Percentile Total days to MDUFA III decision	0	0	0		
Maximum Total days to MDUFA III decision	0	0	0		

**Table 1.9.DCTD - OIR – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	2	3		
Number with MDUFA decision	2	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	0%	0%	N/A		

**Table 1.10.DCTD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0	0		
Number with MDUFA decision	0	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11.DCTD - OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DCTD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.DIHD - OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	0	0		
Closed before RTA action	0	0	0		
Number with accepted RTA review	0	0	0		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of submissions not accepted for filing review	N/A	N/A	N/A		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DIHD - OIR – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	0	0		
Number Accepted	0	0	0		
Completed RTF	0	0	0		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	N/A	N/A	N/A		

**Table 1.3.DIHD - OIR – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	0	0	0		
SI Goal Met	0	0	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	N/A	N/A	N/A		

**Table 1.4.DIHD - OIR – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	0	0	0		
Average number of FDA days to Substantive Interaction	0	0	0		
20th Percentile FDA days to Substantive Interaction	0	0	0		
40th Percentile FDA days to Substantive Interaction	0	0	0		
60th Percentile FDA days to Substantive Interaction	0	0	0		
80th Percentile FDA days to Substantive Interaction	0	0	0		
Maximum FDA days to Substantive Interaction	0	0	0		

**Table 1.5.DIHD - OIR – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	0	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	0	0		
MDUFA III Decisions Goal Met	0	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

**Table 1.6.DIHD - OIR – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	0	0		
MDUFA III Decisions Goal Met	0	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

**Table 1.7.DIHD - OIR – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	0	0		
<b>Average FDA days to MDUFA III decision</b>	0	0	0		
20th Percentile FDA days to MDUFA III decision	0	0	0		
40th Percentile FDA days to MDUFA III decision	0	0	0		
60th Percentile FDA days to MDUFA III decision	0	0	0		
80th Percentile FDA days to MDUFA III decision	0	0	0		
Maximum FDA days to MDUFA III decision	0	0	0		
<b>Average Industry days to MDUFA III decision</b>	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
<b>Average Total days to MDUFA III decision</b>	0	0	0		
20th Percentile Total days to MDUFA III decision	0	0	0		
40th Percentile Total days to MDUFA III decision	0	0	0		
60th Percentile Total days to MDUFA III decision	0	0	0		
80th Percentile Total days to MDUFA III decision	0	0	0		
Maximum Total days to MDUFA III decision	0	0	0		

**Table 1.8.DIHD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	0	0		
<b>Average FDA days to MDUFA III decision</b>	0	0	0		
20th Percentile FDA days to MDUFA III decision	0	0	0		
40th Percentile FDA days to MDUFA III decision	0	0	0		
60th Percentile FDA days to MDUFA III decision	0	0	0		
80th Percentile FDA days to MDUFA III decision	0	0	0		
Maximum FDA days to MDUFA III decision	0	0	0		
<b>Average Industry days to MDUFA III decision</b>	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
<b>Average Total days to MDUFA III decision</b>	0	0	0		
20th Percentile Total days to MDUFA III decision	0	0	0		
40th Percentile Total days to MDUFA III decision	0	0	0		
60th Percentile Total days to MDUFA III decision	0	0	0		
80th Percentile Total days to MDUFA III decision	0	0	0		
Maximum Total days to MDUFA III decision	0	0	0		

**Table 1.9.DIHD - OIR – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0	0		
Number with MDUFA decision	0	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.10.DIHD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0	0		
Number with MDUFA decision	0	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11.DIHD - OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DIHD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		



**Table 1.1.DMD - OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1	1		
Closed before RTA action	0	0	0		
Number with accepted RTA review	2	1	1		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of submissions not accepted for filing review	0%	0%	0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DMD - OIR – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1	1		
Number Accepted	2	1	1		
Completed RTF	2	1	1		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

**Table 1.3.DMD - OIR – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	2	1	1		
SI Goal Met	2	1	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 1.4.DMD - OIR – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	1	1		
Average number of FDA days to Substantive Interaction	86	83	87		
20th Percentile FDA days to Substantive Interaction	86	83	87		
40th Percentile FDA days to Substantive Interaction	86	83	87		
60th Percentile FDA days to Substantive Interaction	86	83	87		
80th Percentile FDA days to Substantive Interaction	86	83	87		
Maximum FDA days to Substantive Interaction	86	83	87		

**Table 1.5.DMD - OIR – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	1	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	1	0		
MDUFA III Decisions Goal Met	1	1	0		
PMAs pending MDUFA III Decision	0	0	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	0%		

**Table 1.6.DMD - OIR – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	0	0		
MDUFA III Decisions Goal Met	1	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	N/A		

**Table 1.7.DMD - OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	1	0		
<b>Average FDA days to MDUFA III decision</b>	177.0	179.0	0		
20th Percentile FDA days to MDUFA III decision	177	179	0		
40th Percentile FDA days to MDUFA III decision	177	179	0		
60th Percentile FDA days to MDUFA III decision	177	179	0		
80th Percentile FDA days to MDUFA III decision	177	179	0		
Maximum FDA days to MDUFA III decision	177	179	0		
<b>Average Industry days to MDUFA III decision</b>	107.0	0	0		
20th Percentile Industry days to MDUFA III decision	107	0	0		
40th Percentile Industry days to MDUFA III decision	107	0	0		
60th Percentile Industry days to MDUFA III decision	107	0	0		
80th Percentile Industry days to MDUFA III decision	107	0	0		
Maximum Industry days to MDUFA III decision	107	0	0		
<b>Average Total days to MDUFA III decision</b>	284.0	179.0	0		
20th Percentile Total days to MDUFA III decision	284	179	0		
40th Percentile Total days to MDUFA III decision	284	179	0		
60th Percentile Total days to MDUFA III decision	284	179	0		
80th Percentile Total days to MDUFA III decision	284	179	0		
Maximum Total days to MDUFA III decision	284	179	0		

**Table 1.8.DMD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	0	0		
<b>Average FDA days to MDUFA III decision</b>	297.0	0	0		
20th Percentile FDA days to MDUFA III decision	297	0	0		
40th Percentile FDA days to MDUFA III decision	297	0	0		
60th Percentile FDA days to MDUFA III decision	297	0	0		
80th Percentile FDA days to MDUFA III decision	297	0	0		
Maximum FDA days to MDUFA III decision	297	0	0		
<b>Average Industry days to MDUFA III decision</b>	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
<b>Average Total days to MDUFA III decision</b>	297.0	0	0		
20th Percentile Total days to MDUFA III decision	297	0	0		
40th Percentile Total days to MDUFA III decision	297	0	0		
60th Percentile Total days to MDUFA III decision	297	0	0		
80th Percentile Total days to MDUFA III decision	297	0	0		
Maximum Total days to MDUFA III decision	297	0	0		

**Table 1.9.DMD - OIR – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1	1		
Number with MDUFA decision	1	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	0%	0%	N/A		

**Table 1.10.DMD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0	0		
Number with MDUFA decision	1	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	N/A	N/A		
Rate of Not Approvable	0%	N/A	N/A		

**Table 1.11.DMD - OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DMD - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.DMGP - OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1	2		
Closed before RTA action	0	0	0		
Number with accepted RTA review	2	1	2		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of submissions not accepted for filing review	0%	0%	0%		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DMGP - OIR – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	1	2		
Number Accepted	4	1	2		
Completed RTF	4	1	2		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

**Table 1.3.DMGP - OIR – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	4	1	2		
SI Goal Met	4	1	2		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 1.4.DMGP - OIR – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	4	1	2		
Average number of FDA days to Substantive Interaction	95.3	86.0	90.0		
20th Percentile FDA days to Substantive Interaction	90	86	90		
40th Percentile FDA days to Substantive Interaction	90	86	90		
60th Percentile FDA days to Substantive Interaction	90	86	90		
80th Percentile FDA days to Substantive Interaction	99	86	90		
Maximum FDA days to Substantive Interaction	112	86	90		



**Table 1.5.DMGP - OIR – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>70% within 180 FDA days</b>	<b>80% within 180 FDA days</b>	<b>80% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>90% within 180 FDA days</b>
Number of PMAs filed	2	1	2		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	2	1	0		
MDUFA III Decisions Goal Met	2	1	0		
PMAs pending MDUFA III Decision	0	0	2		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	N/A		

**Table 1.6.DMGP - OIR – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>50% within 320 FDA days</b>	<b>70% within 320 FDA days</b>	<b>80% within 320 FDA days</b>	<b>80% within 320 FDA days</b>	<b>90% within 320 FDA days</b>
Number of PMAs filed	2	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	2	0	0		
MDUFA III Decisions Goal Met	2	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	N/A		

**Table 1.7.DMGP - OIR – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	2	1	0		
<b>Average FDA days to MDUFA III decision</b>	107.5	86.0	0		
20th Percentile FDA days to MDUFA III decision	102	86	0		
40th Percentile FDA days to MDUFA III decision	106	86	0		
60th Percentile FDA days to MDUFA III decision	109	86	0		
80th Percentile FDA days to MDUFA III decision	113	86	0		
Maximum FDA days to MDUFA III decision	116	86	0		
<b>Average Industry days to MDUFA III decision</b>	94.5	0	0		
20th Percentile Industry days to MDUFA III decision	80	0	0		
40th Percentile Industry days to MDUFA III decision	90	0	0		
60th Percentile Industry days to MDUFA III decision	99	0	0		
80th Percentile Industry days to MDUFA III decision	109	0	0		
Maximum Industry days to MDUFA III decision	118	0	0		
<b>Average Total days to MDUFA III decision</b>	202.0	86	0		
20th Percentile Total days to MDUFA III decision	193	86	0		
40th Percentile Total days to MDUFA III decision	199	86	0		
60th Percentile Total days to MDUFA III decision	205	86	0		
80th Percentile Total days to MDUFA III decision	211	86	0		
Maximum Total days to MDUFA III decision	217	86	0		

**Table 1.8.DMGP - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	2	0	0		
<b>Average FDA days to MDUFA III decision</b>	320.0	0	0		
20th Percentile FDA days to MDUFA III decision	317	0	0		
40th Percentile FDA days to MDUFA III decision	319	0	0		
60th Percentile FDA days to MDUFA III decision	321	0	0		
80th Percentile FDA days to MDUFA III decision	323	0	0		
Maximum FDA days to MDUFA III decision	325	0	0		
<b>Average Industry days to MDUFA III decision</b>	147.0	0	0		
20th Percentile Industry days to MDUFA III decision	122	0	0		
40th Percentile Industry days to MDUFA III decision	139	0	0		
60th Percentile Industry days to MDUFA III decision	155	0	0		
80th Percentile Industry days to MDUFA III decision	172	0	0		
Maximum Industry days to MDUFA III decision	189	0	0		
<b>Average Total days to MDUFA III decision</b>	467.0	0	0		
20th Percentile Total days to MDUFA III decision	445	0	0		
40th Percentile Total days to MDUFA III decision	460	0	0		
60th Percentile Total days to MDUFA III decision	474	0	0		
80th Percentile Total days to MDUFA III decision	489	0	0		
Maximum Total days to MDUFA III decision	504	0	0		

**Table 1.9.DMGP - OIR – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	1	2		
Number with MDUFA decision	2	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	0%	0%	N/A		

**Table 1.10.DMGP - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	0	0		
Number with MDUFA decision	2	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	1	0	0		
Rate of Withdrawals	0%	N/A	N/A		
Rate of Not Approvable	50.0%	N/A	N/A		

**Table 1.11.DMGP - OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DMGP - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.1.DRH - OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	2	0		
Closed before RTA action	0	0	0		
Number with accepted RTA review	1	1	0		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	1	0		
Rate of submissions not accepted for filing review	0%	50.0%	N/A		

\*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013.

**Table 1.2.DRH - OIR – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	2	0		
Number Accepted	2	1	0		
Completed RTF	2	2	0		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	N/A		

**Table 1.3.DRH - OIR – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	2	2	0		
SI Goal Met	2	2	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	N/A		

**Table 1.4.DRH - OIR – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	2	0		
Average number of FDA days to Substantive Interaction	77.5	86.5	0		
20th Percentile FDA days to Substantive Interaction	70	86	0		
40th Percentile FDA days to Substantive Interaction	75	86	0		
60th Percentile FDA days to Substantive Interaction	80	87	0		
80th Percentile FDA days to Substantive Interaction	85	87	0		
Maximum FDA days to Substantive Interaction	90	88	0		

**Table 1.5.DRH - OIR – PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	2	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	1	0		
MDUFA III Decisions Goal Met	1	1	0		
PMAs pending MDUFA III Decision	0	1	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	N/A		

**Table 1.6.DRH - OIR – PMA Originals & Panel-Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	0	0		
MDUFA III Decisions Goal Met	1	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	N/A		

**Table 1.7.DRH - OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	1	0		
<b>Average FDA days to MDUFA III decision</b>	167.0	177.0	0		
20th Percentile FDA days to MDUFA III decision	167	177	0		
40th Percentile FDA days to MDUFA III decision	167	177	0		
60th Percentile FDA days to MDUFA III decision	167	177	0		
80th Percentile FDA days to MDUFA III decision	167	177	0		
Maximum FDA days to MDUFA III decision	167	177	0		
<b>Average Industry days to MDUFA III decision</b>	81.0	106.0	0		
20th Percentile Industry days to MDUFA III decision	81	106	0		
40th Percentile Industry days to MDUFA III decision	81	106	0		
60th Percentile Industry days to MDUFA III decision	81	106	0		
80th Percentile Industry days to MDUFA III decision	81	106	0		
Maximum Industry days to MDUFA III decision	81	106	0		
<b>Average Total days to MDUFA III decision</b>	248.0	283.0	0		
20th Percentile Total days to MDUFA III decision	248	283	0		
40th Percentile Total days to MDUFA III decision	248	283	0		
60th Percentile Total days to MDUFA III decision	248	283	0		
80th Percentile Total days to MDUFA III decision	248	283	0		
Maximum Total days to MDUFA III decision	248	283	0		



**Table 1.8.DRH - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	1	0	0		
<b>Average FDA days to MDUFA III decision</b>	206.0	0	0		
20th Percentile FDA days to MDUFA III decision	206	0	0		
40th Percentile FDA days to MDUFA III decision	206	0	0		
60th Percentile FDA days to MDUFA III decision	206	0	0		
80th Percentile FDA days to MDUFA III decision	206	0	0		
Maximum FDA days to MDUFA III decision	206	0	0		
<b>Average Industry days to MDUFA III decision</b>	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
<b>Average Total days to MDUFA III decision</b>	206.0	0	0		
20th Percentile Total days to MDUFA III decision	206	0	0		
40th Percentile Total days to MDUFA III decision	206	0	0		
60th Percentile Total days to MDUFA III decision	206	0	0		
80th Percentile Total days to MDUFA III decision	206	0	0		
Maximum Total days to MDUFA III decision	206	0	0		

**Table 1.9.DRH - OIR – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	2	0		
Number with MDUFA decision	1	1	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	1	0	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	100%	0%	N/A		

**Table 1.10.DRH - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0	0		
Number with MDUFA decision	1	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0%	N/A	N/A		
Rate of Not Approvable	0%	N/A	N/A		

**Table 1.11.DRH - OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

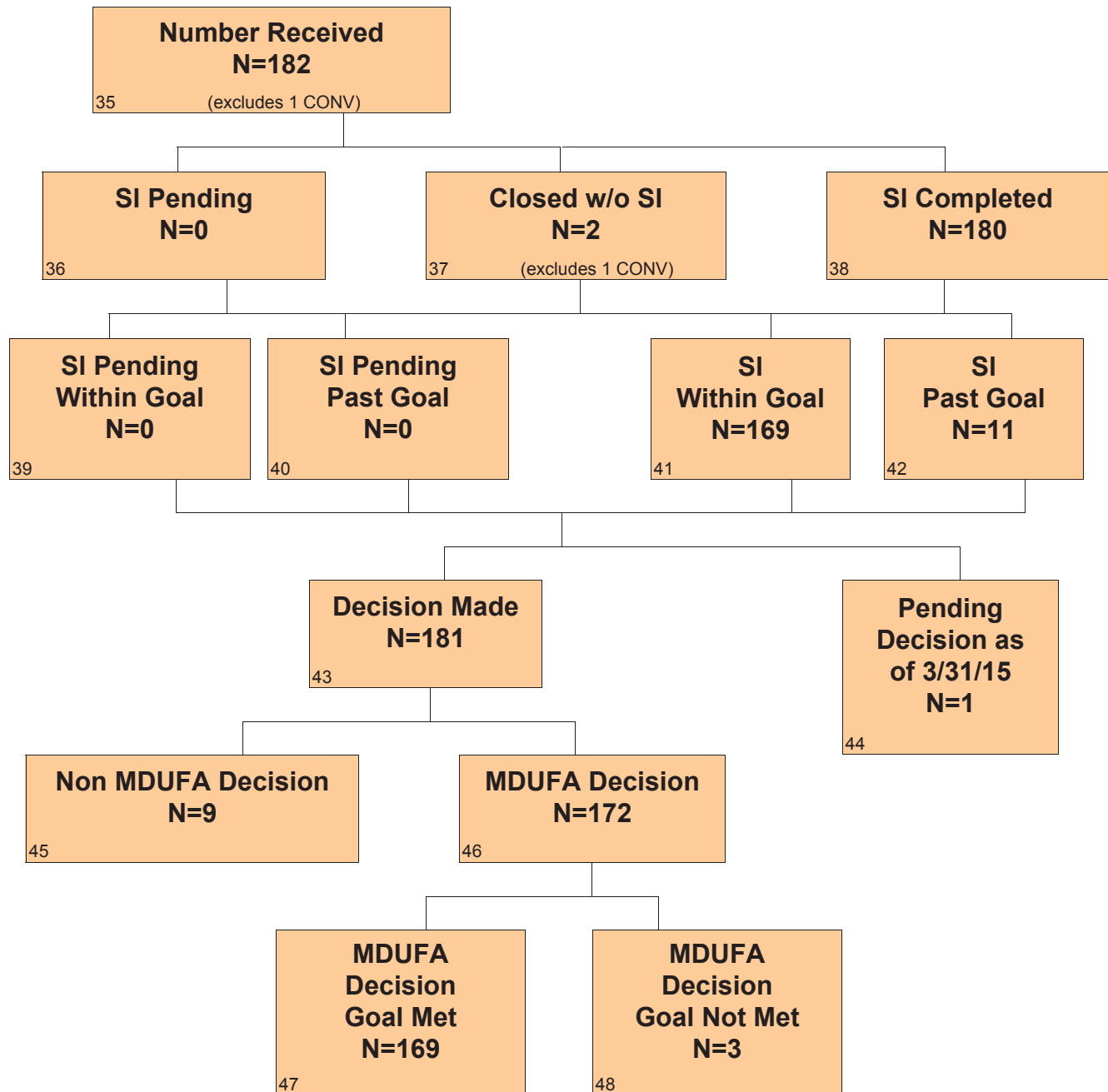
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.12.DRH - OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

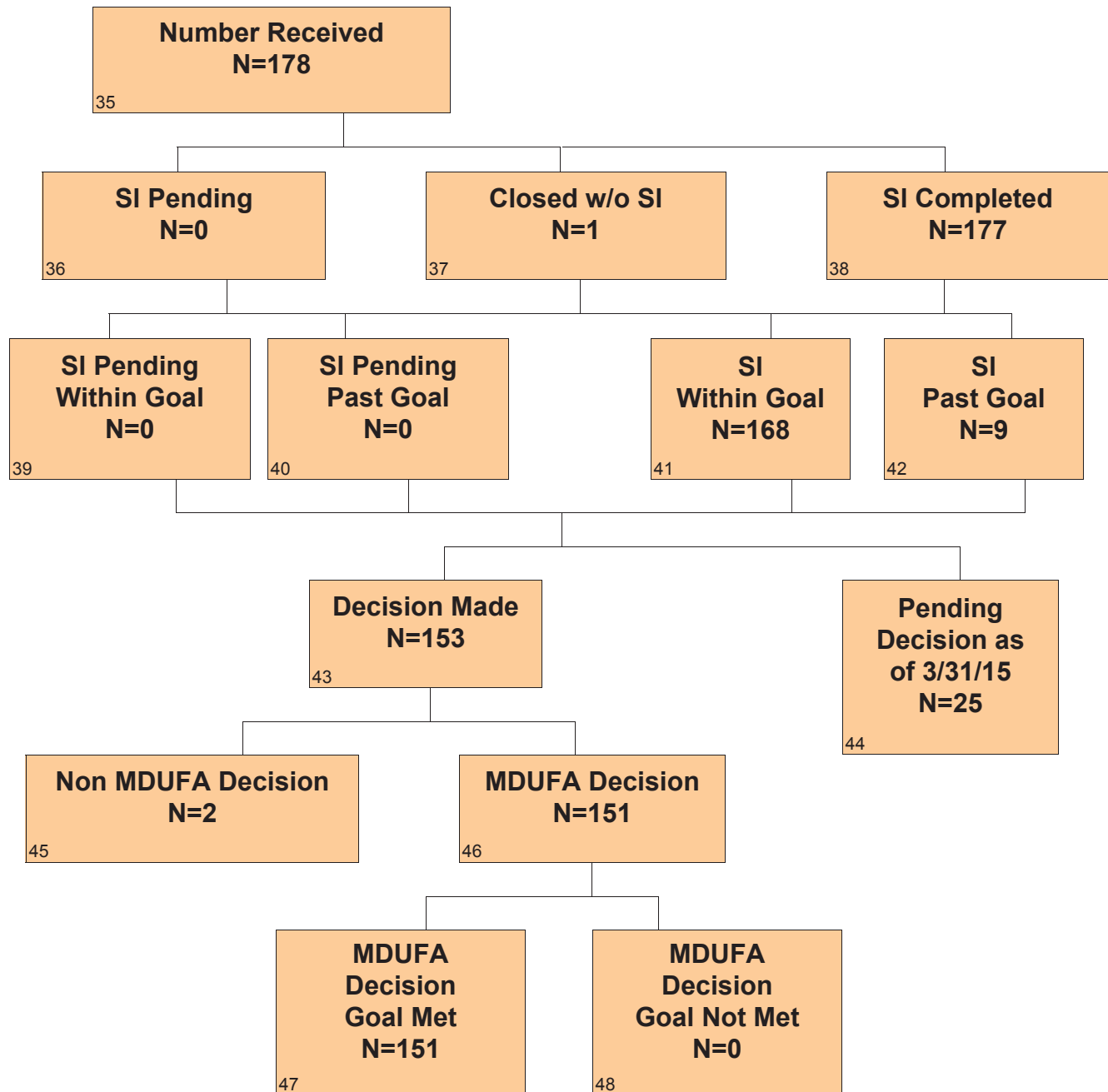
# CDRH PMA 180 Day Supplements - FY 2013 As of 3/31/15

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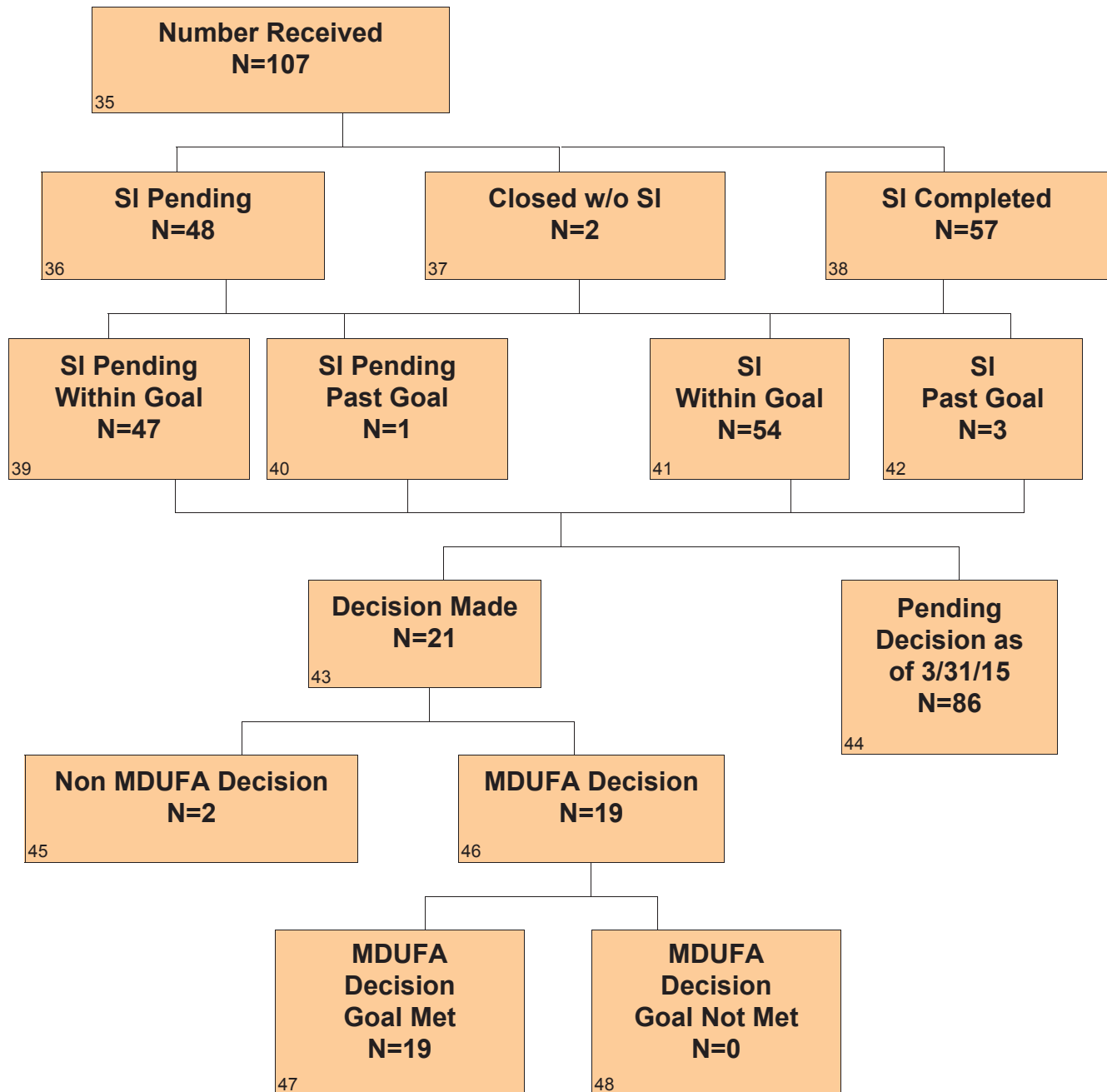
# CDRH PMA 180 Day Supplements - FY 2014 As of 3/31/15

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# CDRH PMA 180 Day Supplements - FY 2015 As of 3/31/15

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## Section 2 PMA 180 Day Supplements - Center Level

**Table 2.1 CDRH – PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	183	178	107		
SI Goal Met	169	168	54		
SI Goal Not Met	11	9	3		
SI Pending Within Goal	0	0	47		
SI Pending Past Goal	0	0	1		
Closed without SI	3	1	2		
Current SI Performance Percent Goal Met	93.9%	94.9%	93.1%		

**Table 2.2 CDRH – PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	183	178	107		
Non-MDUFA III Decisions	10	6	2		
MDUFA III Decisions	172	151	19		
MDUFA III Decisions Goal Met	169	151	19		
Supplements pending MDUFA III Decision	1	25	86		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.3%	100%	100%		

**Table 2.3 CDRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	183	178	107		
Number with MDUFA decision	172	151	19		
Number of Not Approvable	11	2	0		
Rate of Not Approvable	6.4%	1.3%	0%		

**Table 2.4 CDRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3	0	0		
Mean FDA days for submissions that missed goal	219	0	0		
Mean Industry days for submissions that missed goal	154	0	0		

## Section 2 PMA 180 Day Supplements - Office Level

**Table 2.1.ODE - CDRH – PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	162	165	90		
SI Goal Met	148	155	49		
SI Goal Not Met	11	9	3		
SI Pending Within Goal	0	0	37		
SI Pending Past Goal	0	0	1		
Closed without SI	3	1	0		
Current SI Performance Percent Goal Met	93.1%	94.5%	92.5%		

**Table 2.2.ODE - CDRH – PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	162	165	90		
Non-MDUFA III Decisions	9	2	0		
MDUFA III Decisions	152	142	17		
MDUFA III Decisions Goal Met	149	142	17		
Supplements pending MDUFA III Decision	1	21	73		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.0%	100%	100%		



**Table 2.3.ODE - CDRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	162	165	90		
Number with MDUFA decision	152	142	17		
Number of Not Approvable	11	2	0		
Rate of Not Approvable	7.2%	1.4%	0%		

**Table 2.4.ODE - CDRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3	0	0		
Mean FDA days for submissions that missed goal	219	0	0		
Mean Industry days for submissions that missed goal	154	0	0		

**Table 2.1.OIR - CDRH – PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	21	13	17		
SI Goal Met	21	13	5		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	10		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	2		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 2.2.OIR - CDRH – PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	21	13	17		
Non-MDUFA III Decisions	1	0	2		
MDUFA III Decisions	20	9	2		
MDUFA III Decisions Goal Met	20	9	2		
Supplements pending MDUFA III Decision	0	4	13		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 2.3.OIR - CDRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	21	13	17		
Number with MDUFA decision	20	9	2		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

**Table 2.4.OIR - CDRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

## Section 2 PMA 180 Day Supplements - Division Level

**Table 2.1.DAGRID - ODE - PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	10	9	5		
SI Goal Met	8	7	1		
SI Goal Not Met	2	2	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	80.0%	77.8%	100%		

**Table 2.2.DAGRID - ODE - PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	10	9	5		
Non-MDUFA III Decisions	2	1	0		
MDUFA III Decisions	7	4	0		
MDUFA III Decisions Goal Met	6	4	0		
Supplements pending MDUFA III Decision	1	4	5		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	85.7%	100%	N/A		

**Table 2.3.DAGRID DAGRID - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	9	5		
Number with MDUFA decision	7	4	0		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	14.3%	0%	N/A		

**Table 2.4.DAGRID - ODE - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0		
Mean FDA days for submissions that missed goal	213	0	0		
Mean Industry days for submissions that missed goal	103	0	0		

**Table 2.1.DCD - ODE - PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	116	94	55		
SI Goal Met	108	93	33		
SI Goal Not Met	5	1	0		
SI Pending Within Goal	0	0	22		
SI Pending Past Goal	0	0	0		
Closed without SI	3	0	0		
Current SI Performance Percent Goal Met	95.6%	98.9%	100%		

**Table 2.2.DCD - ODE - PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	116	94	55		
Non-MDUFA III Decisions	4	0	0		
MDUFA III Decisions	112	91	10		
MDUFA III Decisions Goal Met	111	91	10		
Supplements pending MDUFA III Decision	0	3	45		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	99.1%	100%	100%		

**Table 2.3.DCD DCD - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	116	94	55		
Number with MDUFA decision	112	91	10		
Number of Not Approvable	6	0	0		
Rate of Not Approvable	5.4%	0%	0%		

**Table 2.4.DCD - ODE - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0		
Mean FDA days for submissions that missed goal	182	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DNPMD - ODE - PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	8	14	6		
SI Goal Met	7	13	4		
SI Goal Not Met	1	0	1		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed without SI	0	1	0		
Current SI Performance Percent Goal Met	87.5%	100%	80.0%		

**Table 2.2.DNPMD - ODE - PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	8	14	6		
Non-MDUFA III Decisions	2	1	0		
MDUFA III Decisions	6	12	1		
MDUFA III Decisions Goal Met	6	12	1		
Supplements pending MDUFA III Decision	0	1	5		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		



**Table 2.3.DNPMD DNPMD - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	14	6		
Number with MDUFA decision	6	12	1		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	16.7%	0%	0%		

**Table 2.4.DNPMD - ODE - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DOD - ODE - PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	2	4	1		
SI Goal Met	2	2	1		
SI Goal Not Met	0	2	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	50.0%	100%		

**Table 2.2.DOD - ODE - PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	2	4	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	2	2	1		
MDUFA III Decisions Goal Met	2	2	1		
Supplements pending MDUFA III Decision	0	2	0		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 2.3.DOD DOD - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	4	1		
Number with MDUFA decision	2	2	1		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

**Table 2.4.DOD - ODE - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DOED - ODE - PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	12	24	13		
SI Goal Met	11	24	5		
SI Goal Not Met	1	0	1		
SI Pending Within Goal	0	0	7		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	91.7%	100%	83.3%		

**Table 2.2.DOED - ODE - PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	12	24	13		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	12	16	3		
MDUFA III Decisions Goal Met	12	16	3		
Supplements pending MDUFA III Decision	0	8	10		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 2.3.DOED DOED - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	12	24	13		
Number with MDUFA decision	12	16	3		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	8.3%	0%	0%		

**Table 2.4.DOED - ODE - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DRGUD - ODE - PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	10	7	5		
SI Goal Met	9	7	3		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	90.0%	100%	100%		

**Table 2.2.DRGUD - ODE - PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	10	7	5		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	10	6	1		
MDUFA III Decisions Goal Met	10	6	1		
Supplements pending MDUFA III Decision	0	1	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 2.3.DRGUD DRGUD - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	7	5		
Number with MDUFA decision	10	6	1		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	10.0%	16.7%	0%		

**Table 2.4.DRGUD - ODE - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DSD - ODE - PMA 180 Day Supplements Substantive Interaction Goals**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>Substantive Interaction (SI) Goals:</b>	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	4	13	5		
SI Goal Met	3	9	2		
SI Goal Not Met	1	4	1		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	1		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	75.0%	69.2%	50.0%		

**Table 2.2.DSD - ODE - PMA 180 Day Supplements MDUFA Decision Performance Goals**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>Performance Goals:</b>	<b>85% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>95% within 180 FDA days</b>	<b>95% within 180 FDA days</b>
Supplements received	4	13	5		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	3	11	1		
MDUFA III Decisions Goal Met	2	11	1		
Supplements pending MDUFA III Decision	0	2	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	66.7%	100%	100%		



**Table 2.3.DSD DSD - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	13	5		
Number with MDUFA decision	3	11	1		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	33.3%	9.1%	0%		

**Table 2.4.DSD - ODE - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0		
Mean FDA days for submissions that missed goal	261	0	0		
Mean Industry days for submissions that missed goal	358	0	0		

**Table 2.1.DCTD - OIR - PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	3	3	3		
SI Goal Met	3	3	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	N/A		

**Table 2.2.DCTD - OIR - PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>85% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>95% within 180 FDA days</b>	<b>95% within 180 FDA days</b>
Supplements received	3	3	3		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	3	1	0		
MDUFA III Decisions Goal Met	3	1	0		
Supplements pending MDUFA III Decision	0	2	3		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	N/A		

**Table 2.3.DCTD DCTD - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	3	3		
Number with MDUFA decision	3	1	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	N/A		

**Table 2.4.DCTD - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DIHD - OIR - PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	1	1	0		
SI Goal Met	1	1	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	N/A		

**Table 2.2.DIHD - OIR - PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	1	1	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	0	0		
MDUFA III Decisions Goal Met	1	0	0		
Supplements pending MDUFA III Decision	0	1	0		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	N/A		

**Table 2.3.DIHD DIHD - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	1	0		
Number with MDUFA decision	1	0	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	N/A	N/A		

**Table 2.4.DIHD - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DMD - OIR - PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	7	4	1		
SI Goal Met	7	4	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 2.2.DMD - OIR - PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>85% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>95% within 180 FDA days</b>	<b>95% within 180 FDA days</b>
Supplements received	7	4	1		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	6	4	1		
MDUFA III Decisions Goal Met	6	4	1		
Supplements pending MDUFA III Decision	0	0	0		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 2.3.DMD DMD - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	4	1		
Number with MDUFA decision	6	4	1		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

**Table 2.4.DMD - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DMGP - OIR - PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	5	4	10		
SI Goal Met	5	4	3		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	5		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	2		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 2.2.DMGP - OIR - PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>85% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>95% within 180 FDA days</b>	<b>95% within 180 FDA days</b>
Supplements received	5	4	10		
Non-MDUFA III Decisions	0	0	2		
MDUFA III Decisions	5	3	0		
MDUFA III Decisions Goal Met	5	3	0		
Supplements pending MDUFA III Decision	0	1	8		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	N/A		



**Table 2.3.DMGP DMGP - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	4	10		
Number with MDUFA decision	5	3	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	N/A		

**Table 2.4.DMGP - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 2.1.DRH - OIR - PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>65% SI within 90 FDA days</b>	<b>75% SI within 90 FDA days</b>	<b>85% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>	<b>95% SI within 90 FDA days</b>
Eligible for SI	5	1	3		
SI Goal Met	5	1	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

**Table 2.2.DRH - OIR - PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>85% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>90% within 180 FDA days</b>	<b>95% within 180 FDA days</b>	<b>95% within 180 FDA days</b>
Supplements received	5	1	3		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	5	1	1		
MDUFA III Decisions Goal Met	5	1	1		
Supplements pending MDUFA III Decision	0	0	2		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 2.3.DRH DRH - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

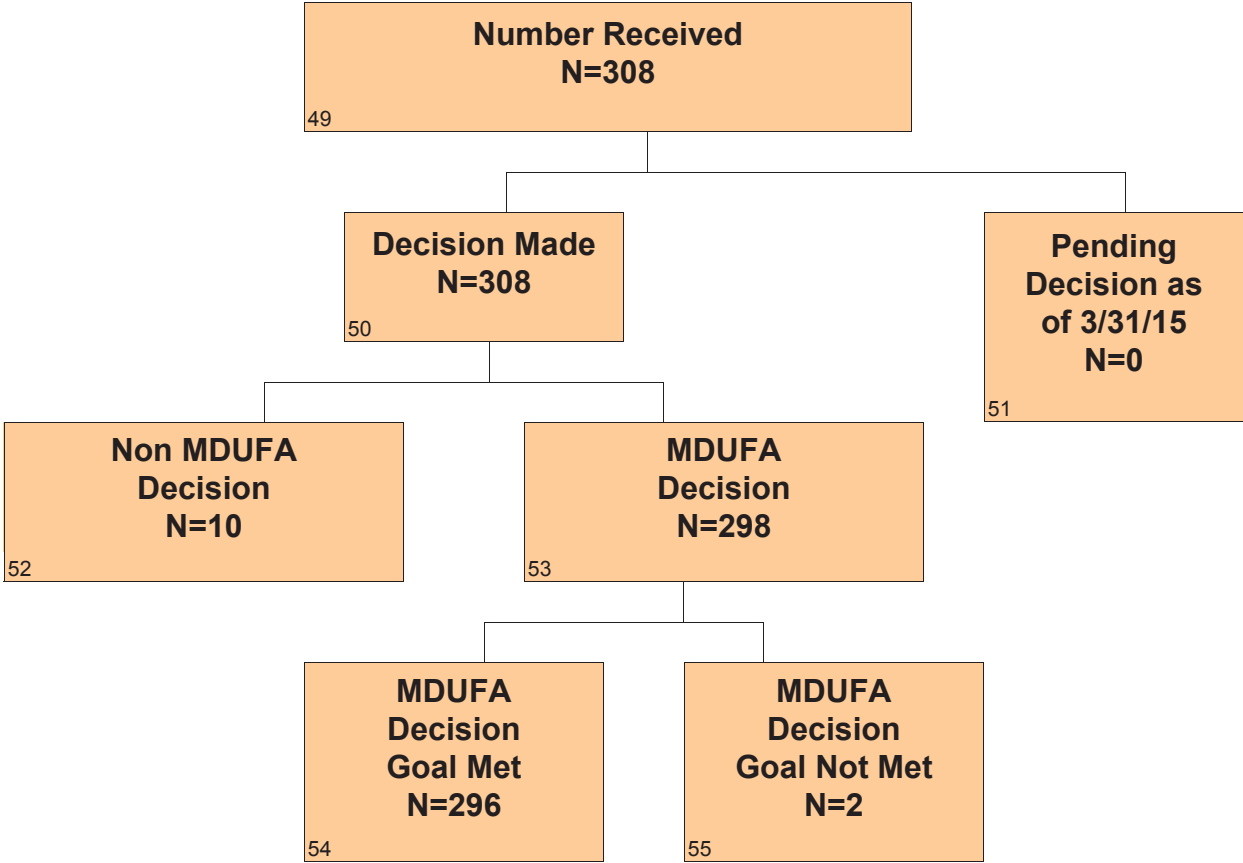
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1	3		
Number with MDUFA decision	5	1	1		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

**Table 2.4.DRH - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

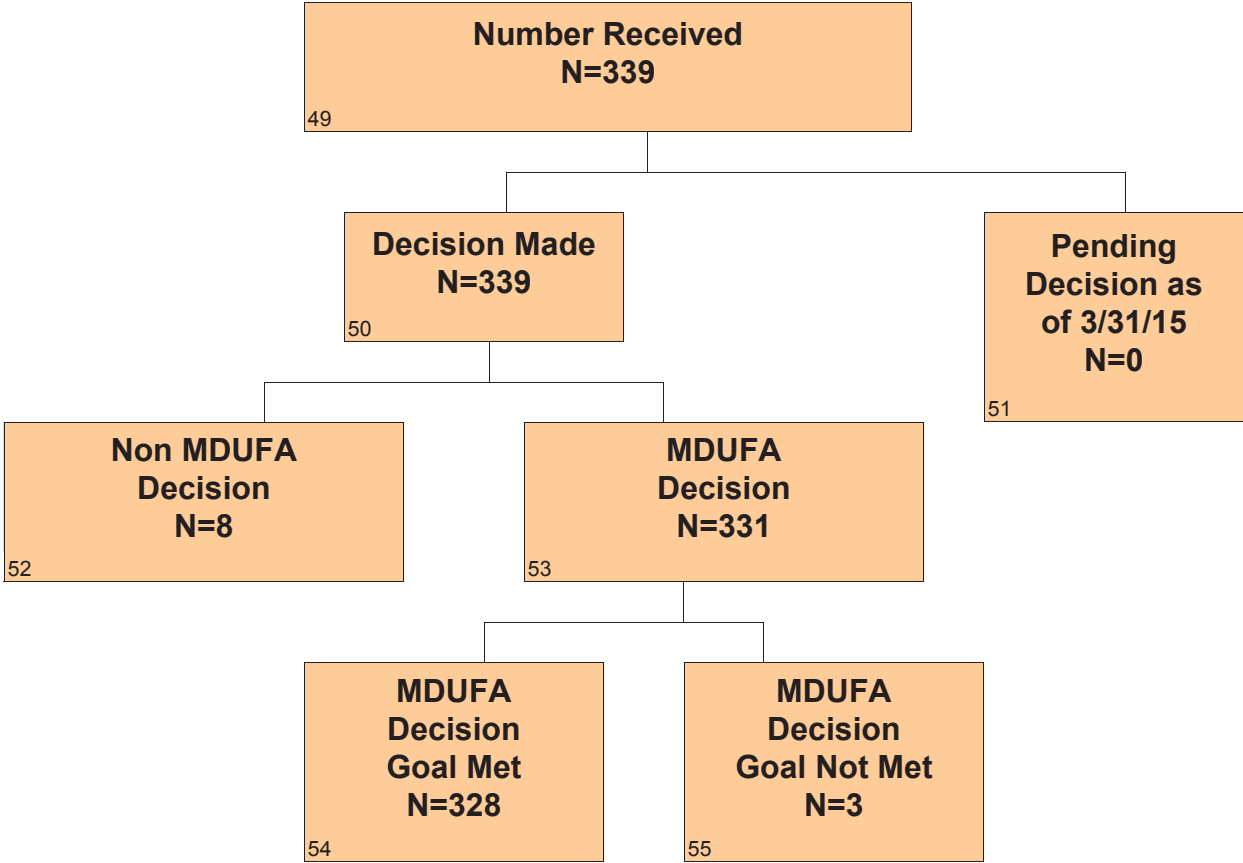
# CDRH PMA Real Time Supplements - FY 2013 As of 3/31/15

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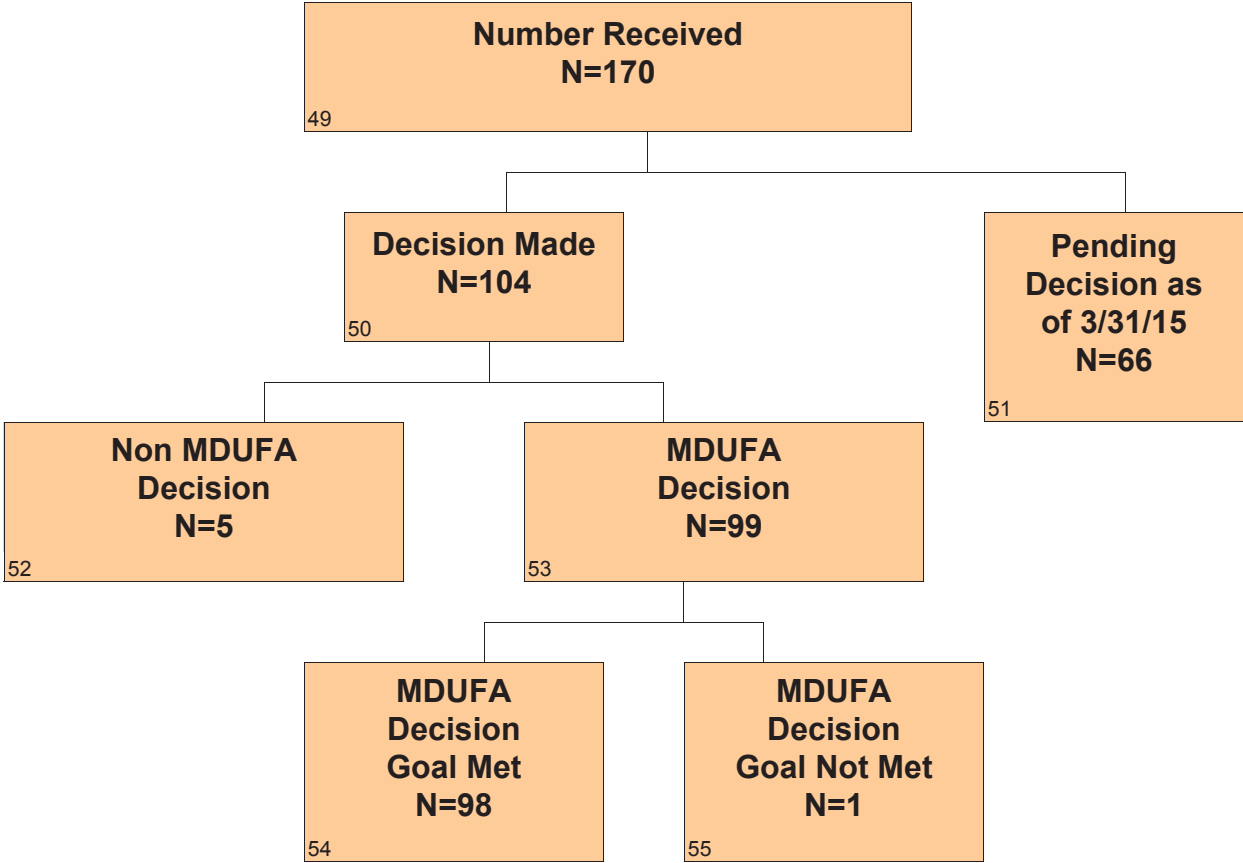
# CDRH PMA Real Time Supplements - FY 2014 As of 3/31/15

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# CDRH PMA Real Time Supplements - FY 2015 As of 3/31/15

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### Section 3 PMA Real Time Supplements - Center Level Metrics

**Table 3.1 CDRH – Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	308	339	170		
Non-MDUFA III Decisions	10	8	5		
MDUFA III Decisions	298	331	99		
MDUFA III Decisions Goal Met	296	328	98		
Supplements pending MDUFA III Decision	0	0	66		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	99.3%	99.1%	99.0%		

**Table 3.2 CDRH – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	308	339	170		
Number with MDUFA decision	298	331	99		
Number of Not Approvable	20	3	9		
Rate of Not Approvable	6.7%	0.9%	9.1%		

**Table 3.3 CDRH – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	3	1		
Mean FDA days for submissions that missed goal	143	99	97		
Mean Industry days for submissions that missed goal	0	0	0		

### Section 3 PMA Real Time Supplements - Office Level Metrics

**Table 3.1.ODE - CDRH – Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	269	283	140		
Non-MDUFA III Decisions	9	6	5		
MDUFA III Decisions	260	277	83		
MDUFA III Decisions Goal Met	258	274	82		
Supplements pending MDUFA III Decision	0	0	52		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	99.2%	98.9%	98.8%		

**Table 3.2.ODE - CDRH – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	269	283	140		
Number with MDUFA decision	260	277	83		
Number of Not Approvable	15	3	7		
Rate of Not Approvable	5.8%	1.1%	8.4%		

**Table 3.3.ODE - CDRH – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	3	1		
Mean FDA days for submissions that missed goal	143	99	97		
Mean Industry days for submissions that missed goal	0	0	0		



**Table 3.1.OIR - CDRH – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>90% within 90 FDA days</b>	<b>90% within 90 FDA days</b>	<b>95% within 90 FDA days</b>	<b>95% within 90 FDA days</b>	<b>95% within 90 FDA days</b>
Supplements received	39	56	30		
Non-MDUFA III Decisions	1	2	0		
MDUFA III Decisions	38	54	16		
MDUFA III Decisions Goal Met	38	54	16		
Supplements pending MDUFA III Decision	0	0	14		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 3.2.OIR - CDRH – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	39	56	30		
Number with MDUFA decision	38	54	16		
Number of Not Approvable	5	0	2		
Rate of Not Approvable	13.2%	0%	12.5%		

**Table 3.3.OIR - CDRH – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

### Section 3 PMA Real Time Supplements - Division Level Metrics

**Table 3.1.DAGRID - ODE - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	13	8	1		
Non-MDUFA III Decisions	0	1	0		
MDUFA III Decisions	13	7	1		
MDUFA III Decisions Goal Met	13	5	1		
Supplements pending MDUFA III Decision	0	0	0		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	71.4%	100%		

**Table 3.2.DAGRID - ODE - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	13	8	1		
Number with MDUFA decision	13	7	1		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	7.7%	14.3%	0.0%		

**Table 3.3.DAGRID - ODE - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	2	0		
Mean FDA days for submissions that missed goal	0	101	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DCD - ODE - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	176	218	96		
Non-MDUFA III Decisions	6	3	4		
MDUFA III Decisions	170	215	57		
MDUFA III Decisions Goal Met	170	215	56		
Supplements pending MDUFA III Decision	0	0	35		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	98.2%		

**Table 3.2.DCD - ODE - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	176	218	96		
Number with MDUFA decision	170	215	57		
Number of Not Approvable	7	1	7		
Rate of Not Approvable	4.1%	0.5%	12.3%		

**Table 3.3.DCD - ODE - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	1		
Mean FDA days for submissions that missed goal	0	0	97		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DNPMD - ODE - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	23	17	11		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	23	17	7		
MDUFA III Decisions Goal Met	23	16	7		
Supplements pending MDUFA III Decision	0	0	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	94.1%	100%		

**Table 3.2.DNPMD - ODE - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	23	17	11		
Number with MDUFA decision	23	17	7		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	4.3%	5.9%	0%		

**Table 3.3.DNPMD - ODE - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	1	0		
Mean FDA days for submissions that missed goal	0	97	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DOD - ODE - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	8	10	7		
Non-MDUFA III Decisions	0	2	1		
MDUFA III Decisions	8	8	5		
MDUFA III Decisions Goal Met	8	8	5		
Supplements pending MDUFA III Decision	0	0	1		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 3.2.DOD - ODE - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	10	7		
Number with MDUFA decision	8	8	5		
Number of Not Approvable	2	0	0		
Rate of Not Approvable	25.0%	0%	0%		

**Table 3.3.DOD - ODE - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DOED - ODE - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	16	17	16		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	16	17	9		
MDUFA III Decisions Goal Met	16	17	9		
Supplements pending MDUFA III Decision	0	0	7		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 3.2.DOED - ODE - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	16	17	16		
Number with MDUFA decision	16	17	9		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

**Table 3.3.DOED - ODE - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DRGUD - ODE - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	19	2	7		
Non-MDUFA III Decisions	2	0	0		
MDUFA III Decisions	17	2	3		
MDUFA III Decisions Goal Met	17	2	3		
Supplements pending MDUFA III Decision	0	0	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 3.2.DRGUD - ODE - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	19	2	7		
Number with MDUFA decision	17	2	3		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	5.9%	0%	0%		

**Table 3.3.DRGUD - ODE - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DSD - ODE - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	14	11	2		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	13	11	1		
MDUFA III Decisions Goal Met	11	11	1		
Supplements pending MDUFA III Decision	0	0	1		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	84.6%	100%	100%		

**Table 3.2.DSD - ODE - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	14	11	2		
Number with MDUFA decision	13	11	1		
Number of Not Approvable	3	0	0		
Rate of Not Approvable	23.1%	0%	0%		

**Table 3.3.DSD - ODE - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0		
Mean FDA days for submissions that missed goal	143	0	0		
Mean Industry days for submissions that missed goal	0	0	0		



**Table 3.1.DCTD - OIR - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	6	19	12		
Non-MDUFA III Decisions	0	2	0		
MDUFA III Decisions	6	17	7		
MDUFA III Decisions Goal Met	6	17	7		
Supplements pending MDUFA III Decision	0	0	5		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 3.2.DCTD - OIR - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	19	12		
Number with MDUFA decision	6	17	7		
Number of Not Approvable	0	0	2		
Rate of Not Approvable	0%	0%	28.6%		

**Table 3.3.DCTD - OIR - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DIHD - OIR - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	12	10	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	12	10	0		
MDUFA III Decisions Goal Met	12	10	0		
Supplements pending MDUFA III Decision	0	0	0		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	N/A		

**Table 3.2.DIHD - OIR - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	12	10	0		
Number with MDUFA decision	12	10	0		
Number of Not Approvable	2	0	0		
Rate of Not Approvable	16.7%	0%	N/A		

**Table 3.3.DIHD - OIR - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DMD - OIR - Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>90% within 90 FDA days</b>	<b>90% within 90 FDA days</b>	<b>95% within 90 FDA days</b>	<b>95% within 90 FDA days</b>	<b>95% within 90 FDA days</b>
Supplements received	13	12	10		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	13	12	6		
MDUFA III Decisions Goal Met	13	12	6		
Supplements pending MDUFA III Decision	0	0	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 3.2.DMD - OIR - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	13	12	10		
Number with MDUFA decision	13	12	6		
Number of Not Approvable	3	0	0		
Rate of Not Approvable	23.1%	0%	0%		

**Table 3.3.DMD - OIR - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DMGP - OIR - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	8	13	6		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	7	13	2		
MDUFA III Decisions Goal Met	7	13	2		
Supplements pending MDUFA III Decision	0	0	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 3.2.DMGP - OIR - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	13	6		
Number with MDUFA decision	7	13	2		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

**Table 3.3.DMGP - OIR - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

**Table 3.1.DRH - OIR - Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	0	2	2		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	2	1		
MDUFA III Decisions Goal Met	0	2	1		
Supplements pending MDUFA III Decision	0	0	1		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	100%	100%		

**Table 3.2.DRH - OIR - Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	2	2		
Number with MDUFA decision	0	2	1		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	N/A	0%	0%		

**Table 3.3.DRH - OIR - Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

## **Section 4 Pre-Market Report Submissions**

There were no pre-market reports received by FDA between October 1, 2014 and March 31, 2015.

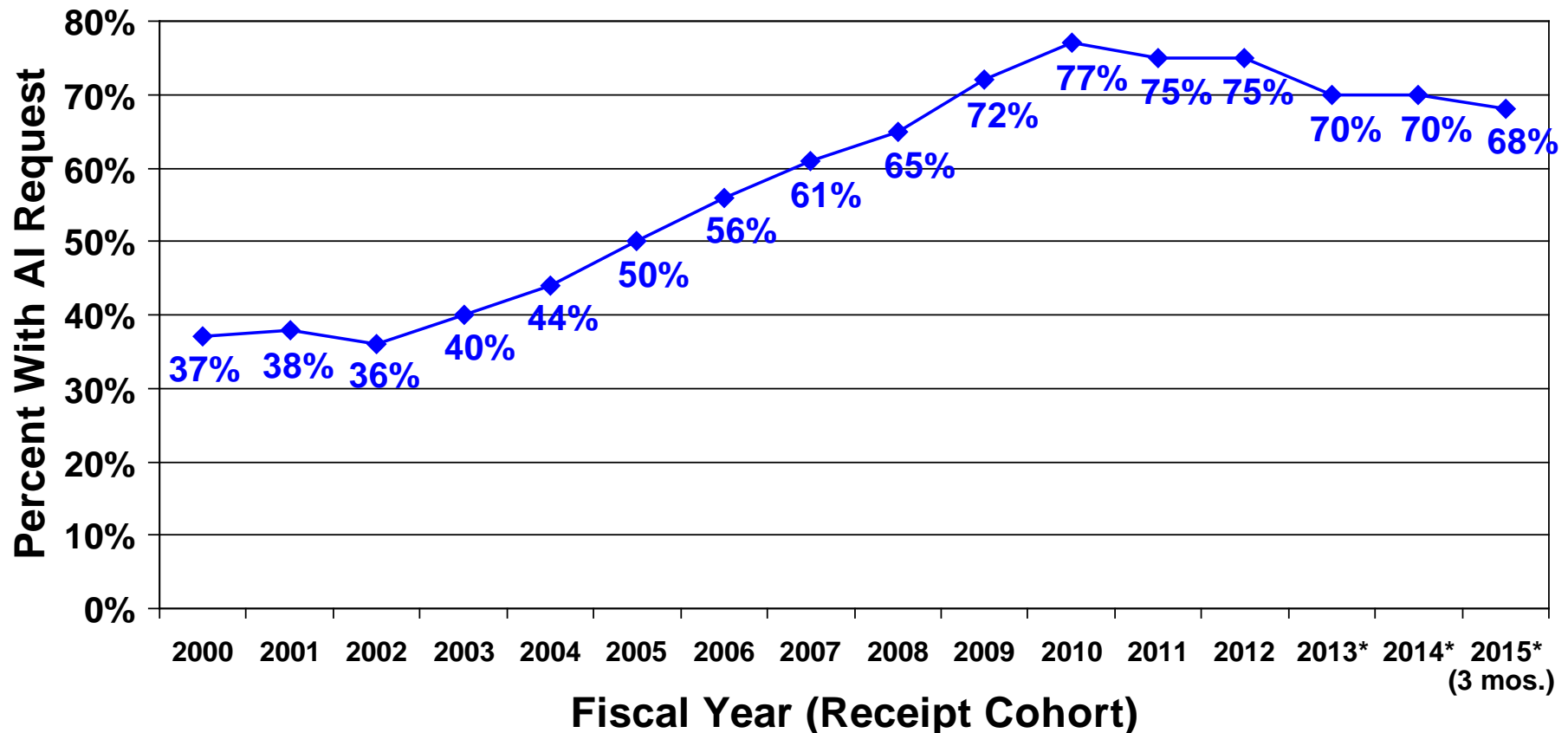
## **Section 5 PMA Annual Metrics and Goals**

PMA Annual Metrics and Goals will be reported in the Annual Report.

510(k)s

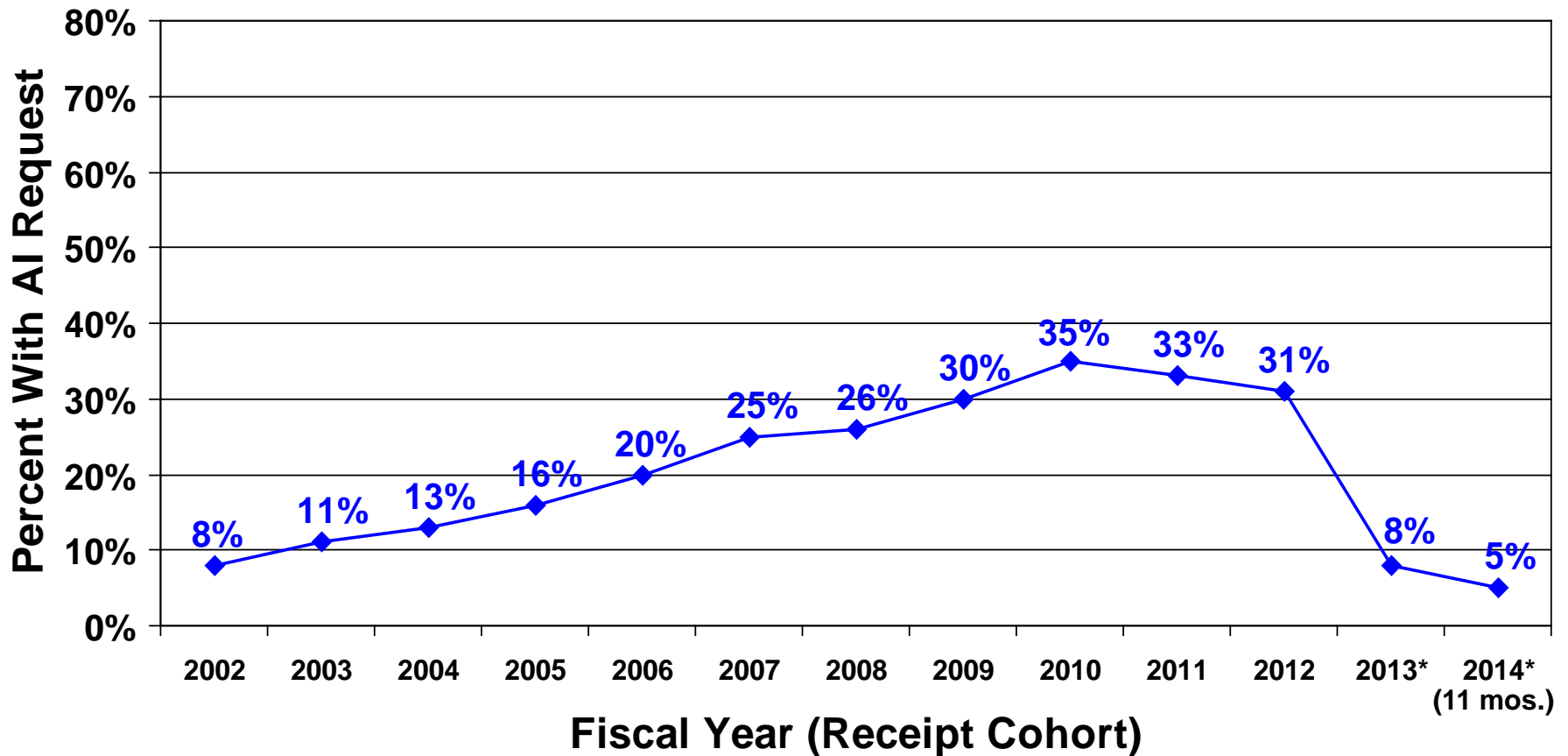


# Percent of 510(k)s With Additional Information (AI) Request on 1<sup>st</sup> FDA Review Cycle



\*FY 2013 - FY 2015 data are based on the 1<sup>st</sup> substantive review cycle (i.e., excluding RTA cycles) for submissions accepted as of 12/31/2014; FY 2015 1<sup>st</sup> cycle cohort is still open and data may change

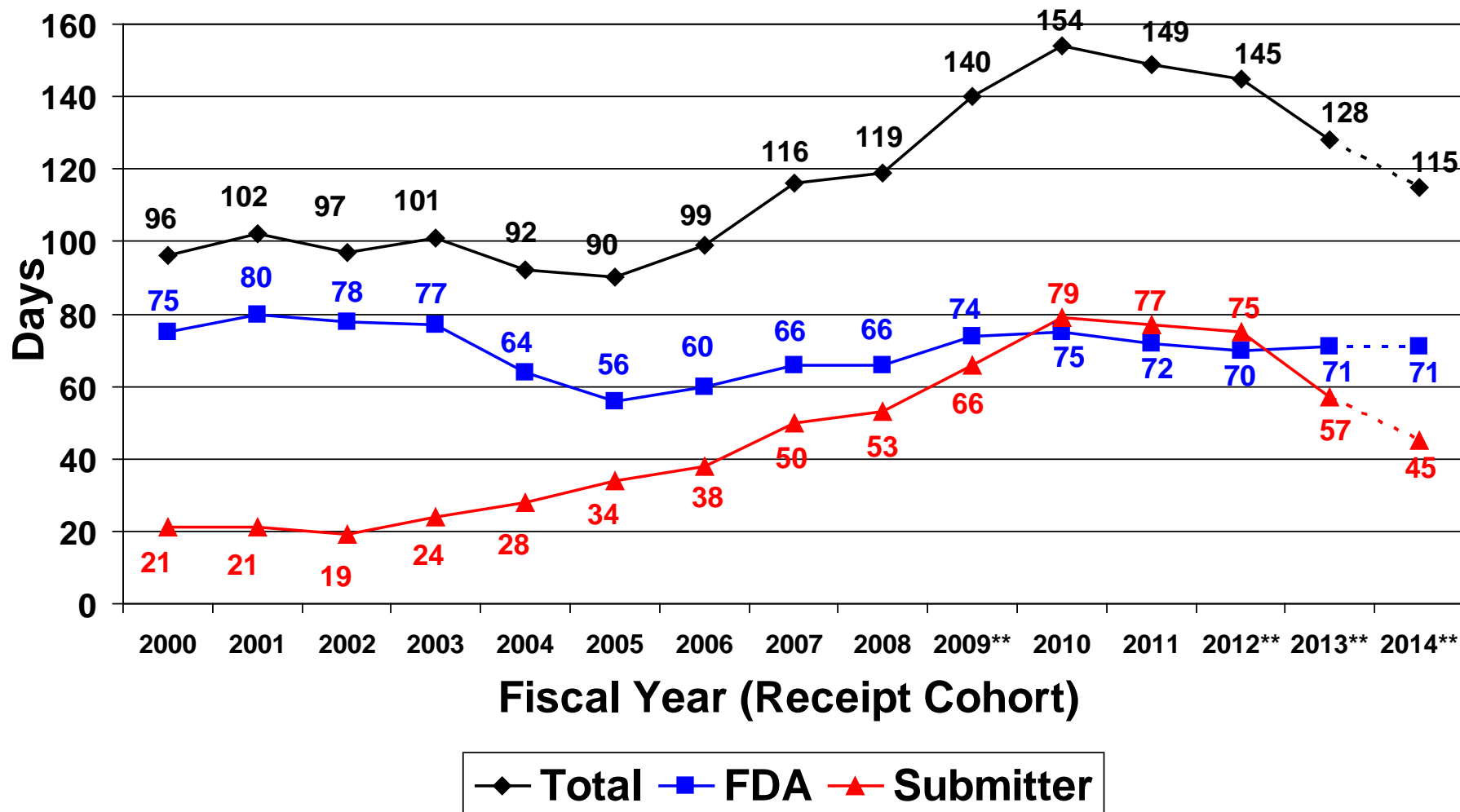
# Percent of 510(k)s With Additional Information (AI) Request on 2<sup>nd</sup> FDA Review Cycle



\*FY 2013 and FY 2014 data are for 510(k)s accepted as of 08/31/2014; FY 2014 2<sup>nd</sup> cycle cohort is still open and data may change

# Average Time to Decision: 510(k)s\*

(Receipt Cohorts as of March 31, 2015)

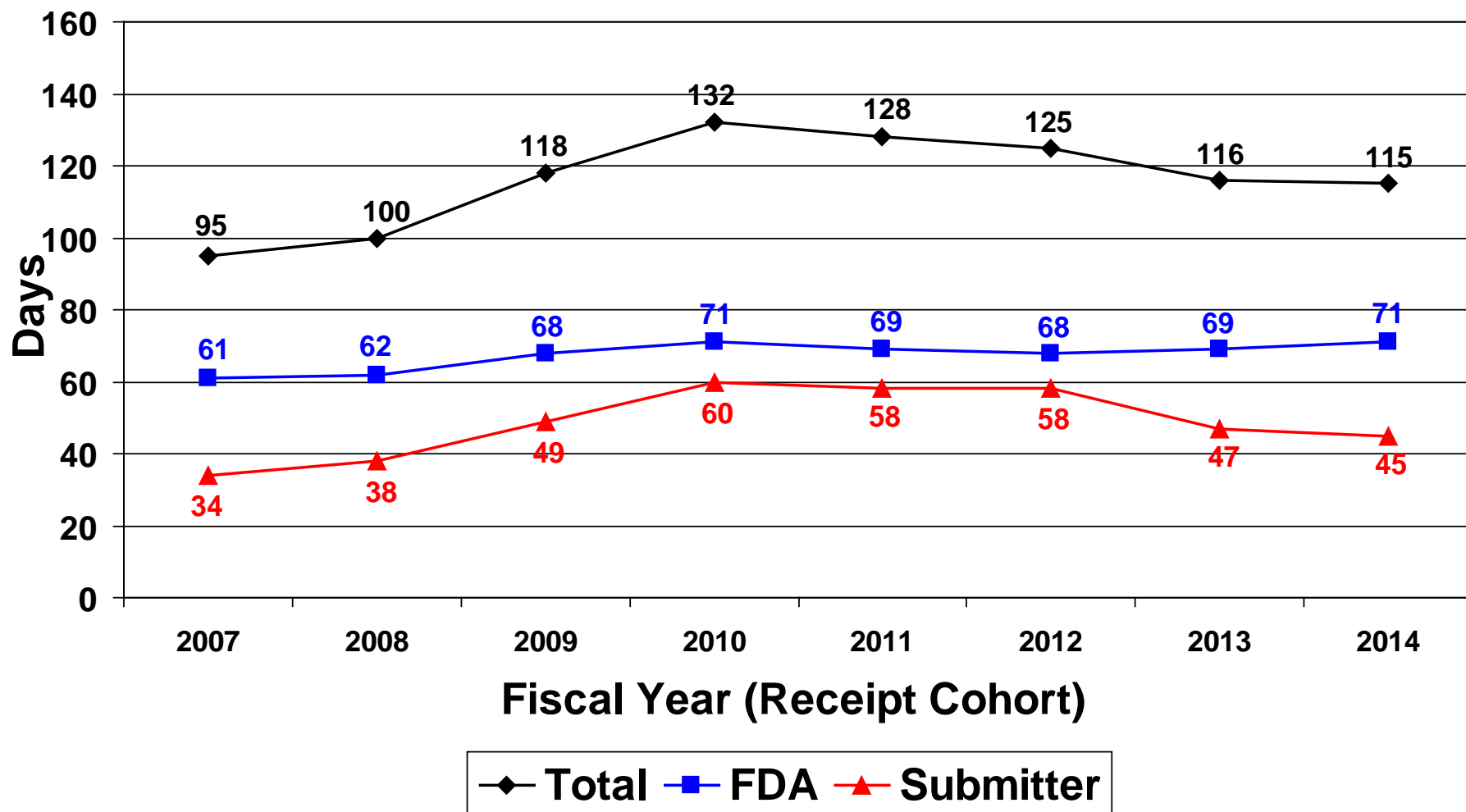


\*SE and NSE decisions only; times may not add to total due to rounding

\*\*Cohorts still open; percentage of cohort closed: FY 2009 = 99.9%, FY 2012 = 99.9%, FY 2013 = 99.9% and FY 2014 = 88.3%—average times for FY 2014 will increase

# Average Time to Decision: 510(k)s\*

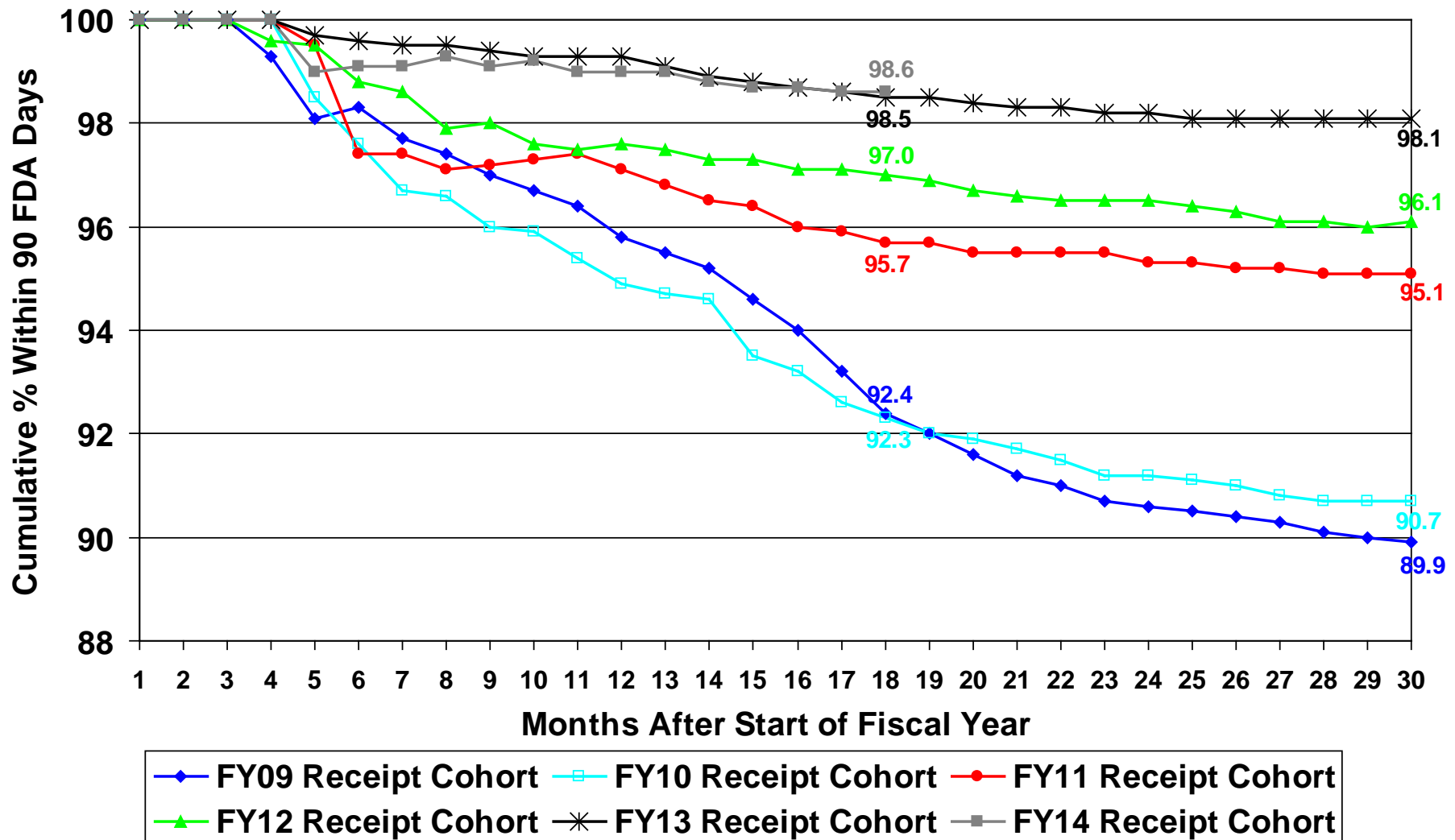
- Comparison of Receipt Cohorts When 88.3% Closed -



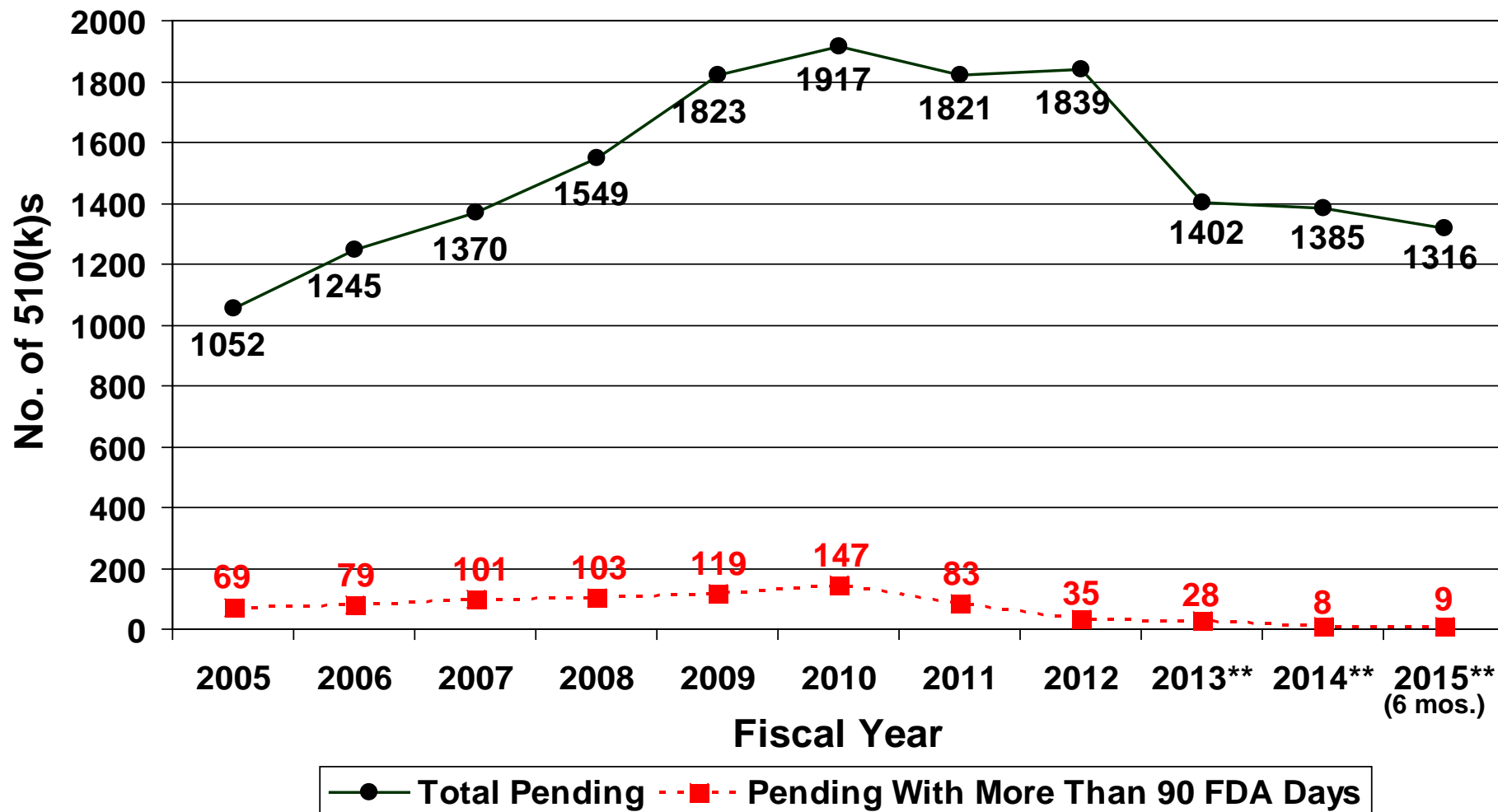
\*SE and NSE decisions only; times may not add to total due to rounding

# Trend in 510(k) MDUFA Decision Goal Performance

## - Comparison of FY09 - FY14 Receipt Cohorts -



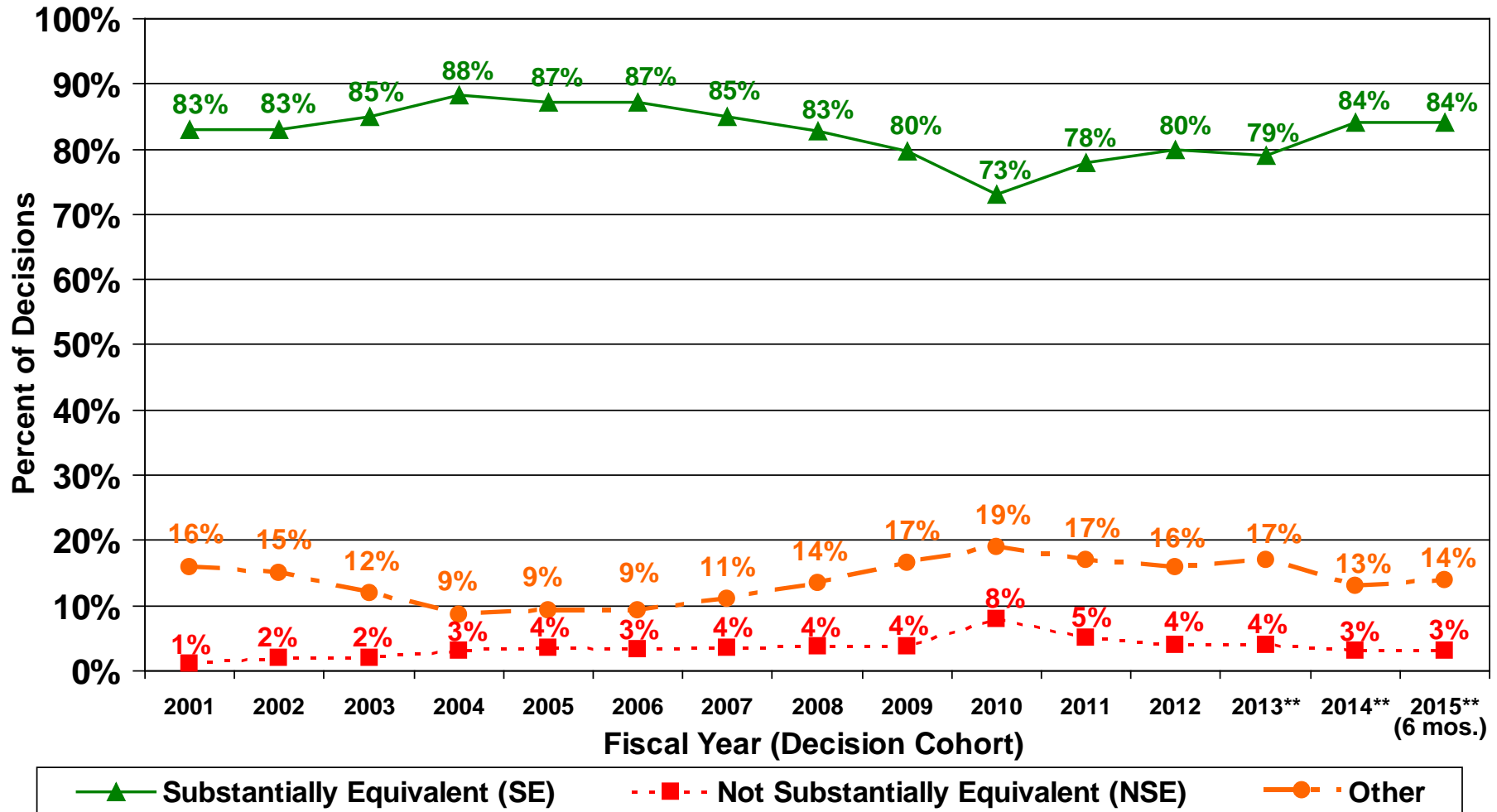
# 510(k)s Pending\* at End of Year



\*Under review or on hold; FY 2015 is as of 03/31/2015

\*\*Excludes FY 2013 - FY 2015 receipts that were not accepted for review as of end of year

# Percent of 510(k)s Determined to be Substantially Equivalent (SE)\*



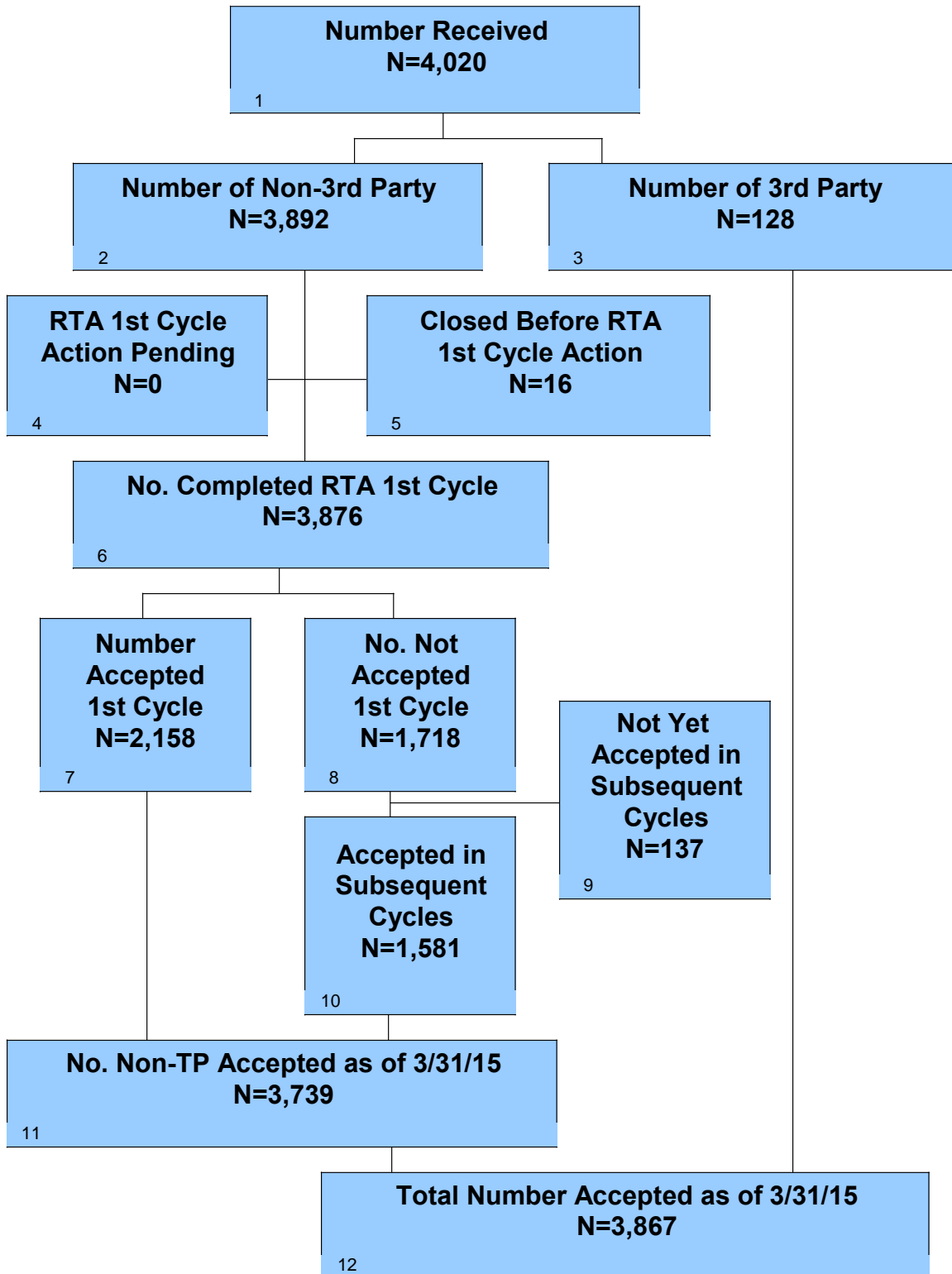
\*Percentages may not add to 100% due to rounding

\*\*Excludes final decisions made on FY 2013 - FY 2015 receipts that were not accepted for review as of 03/31/2015

# CDRH 510(k)s - FY 2013

## As of 3/31/15

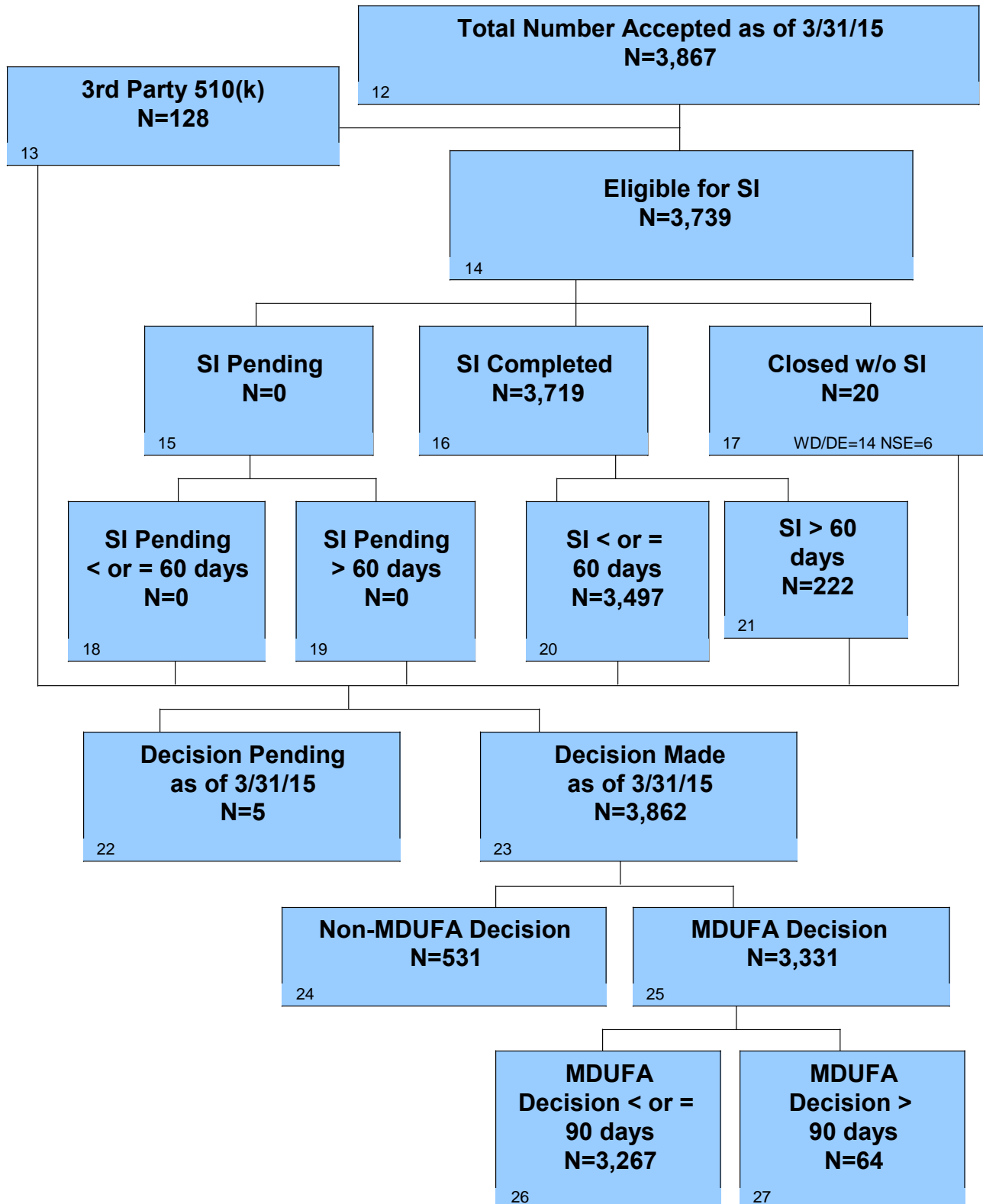
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# CDRH 510(k)s - FY 2013

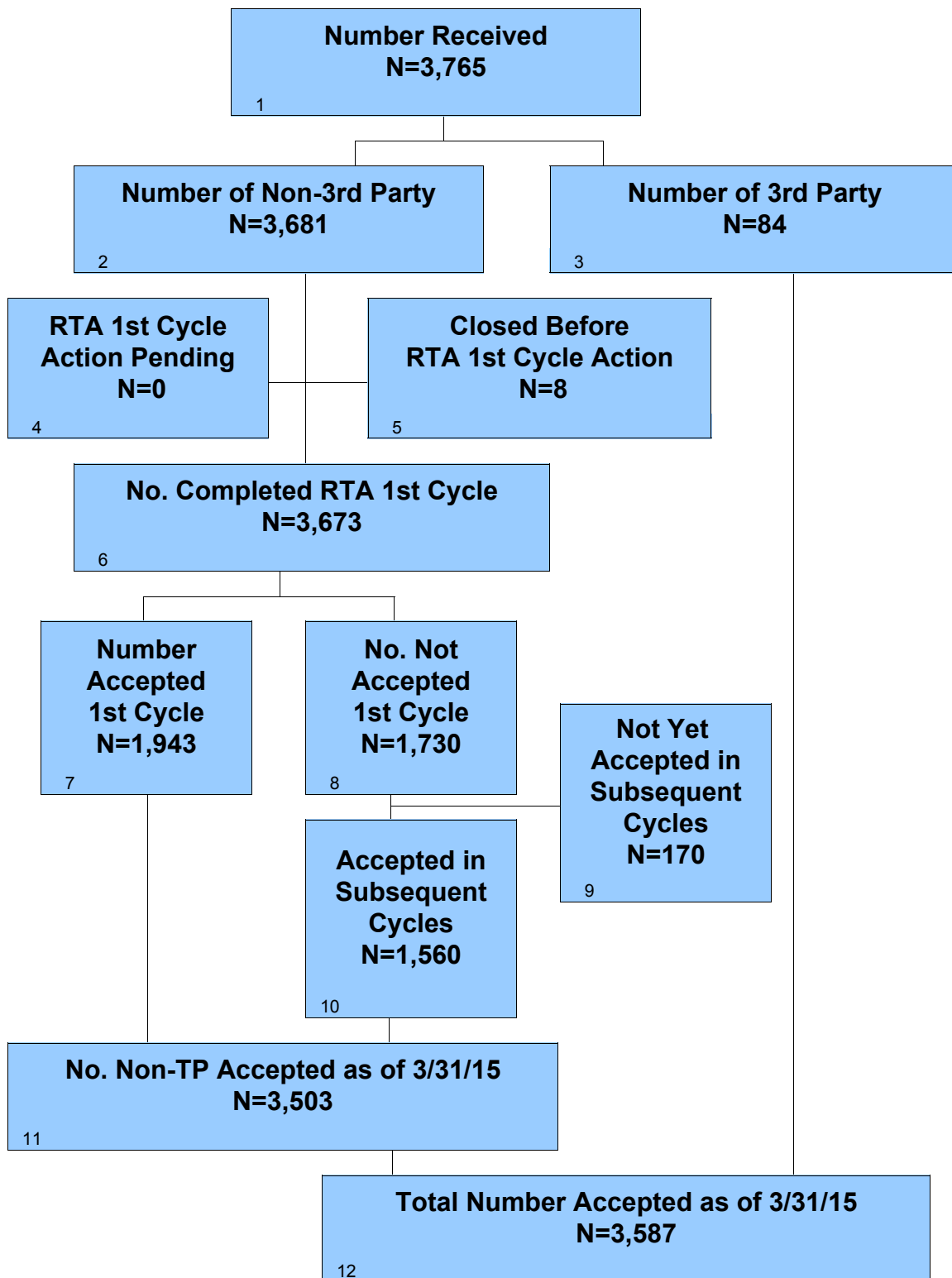
## As of 3/31/15 Cobhbi YX



# CDRH 510(k)s - FY 2014

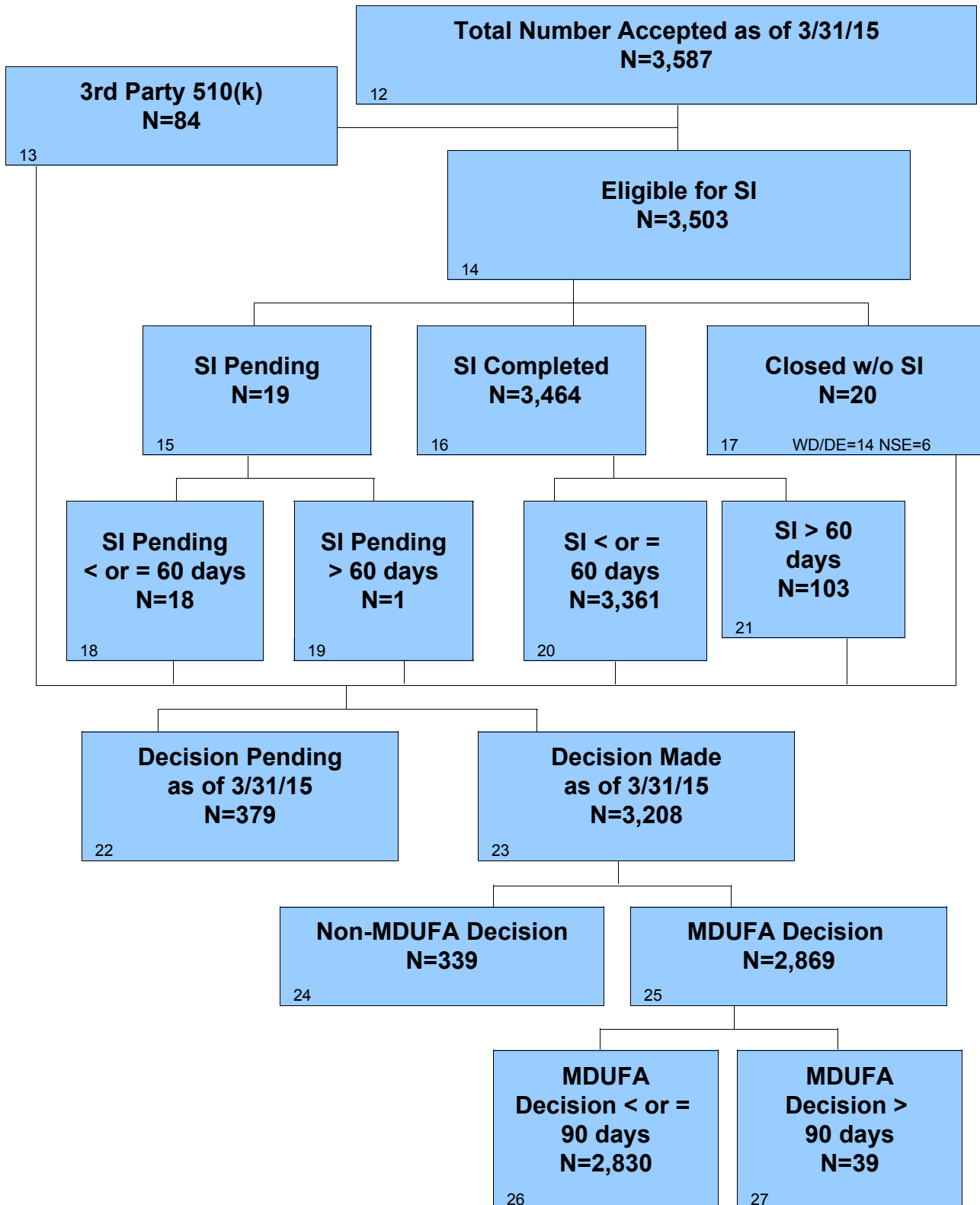
## As of 3/31/15

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# CDRH 510(k)s - FY 2014

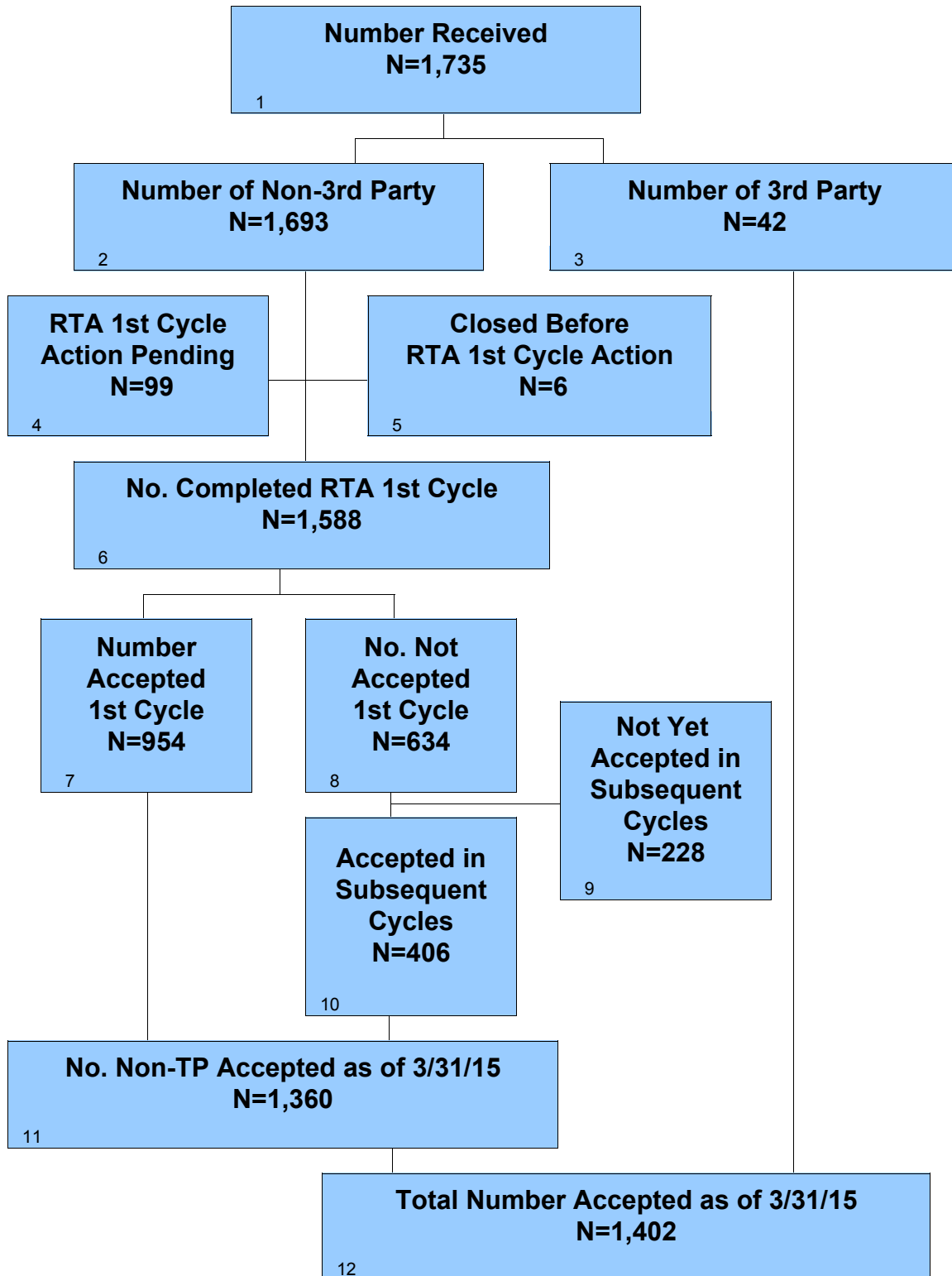
## As of 3/31/15 Continued



# CDRH 510(k)s - FY 2015

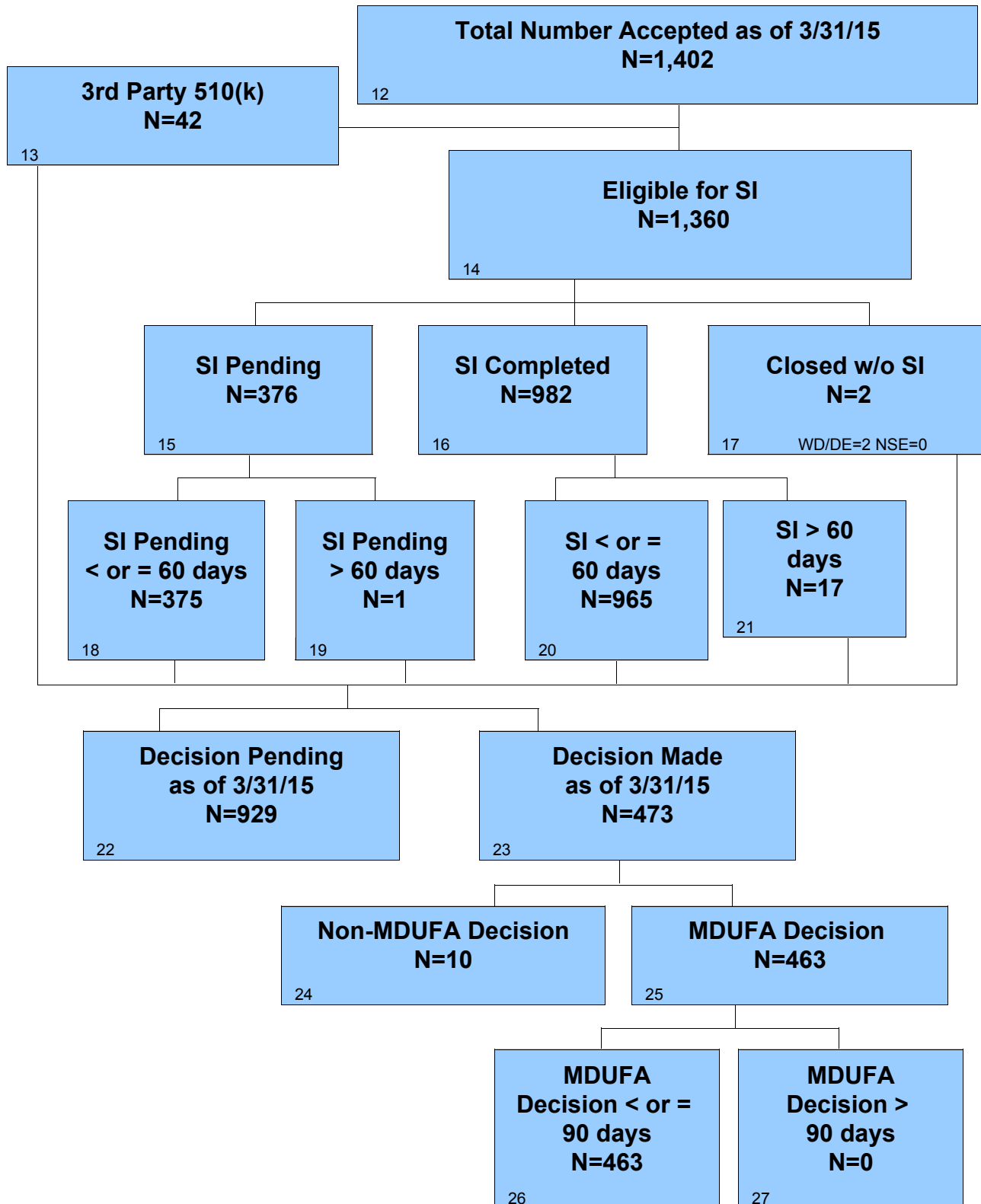
## As of 3/31/15

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# CDRH 510(k)s - FY 2015

## As of 3/31/15 Continued



## Section 6 510(k) Center Level Metrics

**Table 6.1 CDRH – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,965	3,681	1,693		
Closed before RTA action	11	8	6		
Number Accepted	1,197	1,886	938		
Number without a RTA Review and > 15 Days since Date Received	42	57	16		
Number without a RTA Review and <= 15 Days since Date Received	0	0	99		
Number Not Accepted	1,715	1,730	634		
Rate of submissions not accepted for filing review	58.1%	47.1%	39.9%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2 CDRH – 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	3,739	3,503	1,360		
Deleted or withdrawn prior to SI	14	14	2		
SI within 60 FDA days	3,497	3,361	965		
SI over 60 FDA days	222	103	17		
SI pending within 60 FDA days	0	18	375		
SI pending over 60 FDA days	0	1	1		
510(k)s NSE without SI	6	6	0		
Current SI Performance Percent within 60 FDA days	93.9%	96.8%	98.2%		

**Table 6.3 CDRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	3,719	3,464	982		
Average number of FDA days to Substantive Interaction	47.6	49.3	47.6		
20th Percentile FDA days to Substantive Interaction	30	33	30		
40th Percentile FDA days to Substantive Interaction	48	51	49		
60th Percentile FDA days to Substantive Interaction	56	57	56		
80th Percentile FDA days to Substantive Interaction	59	59	59		
Maximum FDA days to Substantive Interaction	98	100	92		

**Table 6.4 CDRH – 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	3,867	3,587	1,402		
Non-MDUFA III Decisions	531	339	10		
MDUFA III Decisions (SE/NSE)	3,331	2,869	463		
MDUFA III Decisions within 90 FDA Days	3,267	2,830	463		
510(k)s pending MDUFA III Decision	5	379	929		
510(k) pending MDUFA III Decision over 90 FDA days	0	4	4		
Current Performance Percent within 90 FDA Days	98.1%	98.5%	99.1%		

**Table 6.5 CDRH – 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.7	1.4		
Number with MDUFA III decision	3,331	2,869	463		
<b>Average FDA days to MDUFA III decision</b>	70.7	70.6	57.1		
20th Percentile FDA days to MDUFA III decision	48	49	29		
40th Percentile FDA days to MDUFA III decision	76	77	49		
60th Percentile FDA days to MDUFA III decision	86	87	70		
80th Percentile FDA days to MDUFA III decision	89	89	87		
Maximum FDA days to MDUFA III decision	342	245	90		
<b>Average Industry days to MDUFA III decision</b>	56.8	44.7	9.8		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	14	9	0		
60th Percentile Industry days to MDUFA III decision	44	34	0		
80th Percentile Industry days to MDUFA III decision	116	85	19		
Maximum Industry days to MDUFA III decision	448	359	99		
<b>Average Total days to MDUFA III decision</b>	127.6	115.3	66.9		
20th Percentile Total days to MDUFA III decision	56	55	29		
40th Percentile Total days to MDUFA III decision	90	88	53		
60th Percentile Total days to MDUFA III decision	127	117	82		
80th Percentile Total days to MDUFA III decision	199	171	100		
Maximum Total days to MDUFA III decision	691	447	174		



**Table 6.6 CDRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,867	3,587	1,402		
Number with MDUFA decision	3,331	2,869	463		
Number of SE decisions	3,198	2,801	463		
Number of NSE decisions	133	68	0		
Number of Withdrawals	231	166	5		
Number deleted	278	141	0		
Rate of SE decisions	96.0%	97.6%	100%		
Rate of NSE decisions	4.0%	2.4%	0%		
Rate of Withdrawals	6.0%	4.6%	0.4%		
Rate of Deleted	7.2%	3.9%	0%		

**Table 6.7 CDRH – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	64	39	0		
Mean FDA days for submissions that missed goal	119	107	N/A		
Mean industry days for submissions that missed goal	138	96	N/A		

## Section 6 510(k) Office Level Metrics

**Table 6.1.ODE - CDRH – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,389	2,955	1,394		
Closed before RTA action	9	6	5		
Number Accepted	821	1,339	717		
Number without a RTA Review and > 15 Days since Date Received	24	50	14		
Number without a RTA Review and <= 15 Days since Date Received	0	0	75		
Number Not Accepted	1,535	1,560	583		
Rate of submissions not accepted for filing review	64.5%	52.9%	44.4%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.ODE - CDRH – 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	2,976	2,812	1,112		
Deleted or withdrawn prior to SI	13	14	1		
SI within 60 FDA days	2,778	2,686	770		
SI over 60 FDA days	179	88	14		
SI pending within 60 FDA days	0	17	326		
SI pending over 60 FDA days	0	1	1		
510(k)s NSE without SI	6	6	0		
Current SI Performance Percent within 60 FDA days	93.8%	96.6%	98.1%		

**Table 6.3.ODE - CDRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2,957	2,774	784		
Average number of FDA days to Substantive Interaction	48.3	50.3	48.5		
20th Percentile FDA days to Substantive Interaction	30	37	30		
40th Percentile FDA days to Substantive Interaction	49	54	51		
60th Percentile FDA days to Substantive Interaction	57	58	57		
80th Percentile FDA days to Substantive Interaction	59	60	59		
Maximum FDA days to Substantive Interaction	98	100	92		

**Table 6.4.ODE - CDRH – 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	3,050	2,859	1,136		
Non-MDUFA III Decisions	445	286	9		
MDUFA III Decisions (SE/NSE)	2,603	2,262	355		
MDUFA III Decisions within 90 FDA Days	2,546	2,237	355		
510(k)s pending MDUFA III Decision	2	311	772		
510(k) pending MDUFA III Decision over 90 FDA days	0	4	4		
Current Performance Percent within 90 FDA Days	97.8%	98.7%	98.9%		

**Table 6.5.ODE - CDRH – 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.7	1.4		
Number with MDUFA III decision	2,603	2,262	355		
<b>Average FDA days to MDUFA III decision</b>	72.8	72.4	59.6		
20th Percentile FDA days to MDUFA III decision	53	53	29		
40th Percentile FDA days to MDUFA III decision	80	80	53		
60th Percentile FDA days to MDUFA III decision	87	87	76		
80th Percentile FDA days to MDUFA III decision	89	89	88		
Maximum FDA days to MDUFA III decision	342	245	90		
<b>Average Industry days to MDUFA III decision</b>	57.3	45.7	10.6		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	17	11	0		
60th Percentile Industry days to MDUFA III decision	46	36	2		
80th Percentile Industry days to MDUFA III decision	117	88	20		
Maximum Industry days to MDUFA III decision	438	359	99		
<b>Average Total days to MDUFA III decision</b>	130.1	118.0	70.1		
20th Percentile Total days to MDUFA III decision	59	58	29		
40th Percentile Total days to MDUFA III decision	94	90	57		
60th Percentile Total days to MDUFA III decision	129	119	86		
80th Percentile Total days to MDUFA III decision	200	174	103		
Maximum Total days to MDUFA III decision	691	447	174		

**Table 6.6.ODE - CDRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,050	2,859	1,136		
Number with MDUFA decision	2,603	2,262	355		
Number of SE decisions	2,492	2,211	355		
Number of NSE decisions	111	51	0		
Number of Withdrawals	189	136	4		
Number deleted	236	119	0		
Rate of SE decisions	95.7%	97.7%	100%		
Rate of NSE decisions	4.3%	2.3%	0%		
Rate of Withdrawals	6.2%	4.8%	0.4%		
Rate of Deleted	7.7%	4.2%	0%		

**Table 6.7.ODE - CDRH – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	57	25	0		
Mean FDA days for submissions that missed goal	121	111	N/A		
Mean industry days for submissions that missed goal	137	122	N/A		

**Table 6.1.OIR - CDRH – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	576	726	299		
Closed before RTA action	2	2	1		
Number Accepted	376	547	221		
Number without a RTA Review and > 15 Days since Date Received	18	7	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	24		
Number Not Accepted	180	170	51		
Rate of submissions not accepted for filing review	31.4%	23.5%	18.6%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.OIR - CDRH – 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	763	691	248		
Deleted or withdrawn prior to SI	1	0	1		
SI within 60 FDA days	719	675	195		
SI over 60 FDA days	43	15	3		
SI pending within 60 FDA days	0	1	49		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	94.4%	97.8%	98.5%		

**Table 6.3.OIR - CDRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	762	690	198		
Average number of FDA days to Substantive Interaction	45.0	45.6	43.8		
20th Percentile FDA days to Substantive Interaction	29	30	29		
40th Percentile FDA days to Substantive Interaction	43	45	41		
60th Percentile FDA days to Substantive Interaction	51	53	50		
80th Percentile FDA days to Substantive Interaction	58	58	58		
Maximum FDA days to Substantive Interaction	91	93	70		

**Table 6.4.OIR - CDRH – 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	817	728	266		
Non-MDUFA III Decisions	86	53	1		
MDUFA III Decisions (SE/NSE)	728	607	108		
MDUFA III Decisions within 90 FDA Days	721	593	108		
510(k)s pending MDUFA III Decision	3	68	157		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	99.0%	97.7%	100%		

**Table 6.5.OIR - CDRH – 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.6	1.3		
Number with MDUFA III decision	728	607	108		
<b>Average FDA days to MDUFA III decision</b>	63.4	64.0	48.9		
20th Percentile FDA days to MDUFA III decision	34	32	28		
40th Percentile FDA days to MDUFA III decision	58	59	31		
60th Percentile FDA days to MDUFA III decision	80	82	55		
80th Percentile FDA days to MDUFA III decision	88	88	78		
Maximum FDA days to MDUFA III decision	121	137	88		
<b>Average Industry days to MDUFA III decision</b>	55.2	41.1	7.3		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	35	28	0		
80th Percentile Industry days to MDUFA III decision	111	77	14		
Maximum Industry days to MDUFA III decision	448	353	83		
<b>Average Total days to MDUFA III decision</b>	118.6	105.1	56.3		
20th Percentile Total days to MDUFA III decision	36	32	28		
40th Percentile Total days to MDUFA III decision	77	79	33		
60th Percentile Total days to MDUFA III decision	111	104	60		
80th Percentile Total days to MDUFA III decision	190	155	86		
Maximum Total days to MDUFA III decision	538	440	148		



**Table 6.6.OIR - CDRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	817	728	266		
Number with MDUFA decision	728	607	108		
Number of SE decisions	706	590	108		
Number of NSE decisions	22	17	0		
Number of Withdrawals	42	30	1		
Number deleted	42	22	0		
Rate of SE decisions	97.0%	97.2%	100%		
Rate of NSE decisions	3.0%	2.8%	0%		
Rate of Withdrawals	5.1%	4.1%	0.4%		
Rate of Deleted	5.1%	3.0%	0%		

**Table 6.7.OIR - CDRH – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	7	14	0		
Mean FDA days for submissions that missed goal	103	100	N/A		
Mean industry days for submissions that missed goal	143	49	N/A		

## Section 6 510(k) Division Level Metrics

**Table 6.1.DAGRID - ODE - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	637	775	338		
Closed before RTA action	6	1	1		
Number Accepted	189	317	158		
Number without a RTA Review and > 15 Days since Date Received	5	14	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	11		
Number Not Accepted	437	443	166		
Rate of submissions not accepted for filing review	69.3%	57.2%	50.9%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DAGRID - ODE - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	782	717	255		
Deleted or withdrawn prior to SI	3	7	0		
SI within 60 FDA days	749	697	171		
SI over 60 FDA days	26	2	0		
SI pending within 60 FDA days	0	7	84		
SI pending over 60 FDA days	0	1	0		
510(k)s NSE without SI	4	3	0		
Current SI Performance Percent within 60 FDA days	96.1%	99.1%	100%		

**Table 6.3.DAGRID - ODE - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	775	699	171		
Average number of FDA days to Substantive Interaction	50.9	53.1	51.9		
20th Percentile FDA days to Substantive Interaction	43	50	46		
40th Percentile FDA days to Substantive Interaction	55	57	56		
60th Percentile FDA days to Substantive Interaction	58	59	58		
80th Percentile FDA days to Substantive Interaction	60	60	59		
Maximum FDA days to Substantive Interaction	90	68	60		

**Table 6.4.DAGRID - ODE - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	797	731	261		
Non-MDUFA III Decisions	164	79	4		
MDUFA III Decisions (SE/NSE)	632	542	54		
MDUFA III Decisions within 90 FDA Days	613	533	54		
510(k)s pending MDUFA III Decision	1	110	203		
510(k) pending MDUFA III Decision over 90 FDA days	0	2	0		
Current Performance Percent within 90 FDA Days	97.0%	98.0%	100%		

**Table 6.5.DAGRID - ODE - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.8	1.5		
Number with MDUFA III decision	632	542	54		
<b>Average FDA days to MDUFA III decision</b>	78.0	78.7	69.6		
20th Percentile FDA days to MDUFA III decision	63	73	30		
40th Percentile FDA days to MDUFA III decision	84	86	83		
60th Percentile FDA days to MDUFA III decision	88	88	87		
80th Percentile FDA days to MDUFA III decision	90	89	89		
Maximum FDA days to MDUFA III decision	280	107	90		
<b>Average Industry days to MDUFA III decision</b>	64.2	56.1	13.6		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	21	24	0		
60th Percentile Industry days to MDUFA III decision	54	54	14		
80th Percentile Industry days to MDUFA III decision	141	107	23		
Maximum Industry days to MDUFA III decision	420	248	70		
<b>Average Total days to MDUFA III decision</b>	142.2	134.8	83.2		
20th Percentile Total days to MDUFA III decision	78	84	43		
40th Percentile Total days to MDUFA III decision	102	105	87		
60th Percentile Total days to MDUFA III decision	140	135	98		
80th Percentile Total days to MDUFA III decision	220	193	111		
Maximum Total days to MDUFA III decision	610	345	153		

**Table 6.6.DAGRID - ODE - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	797	731	261		
Number with MDUFA decision	632	542	54		
Number of SE decisions	603	521	54		
Number of NSE decisions	29	21	0		
Number of Withdrawals	56	40	2		
Number deleted	103	28	0		
Rate of SE decisions	95.4%	96.1%	100%		
Rate of NSE decisions	4.6%	3.9%	0%		
Rate of Withdrawals	7.0%	5.5%	0.8%		
Rate of Deleted	12.9%	3.8%	0%		

**Table 6.7.DAGRID - ODE - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	19	9	0		
Mean FDA days for submissions that missed goal	125	98	N/A		
Mean industry days for submissions that missed goal	157	159	N/A		

**Table 6.1.DCD - ODE - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	336	407	169		
Closed before RTA action	0	1	1		
Number Accepted	151	196	92		
Number without a RTA Review and > 15 Days since Date Received	10	9	5		
Number without a RTA Review and <= 15 Days since Date Received	0	0	9		
Number Not Accepted	175	201	62		
Rate of submissions not accepted for filing review	52.1%	49.5%	39.0%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DCD - ODE - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	432	400	139		
Deleted or withdrawn prior to SI	2	2	0		
SI within 60 FDA days	392	379	96		
SI over 60 FDA days	38	19	3		
SI pending within 60 FDA days	0	0	40		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	91.2%	95.2%	97.0%		

**Table 6.3.DCD - ODE - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	430	398	99		
Average number of FDA days to Substantive Interaction	45.5	46.5	46.1		
20th Percentile FDA days to Substantive Interaction	29	29	29		
40th Percentile FDA days to Substantive Interaction	43	46	47		
60th Percentile FDA days to Substantive Interaction	50	55	52		
80th Percentile FDA days to Substantive Interaction	58	59	58		
Maximum FDA days to Substantive Interaction	98	90	83		

**Table 6.4.DCD - ODE - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	456	414	144		
Non-MDUFA III Decisions	29	37	0		
MDUFA III Decisions (SE/NSE)	427	350	46		
MDUFA III Decisions within 90 FDA Days	412	345	46		
510(k)s pending MDUFA III Decision	0	27	98		
510(k) pending MDUFA III Decision over 90 FDA days	0	1	1		
Current Performance Percent within 90 FDA Days	96.5%	98.3%	97.9%		

**Table 6.5.DCD - ODE - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.6	1.4		
Number with MDUFA III decision	427	350	46		
<b>Average FDA days to MDUFA III decision</b>	67.2	66.8	52.7		
20th Percentile FDA days to MDUFA III decision	36	36	28		
40th Percentile FDA days to MDUFA III decision	59	59	46		
60th Percentile FDA days to MDUFA III decision	86	86	60		
80th Percentile FDA days to MDUFA III decision	89	89	83		
Maximum FDA days to MDUFA III decision	237	140	90		
<b>Average Industry days to MDUFA III decision</b>	47.5	41.4	11.7		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	11	5	0		
60th Percentile Industry days to MDUFA III decision	38	31	0		
80th Percentile Industry days to MDUFA III decision	84	80	20		
Maximum Industry days to MDUFA III decision	358	226	84		
<b>Average Total days to MDUFA III decision</b>	114.8	108.1	64.4		
20th Percentile Total days to MDUFA III decision	41	36	29		
40th Percentile Total days to MDUFA III decision	85	81	46		
60th Percentile Total days to MDUFA III decision	119	113	66		
80th Percentile Total days to MDUFA III decision	171	167	105		
Maximum Total days to MDUFA III decision	451	315	159		



**Table 6.6.DCD - ODE - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	456	414	144		
Number with MDUFA decision	427	350	46		
Number of SE decisions	418	349	46		
Number of NSE decisions	9	1	0		
Number of Withdrawals	14	20	0		
Number deleted	14	17	0		
Rate of SE decisions	97.9%	100%	100%		
Rate of NSE decisions	2.1%	0%	0%		
Rate of Withdrawals	3.1%	4.8%	0%		
Rate of Deleted	3.1%	4.1%	0%		

**Table 6.7.DCD - ODE - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	15	5	0		
Mean FDA days for submissions that missed goal	123	110	N/A		
Mean industry days for submissions that missed goal	114	104	N/A		

**Table 6.1.DNPMD - ODE - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	190	206	105		
Closed before RTA action	0	1	0		
Number Accepted	39	81	37		
Number without a RTA Review and > 15 Days since Date Received	1	4	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	5		
Number Not Accepted	150	120	61		
Rate of submissions not accepted for filing review	78.9%	58.5%	61.0%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DNPMD - ODE - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	230	188	79		
Deleted or withdrawn prior to SI	1	1	0		
SI within 60 FDA days	203	180	54		
SI over 60 FDA days	26	7	1		
SI pending within 60 FDA days	0	0	24		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	88.6%	96.3%	98.2%		

**Table 6.3.DNPMD - ODE - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	229	187	55		
Average number of FDA days to Substantive Interaction	51.9	53.8	55.4		
20th Percentile FDA days to Substantive Interaction	43	53	53		
40th Percentile FDA days to Substantive Interaction	55	58	58		
60th Percentile FDA days to Substantive Interaction	58	59	60		
80th Percentile FDA days to Substantive Interaction	60	60	60		
Maximum FDA days to Substantive Interaction	80	64	61		

**Table 6.4.DNPMD - ODE - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	236	191	84		
Non-MDUFA III Decisions	31	28	1		
MDUFA III Decisions (SE/NSE)	204	133	15		
MDUFA III Decisions within 90 FDA Days	198	129	15		
510(k)s pending MDUFA III Decision	1	30	68		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1		
Current Performance Percent within 90 FDA Days	97.1%	97.0%	93.8%		

**Table 6.5.DNPMD - ODE - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.9	1.8	1.6		
Number with MDUFA III decision	204	133	15		
<b>Average FDA days to MDUFA III decision</b>	83.7	83.2	77.1		
20th Percentile FDA days to MDUFA III decision	86	85	70		
40th Percentile FDA days to MDUFA III decision	88	88	88		
60th Percentile FDA days to MDUFA III decision	89	89	90		
80th Percentile FDA days to MDUFA III decision	90	90	90		
Maximum FDA days to MDUFA III decision	148	245	90		
<b>Average Industry days to MDUFA III decision</b>	77.3	62.3	14.0		
20th Percentile Industry days to MDUFA III decision	8	2	0		
40th Percentile Industry days to MDUFA III decision	41	32	3		
60th Percentile Industry days to MDUFA III decision	84	57	14		
80th Percentile Industry days to MDUFA III decision	152	120	26		
Maximum Industry days to MDUFA III decision	345	191	46		
<b>Average Total days to MDUFA III decision</b>	161.0	145.5	91.1		
20th Percentile Total days to MDUFA III decision	90	88	70		
40th Percentile Total days to MDUFA III decision	127	116	90		
60th Percentile Total days to MDUFA III decision	174	146	99		
80th Percentile Total days to MDUFA III decision	240	210	116		
Maximum Total days to MDUFA III decision	435	291	136		

**Table 6.6.DNPMD - ODE - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	236	191	84		
Number with MDUFA decision	204	133	15		
Number of SE decisions	186	126	15		
Number of NSE decisions	18	7	0		
Number of Withdrawals	13	13	0		
Number deleted	13	12	0		
Rate of SE decisions	91.2%	94.7%	100%		
Rate of NSE decisions	8.8%	5.3%	0%		
Rate of Withdrawals	5.5%	6.8%	0%		
Rate of Deleted	5.5%	6.3%	0%		

**Table 6.7.DNPMD - ODE - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	6	4	0		
Mean FDA days for submissions that missed goal	105	150	N/A		
Mean industry days for submissions that missed goal	122	95	N/A		

**Table 6.1.DOD - ODE - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	523	665	334		
Closed before RTA action	0	1	1		
Number Accepted	181	313	177		
Number without a RTA Review and > 15 Days since Date Received	0	3	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	17		
Number Not Accepted	342	348	139		
Rate of submissions not accepted for filing review	65.4%	52.4%	44.0%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DOD - ODE - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	655	651	281		
Deleted or withdrawn prior to SI	3	1	0		
SI within 60 FDA days	623	630	201		
SI over 60 FDA days	29	15	4		
SI pending within 60 FDA days	0	3	76		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	2	0		
Current SI Performance Percent within 60 FDA days	95.6%	97.4%	98.0%		

**Table 6.3.DOD - ODE - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	652	645	205		
Average number of FDA days to Substantive Interaction	47.9	48.7	46.7		
20th Percentile FDA days to Substantive Interaction	30	29	29		
40th Percentile FDA days to Substantive Interaction	48	52	48		
60th Percentile FDA days to Substantive Interaction	56	57	56		
80th Percentile FDA days to Substantive Interaction	59	59	58		
Maximum FDA days to Substantive Interaction	88	90	92		

**Table 6.4.DOD - ODE - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	656	651	281		
Non-MDUFA III Decisions	73	39	1		
MDUFA III Decisions (SE/NSE)	583	572	127		
MDUFA III Decisions within 90 FDA Days	579	570	127		
510(k)s pending MDUFA III Decision	0	40	153		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1		
Current Performance Percent within 90 FDA Days	99.3%	99.7%	99.2%		

**Table 6.5.DOD - ODE - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.6	1.5	1.3		
Number with MDUFA III decision	583	572	127		
<b>Average FDA days to MDUFA III decision</b>	69.9	68.0	58.9		
20th Percentile FDA days to MDUFA III decision	49	44	29		
40th Percentile FDA days to MDUFA III decision	74	69	53		
60th Percentile FDA days to MDUFA III decision	85	85	72		
80th Percentile FDA days to MDUFA III decision	88	88	86		
Maximum FDA days to MDUFA III decision	100	94	90		
<b>Average Industry days to MDUFA III decision</b>	40.5	32.0	7.6		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	2	0	0		
60th Percentile Industry days to MDUFA III decision	30	19	0		
80th Percentile Industry days to MDUFA III decision	75	64	13		
Maximum Industry days to MDUFA III decision	430	264	99		
<b>Average Total days to MDUFA III decision</b>	110.4	100.0	66.5		
20th Percentile Total days to MDUFA III decision	52	48	29		
40th Percentile Total days to MDUFA III decision	85	79	55		
60th Percentile Total days to MDUFA III decision	110	99	79		
80th Percentile Total days to MDUFA III decision	163	149	93		
Maximum Total days to MDUFA III decision	520	352	174		



**Table 6.6.DOD - ODE - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	656	651	281		
Number with MDUFA decision	583	572	127		
Number of SE decisions	564	567	127		
Number of NSE decisions	19	5	0		
Number of Withdrawals	37	23	1		
Number deleted	35	16	0		
Rate of SE decisions	96.7%	99.1%	100%		
Rate of NSE decisions	3.3%	0.9%	0%		
Rate of Withdrawals	5.6%	3.5%	0%		
Rate of Deleted	5.3%	2.5%	0%		

**Table 6.7.DOD - ODE - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4	2	0		
Mean FDA days for submissions that missed goal	97	93	N/A		
Mean industry days for submissions that missed goal	104	53	N/A		

**Table 6.1.DOED - ODE - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	118	141	74		
Closed before RTA action	0	0	0		
Number Accepted	59	75	37		
Number without a RTA Review and > 15 Days since Date Received	5	2	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	6		
Number Not Accepted	54	64	30		
Rate of submissions not accepted for filing review	45.8%	45.4%	44.1%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DOED - ODE - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	139	135	62		
Deleted or withdrawn prior to SI	0	0	0		
SI within 60 FDA days	134	132	41		
SI over 60 FDA days	5	1	0		
SI pending within 60 FDA days	0	2	21		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	96.4%	99.2%	100%		

**Table 6.3.DOED - ODE - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	139	133	41		
Average number of FDA days to Substantive Interaction	48.7	51.4	49.7		
20th Percentile FDA days to Substantive Interaction	43	46	41		
40th Percentile FDA days to Substantive Interaction	49	53	53		
60th Percentile FDA days to Substantive Interaction	54	57	56		
80th Percentile FDA days to Substantive Interaction	57	59	58		
Maximum FDA days to Substantive Interaction	88	62	60		

**Table 6.4.DOED - ODE - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	146	137	63		
Non-MDUFA III Decisions	20	16	0		
MDUFA III Decisions (SE/NSE)	126	100	21		
MDUFA III Decisions within 90 FDA Days	123	100	21		
510(k)s pending MDUFA III Decision	0	21	42		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	97.6%	100%	100%		

**Table 6.5.DOED - ODE - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.8	1.6		
Number with MDUFA III decision	126	100	21		
<b>Average FDA days to MDUFA III decision</b>	75.5	77.5	64.5		
20th Percentile FDA days to MDUFA III decision	56	58	43		
40th Percentile FDA days to MDUFA III decision	84	86	55		
60th Percentile FDA days to MDUFA III decision	88	89	86		
80th Percentile FDA days to MDUFA III decision	90	90	89		
Maximum FDA days to MDUFA III decision	91	90	90		
<b>Average Industry days to MDUFA III decision</b>	62.8	44.8	15		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	21	18	0		
60th Percentile Industry days to MDUFA III decision	60	33	16		
80th Percentile Industry days to MDUFA III decision	160	72	27		
Maximum Industry days to MDUFA III decision	250	333	73		
<b>Average Total days to MDUFA III decision</b>	138.3	122.3	79.8		
20th Percentile Total days to MDUFA III decision	70	68	53		
40th Percentile Total days to MDUFA III decision	105	100	69		
60th Percentile Total days to MDUFA III decision	135	122	89		
80th Percentile Total days to MDUFA III decision	230	159	115		
Maximum Total days to MDUFA III decision	332	423	145		

**Table 6.6.DOED - ODE - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	146	137	63		
Number with MDUFA decision	126	100	21		
Number of SE decisions	121	95	21		
Number of NSE decisions	5	5	0		
Number of Withdrawals	8	4	0		
Number deleted	11	10	0		
Rate of SE decisions	96.0%	95.0%	100%		
Rate of NSE decisions	4.0%	5.0%	0%		
Rate of Withdrawals	5.5%	2.9%	0%		
Rate of Deleted	7.5%	7.3%	0%		

**Table 6.7.DOED - ODE - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3	0	0		
Mean FDA days for submissions that missed goal	91	N/A	N/A		
Mean industry days for submissions that missed goal	123	N/A	N/A		

**Table 6.1.DRGUD - ODE - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	210	277	132		
Closed before RTA action	0	2	2		
Number Accepted	66	145	77		
Number without a RTA Review and > 15 Days since Date Received	0	7	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	9		
Number Not Accepted	144	123	43		
Rate of submissions not accepted for filing review	68.6%	44.7%	35.5%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DRGUD - ODE - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	265	267	103		
Deleted or withdrawn prior to SI	1	3	1		
SI within 60 FDA days	253	255	74		
SI over 60 FDA days	9	7	1		
SI pending within 60 FDA days	0	1	27		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	2	1	0		
Current SI Performance Percent within 60 FDA days	95.8%	97.0%	99%		

**Table 6.3.DRGUD - ODE - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	262	262	75		
Average number of FDA days to Substantive Interaction	48.2	48.9	46.3		
20th Percentile FDA days to Substantive Interaction	36	38	32		
40th Percentile FDA days to Substantive Interaction	50	50	46		
60th Percentile FDA days to Substantive Interaction	56	56	52		
80th Percentile FDA days to Substantive Interaction	58	59	57		
Maximum FDA days to Substantive Interaction	73	100	87		

**Table 6.4.DRGUD - ODE - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	278	274	104		
Non-MDUFA III Decisions	42	30	1		
MDUFA III Decisions (SE/NSE)	236	220	30		
MDUFA III Decisions within 90 FDA Days	236	220	30		
510(k)s pending MDUFA III Decision	0	24	73		
510(k) pending MDUFA III Decision over 90 FDA days	0	1	0		
Current Performance Percent within 90 FDA Days	100%	100%	100%		

**Table 6.5.DRGUD - ODE - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.9	1.8	1.3		
Number with MDUFA III decision	236	220	30		
<b>Average FDA days to MDUFA III decision</b>	71.4	69.9	52.7		
20th Percentile FDA days to MDUFA III decision	54	50	27		
40th Percentile FDA days to MDUFA III decision	80	75	42		
60th Percentile FDA days to MDUFA III decision	86	85	60		
80th Percentile FDA days to MDUFA III decision	88	88	82		
Maximum FDA days to MDUFA III decision	90	90	90		
<b>Average Industry days to MDUFA III decision</b>	73.1	50.8	7.2		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	32	20	0		
60th Percentile Industry days to MDUFA III decision	74	44	0		
80th Percentile Industry days to MDUFA III decision	152	91	16		
Maximum Industry days to MDUFA III decision	416	236	48		
<b>Average Total days to MDUFA III decision</b>	144.6	120.6	59.8		
20th Percentile Total days to MDUFA III decision	59	59	27		
40th Percentile Total days to MDUFA III decision	112	97	44		
60th Percentile Total days to MDUFA III decision	154	122	73		
80th Percentile Total days to MDUFA III decision	239	171	90		
Maximum Total days to MDUFA III decision	506	316	121		



**Table 6.6.DRGUD - ODE - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	278	274	104		
Number with MDUFA decision	236	220	30		
Number of SE decisions	221	216	30		
Number of NSE decisions	15	4	0		
Number of Withdrawals	18	10	1		
Number deleted	22	16	0		
Rate of SE decisions	93.6%	98.2%	100%		
Rate of NSE decisions	6.4%	1.8%	0%		
Rate of Withdrawals	6.5%	3.6%	1.0%		
Rate of Deleted	7.9%	5.8%	0%		

**Table 6.7.DRGUD - ODE - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	N/A	N/A	N/A		
Mean industry days for submissions that missed goal	N/A	N/A	N/A		

**Table 6.1.DSD - ODE - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	375	484	242		
Closed before RTA action	3	0	0		
Number Accepted	136	212	139		
Number without a RTA Review and > 15 Days since Date Received	3	11	3		
Number without a RTA Review and <= 15 Days since Date Received	0	0	18		
Number Not Accepted	233	261	82		
Rate of submissions not accepted for filing review	62.6%	53.9%	36.6%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DSD - ODE - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	473	454	193		
Deleted or withdrawn prior to SI	3	0	0		
SI within 60 FDA days	424	413	133		
SI over 60 FDA days	46	37	5		
SI pending within 60 FDA days	0	4	54		
SI pending over 60 FDA days	0	0	1		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	90.2%	91.8%	95.7%		

**Table 6.3.DSD - ODE - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	470	450	138		
Average number of FDA days to Substantive Interaction	45.4	50.4	46.8		
20th Percentile FDA days to Substantive Interaction	28	36	29		
40th Percentile FDA days to Substantive Interaction	44	53	51		
60th Percentile FDA days to Substantive Interaction	56	57	56		
80th Percentile FDA days to Substantive Interaction	59	60	59		
Maximum FDA days to Substantive Interaction	90	90	90		

**Table 6.4.DSD - ODE - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	481	461	199		
Non-MDUFA III Decisions	86	57	2		
MDUFA III Decisions (SE/NSE)	395	345	62		
MDUFA III Decisions within 90 FDA Days	385	340	62		
510(k)s pending MDUFA III Decision	0	59	135		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1		
Current Performance Percent within 90 FDA Days	97.5%	98.6%	98.4%		

**Table 6.5.DSD - ODE - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.7	1.5		
Number with MDUFA III decision	395	345	62		
<b>Average FDA days to MDUFA III decision</b>	69.0	71.1	54.8		
20th Percentile FDA days to MDUFA III decision	43	51	29		
40th Percentile FDA days to MDUFA III decision	70	77	44		
60th Percentile FDA days to MDUFA III decision	85	86	62		
80th Percentile FDA days to MDUFA III decision	89	89	86		
Maximum FDA days to MDUFA III decision	342	147	90		
<b>Average Industry days to MDUFA III decision</b>	60.0	46.9	12.4		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	20	12	0		
60th Percentile Industry days to MDUFA III decision	44	39	8		
80th Percentile Industry days to MDUFA III decision	125	95	25		
Maximum Industry days to MDUFA III decision	438	359	80		
<b>Average Total days to MDUFA III decision</b>	129.1	118.0	67.1		
20th Percentile Total days to MDUFA III decision	51	58	29		
40th Percentile Total days to MDUFA III decision	93	88	56		
60th Percentile Total days to MDUFA III decision	128	119	84		
80th Percentile Total days to MDUFA III decision	204	181	104		
Maximum Total days to MDUFA III decision	691	447	162		

**Table 6.6.DSD - ODE - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	481	461	199		
Number with MDUFA decision	395	345	62		
Number of SE decisions	379	337	62		
Number of NSE decisions	16	8	0		
Number of Withdrawals	43	26	0		
Number deleted	38	20	0		
Rate of SE decisions	95.9%	97.7%	100%		
Rate of NSE decisions	4.1%	2.3%	0%		
Rate of Withdrawals	8.9%	5.6%	0%		
Rate of Deleted	7.9%	4.3%	0%		

**Table 6.7.DSD - ODE - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	10	5	0		
Mean FDA days for submissions that missed goal	137	108	N/A		
Mean industry days for submissions that missed goal	160	126	N/A		

**Table 6.1.DCTD - OIR - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	188	195	99		
Closed before RTA action	1	1	1		
Number Accepted	118	127	71		
Number without a RTA Review and > 15 Days since Date Received	0	1	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	9		
Number Not Accepted	69	66	18		
Rate of submissions not accepted for filing review	36.9%	34.0%	20.2%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DCTD - OIR - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	247	180	79		
Deleted or withdrawn prior to SI	0	0	0		
SI within 60 FDA days	247	179	63		
SI over 60 FDA days	0	0	1		
SI pending within 60 FDA days	0	1	15		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	100%	100%	98.4%		

**Table 6.3.DCTD - OIR - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	247	179	64		
Average number of FDA days to Substantive Interaction	41.0	42.5	39.8		
20th Percentile FDA days to Substantive Interaction	29	30	29		
40th Percentile FDA days to Substantive Interaction	38	43	33		
60th Percentile FDA days to Substantive Interaction	45	47	43		
80th Percentile FDA days to Substantive Interaction	52	54	51		
Maximum FDA days to Substantive Interaction	60	60	65		

**Table 6.4.DCTD - OIR - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	247	180	79		
Non-MDUFA III Decisions	34	26	0		
MDUFA III Decisions (SE/NSE)	210	120	26		
MDUFA III Decisions within 90 FDA Days	209	119	26		
510(k)s pending MDUFA III Decision	3	34	53		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	99.5%	99.2%	100%		

**Table 6.5.DCTD - OIR - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.8	1.2		
Number with MDUFA III decision	210	120	26		
<b>Average FDA days to MDUFA III decision</b>	64.6	62.8	43.2		
20th Percentile FDA days to MDUFA III decision	34	32	29		
40th Percentile FDA days to MDUFA III decision	58	55	31		
60th Percentile FDA days to MDUFA III decision	84	81	35		
80th Percentile FDA days to MDUFA III decision	88	87	60		
Maximum FDA days to MDUFA III decision	99	131	86		
<b>Average Industry days to MDUFA III decision</b>	78.7	51.3	4		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	10	0	0		
60th Percentile Industry days to MDUFA III decision	66	30	0		
80th Percentile Industry days to MDUFA III decision	156	111	0		
Maximum Industry days to MDUFA III decision	448	353	53		
<b>Average Total days to MDUFA III decision</b>	143.3	114.1	47.2		
20th Percentile Total days to MDUFA III decision	35	32	29		
40th Percentile Total days to MDUFA III decision	85	62	31		
60th Percentile Total days to MDUFA III decision	146	107	35		
80th Percentile Total days to MDUFA III decision	240	200	65		
Maximum Total days to MDUFA III decision	538	440	133		



**Table 6.6.DCTD - OIR - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	247	180	79		
Number with MDUFA decision	210	120	26		
Number of SE decisions	204	119	26		
Number of NSE decisions	6	1	0		
Number of Withdrawals	17	17	0		
Number deleted	17	9	0		
Rate of SE decisions	97.1%	99.2%	100%		
Rate of NSE decisions	2.9%	0.8%	0%		
Rate of Withdrawals	6.9%	9.4%	0%		
Rate of Deleted	6.9%	5.0%	0%		

**Table 6.7.DCTD - OIR - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	1	0		
Mean FDA days for submissions that missed goal	99	131	N/A		
Mean industry days for submissions that missed goal	193	190	N/A		

**Table 6.1.DIHD - OIR - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	56	73	33		
Closed before RTA action	1	1	0		
Number Accepted	38	57	22		
Number without a RTA Review and > 15 Days since Date Received	3	0	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	4		
Number Not Accepted	14	15	6		
Rate of submissions not accepted for filing review	25.5%	20.8%	20.7%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DIHD - OIR - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	69	64	25		
Deleted or withdrawn prior to SI	0	0	1		
SI within 60 FDA days	68	64	20		
SI over 60 FDA days	1	0	0		
SI pending within 60 FDA days	0	0	4		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	98.6%	100%	100%		

**Table 6.3.DIHD - OIR - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	69	64	20		
Average number of FDA days to Substantive Interaction	47.6	50.8	47.9		
20th Percentile FDA days to Substantive Interaction	41	46	30		
40th Percentile FDA days to Substantive Interaction	50	51	51		
60th Percentile FDA days to Substantive Interaction	54	57	57		
80th Percentile FDA days to Substantive Interaction	58	58	59		
Maximum FDA days to Substantive Interaction	63	60	60		

**Table 6.4.DIHD - OIR - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	69	64	25		
Non-MDUFA III Decisions	22	15	1		
MDUFA III Decisions (SE/NSE)	47	40	6		
MDUFA III Decisions within 90 FDA Days	47	39	6		
510(k)s pending MDUFA III Decision	0	9	18		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	100%	97.5%	100%		

**Table 6.5.DIHD - OIR - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	2.0	1.8	1.0		
Number with MDUFA III decision	47	40	6		
<b>Average FDA days to MDUFA III decision</b>	71.6	78.4	28.7		
20th Percentile FDA days to MDUFA III decision	50	63	28		
40th Percentile FDA days to MDUFA III decision	77	88	30		
60th Percentile FDA days to MDUFA III decision	86	89	30		
80th Percentile FDA days to MDUFA III decision	88	90	30		
Maximum FDA days to MDUFA III decision	90	91	32		
<b>Average Industry days to MDUFA III decision</b>	115.4	96.2	0		
20th Percentile Industry days to MDUFA III decision	29	40	0		
40th Percentile Industry days to MDUFA III decision	89	54	0		
60th Percentile Industry days to MDUFA III decision	157	139	0		
80th Percentile Industry days to MDUFA III decision	177	175	0		
Maximum Industry days to MDUFA III decision	329	180	0		
<b>Average Total days to MDUFA III decision</b>	187.0	174.6	28.7		
20th Percentile Total days to MDUFA III decision	91	106	28		
40th Percentile Total days to MDUFA III decision	151	140	30		
60th Percentile Total days to MDUFA III decision	236	224	30		
80th Percentile Total days to MDUFA III decision	264	263	30		
Maximum Total days to MDUFA III decision	417	270	32		

**Table 6.6.DIHD - OIR - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	69	64	25		
Number with MDUFA decision	47	40	6		
Number of SE decisions	43	34	6		
Number of NSE decisions	4	6	0		
Number of Withdrawals	6	6	1		
Number deleted	14	9	0		
Rate of SE decisions	91.5%	85.0%	100%		
Rate of NSE decisions	8.5%	15.0%	0%		
Rate of Withdrawals	8.7%	9.4%	4.0%		
Rate of Deleted	20.3%	14.1%	0%		

**Table 6.7.DIHD - OIR - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	1	0		
Mean FDA days for submissions that missed goal	0	91	N/A		
Mean industry days for submissions that missed goal	0	47	N/A		

**Table 6.1.DMD - OIR - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	84	24		
Closed before RTA action	0	0	0		
Number Accepted	55	80	23		
Number without a RTA Review and > 15 Days since Date Received	0	1	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted	4	3	1		
Rate of submissions not accepted for filing review	6.8%	3.6%	4.2%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DMD - OIR - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	80	82	23		
Deleted or withdrawn prior to SI	0	0	0		
SI within 60 FDA days	79	81	20		
SI over 60 FDA days	1	1	0		
SI pending within 60 FDA days	0	0	3		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	98.8%	98.8%	100%		

**Table 6.3.DMD - OIR - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	80	82	20		
Average number of FDA days to Substantive Interaction	43.1	47.5	48.5		
20th Percentile FDA days to Substantive Interaction	28	29	35		
40th Percentile FDA days to Substantive Interaction	39	50	54		
60th Percentile FDA days to Substantive Interaction	53	56	56		
80th Percentile FDA days to Substantive Interaction	57	59	58		
Maximum FDA days to Substantive Interaction	61	61	59		

**Table 6.4.DMD - OIR - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	80	82	23		
Non-MDUFA III Decisions	9	6	0		
MDUFA III Decisions (SE/NSE)	71	71	11		
MDUFA III Decisions within 90 FDA Days	71	71	11		
510(k)s pending MDUFA III Decision	0	5	12		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	100%	100%	100%		

**Table 6.5.DMD - OIR - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.3	1.4	1.3		
Number with MDUFA III decision	71	71	11		
<b>Average FDA days to MDUFA III decision</b>	58.5	64.5	75.3		
20th Percentile FDA days to MDUFA III decision	29	29	83		
40th Percentile FDA days to MDUFA III decision	55	70	84		
60th Percentile FDA days to MDUFA III decision	78	81	85		
80th Percentile FDA days to MDUFA III decision	81	86	87		
Maximum FDA days to MDUFA III decision	89	90	88		
<b>Average Industry days to MDUFA III decision</b>	31.5	40.7	9		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	4	0		
80th Percentile Industry days to MDUFA III decision	65	103	29		
Maximum Industry days to MDUFA III decision	180	182	34		
<b>Average Total days to MDUFA III decision</b>	90.0	105.3	84.0		
20th Percentile Total days to MDUFA III decision	29	29	83		
40th Percentile Total days to MDUFA III decision	58	84	85		
60th Percentile Total days to MDUFA III decision	81	89	87		
80th Percentile Total days to MDUFA III decision	133	165	113		
Maximum Total days to MDUFA III decision	267	264	122		



**Table 6.6.DMD - OIR - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	80	82	23		
Number with MDUFA decision	71	71	11		
Number of SE decisions	71	68	11		
Number of NSE decisions	0	3	0		
Number of Withdrawals	6	4	0		
Number deleted	3	2	0		
Rate of SE decisions	100%	95.8%	100%		
Rate of NSE decisions	0%	4.2%	0%		
Rate of Withdrawals	7.5%	4.9%	0%		
Rate of Deleted	3.8%	2.4%	0%		

**Table 6.7.DMD - OIR - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	N/A	N/A	N/A		
Mean industry days for submissions that missed goal	N/A	N/A	N/A		

**Table 6.1.DMGP - OIR - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	17	9	1		
Closed before RTA action	0	0	0		
Number Accepted	14	9	1		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted	3	0	0		
Rate of submissions not accepted for filing review	17.6%	0%	0%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DMGP - OIR - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	18	9	1		
Deleted or withdrawn prior to SI	0	0	0		
SI within 60 FDA days	18	9	1		
SI over 60 FDA days	0	0	0		
SI pending within 60 FDA days	0	0	0		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	100%	100%	100%		

**Table 6.3.DMGP - OIR - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	18	9	1		
Average number of FDA days to Substantive Interaction	51.7	45.8	49.0		
20th Percentile FDA days to Substantive Interaction	44	29	49		
40th Percentile FDA days to Substantive Interaction	55	47	49		
60th Percentile FDA days to Substantive Interaction	58	56	49		
80th Percentile FDA days to Substantive Interaction	59	58	49		
Maximum FDA days to Substantive Interaction	60	60	49		

**Table 6.4.DMGP - OIR - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	18	9	1		
Non-MDUFA III Decisions	4	1	0		
MDUFA III Decisions (SE/NSE)	14	7	0		
MDUFA III Decisions within 90 FDA Days	14	7	0		
510(k)s pending MDUFA III Decision	0	1	1		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	100%	100%	0%		

**Table 6.5.DMGP - OIR - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	2.4	1.6	0		
Number with MDUFA III decision	14	7	0		
<b>Average FDA days to MDUFA III decision</b>	83.7	78.1	0		
20th Percentile FDA days to MDUFA III decision	81	79	0		
40th Percentile FDA days to MDUFA III decision	88	88	0		
60th Percentile FDA days to MDUFA III decision	88	89	0		
80th Percentile FDA days to MDUFA III decision	89	90	0		
Maximum FDA days to MDUFA III decision	90	90	0		
<b>Average Industry days to MDUFA III decision</b>	151.9	81.7	0		
20th Percentile Industry days to MDUFA III decision	26	0	0		
40th Percentile Industry days to MDUFA III decision	166	16	0		
60th Percentile Industry days to MDUFA III decision	175	122	0		
80th Percentile Industry days to MDUFA III decision	233	177	0		
Maximum Industry days to MDUFA III decision	320	179	0		
<b>Average Total days to MDUFA III decision</b>	235.6	159.9	0		
20th Percentile Total days to MDUFA III decision	103	80	0		
40th Percentile Total days to MDUFA III decision	255	106	0		
60th Percentile Total days to MDUFA III decision	263	211	0		
80th Percentile Total days to MDUFA III decision	317	266	0		
Maximum Total days to MDUFA III decision	408	267	0		

**Table 6.6.DMGP - OIR - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	18	9	1		
Number with MDUFA decision	14	7	0		
Number of SE decisions	11	6	0		
Number of NSE decisions	3	1	0		
Number of Withdrawals	3	1	0		
Number deleted	1	0	0		
Rate of SE decisions	78.6%	85.7%	N/A		
Rate of NSE decisions	21.4%	14.3%	N/A		
Rate of Withdrawals	16.7%	11.1%	0%		
Rate of Deleted	5.6%	0%	0%		

**Table 6.7.DMGP - OIR - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	N/A	N/A	N/A		
Mean industry days for submissions that missed goal	N/A	N/A	N/A		

**Table 6.1.DRH - OIR - 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	256	365	142		
Closed before RTA action	0	0	0		
Number Accepted	151	274	104		
Number without a RTA Review and > 15 Days since Date Received	15	5	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	11		
Number Not Accepted	90	86	26		
Rate of submissions not accepted for filing review	35.2%	23.6%	19.8%		

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DRH - OIR - 510(k) Substantive Interaction Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	349	356	120		
Deleted or withdrawn prior to SI	1	0	0		
SI within 60 FDA days	307	342	91		
SI over 60 FDA days	41	14	2		
SI pending within 60 FDA days	0	0	27		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	88.2%	96.1%	97.8%		

**Table 6.3.DRH - OIR - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	348	356	93		
Average number of FDA days to Substantive Interaction	47.4	45.8	44.6		
20th Percentile FDA days to Substantive Interaction	31	30	28		
40th Percentile FDA days to Substantive Interaction	44	44	45		
60th Percentile FDA days to Substantive Interaction	56	54	51		
80th Percentile FDA days to Substantive Interaction	59	59	58		
Maximum FDA days to Substantive Interaction	91	93	70		

**Table 6.4.DRH - OIR - 510(k) MDUFA Decision Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	403	393	138		
Non-MDUFA III Decisions	17	5	0		
MDUFA III Decisions (SE/NSE)	386	369	65		
MDUFA III Decisions within 90 FDA Days	380	357	65		
510(k)s pending MDUFA III Decision	0	19	73		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	98.4%	96.7%	100%		

**Table 6.5.DRH - OIR - 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.6	1.6	1.3		
Number with MDUFA III decision	386	369	65		
<b>Average FDA days to MDUFA III decision</b>	61.9	62.5	48.6		
20th Percentile FDA days to MDUFA III decision	35	30	27		
40th Percentile FDA days to MDUFA III decision	56	57	35		
60th Percentile FDA days to MDUFA III decision	77	79	56		
80th Percentile FDA days to MDUFA III decision	87	88	73		
Maximum FDA days to MDUFA III decision	121	137	88		
<b>Average Industry days to MDUFA III decision</b>	35.9	31.2	9.1		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	20	24	0		
80th Percentile Industry days to MDUFA III decision	60	57	23		
Maximum Industry days to MDUFA III decision	358	214	83		
<b>Average Total days to MDUFA III decision</b>	97.8	93.6	57.8		
20th Percentile Total days to MDUFA III decision	37	32	28		
40th Percentile Total days to MDUFA III decision	71	74	39		
60th Percentile Total days to MDUFA III decision	90	99	60		
80th Percentile Total days to MDUFA III decision	137	136	85		
Maximum Total days to MDUFA III decision	466	304	148		



**Table 6.6.DRH - OIR - 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	403	393	138		
Number with MDUFA decision	386	369	65		
Number of SE decisions	377	363	65		
Number of NSE decisions	9	6	0		
Number of Withdrawals	10	2	0		
Number deleted	7	2	0		
Rate of SE decisions	97.7%	98.4%	100%		
Rate of NSE decisions	2.3%	1.6%	0%		
Rate of Withdrawals	2.5%	0.5%	0%		
Rate of Deleted	1.7%	0.5%	0%		

**Table 6.7.DRH - OIR - 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	6	12	0		
Mean FDA days for submissions that missed goal	104	98	N/A		
Mean industry days for submissions that missed goal	135	37	N/A		

## **Section 7 510(k) Annual General Metrics**

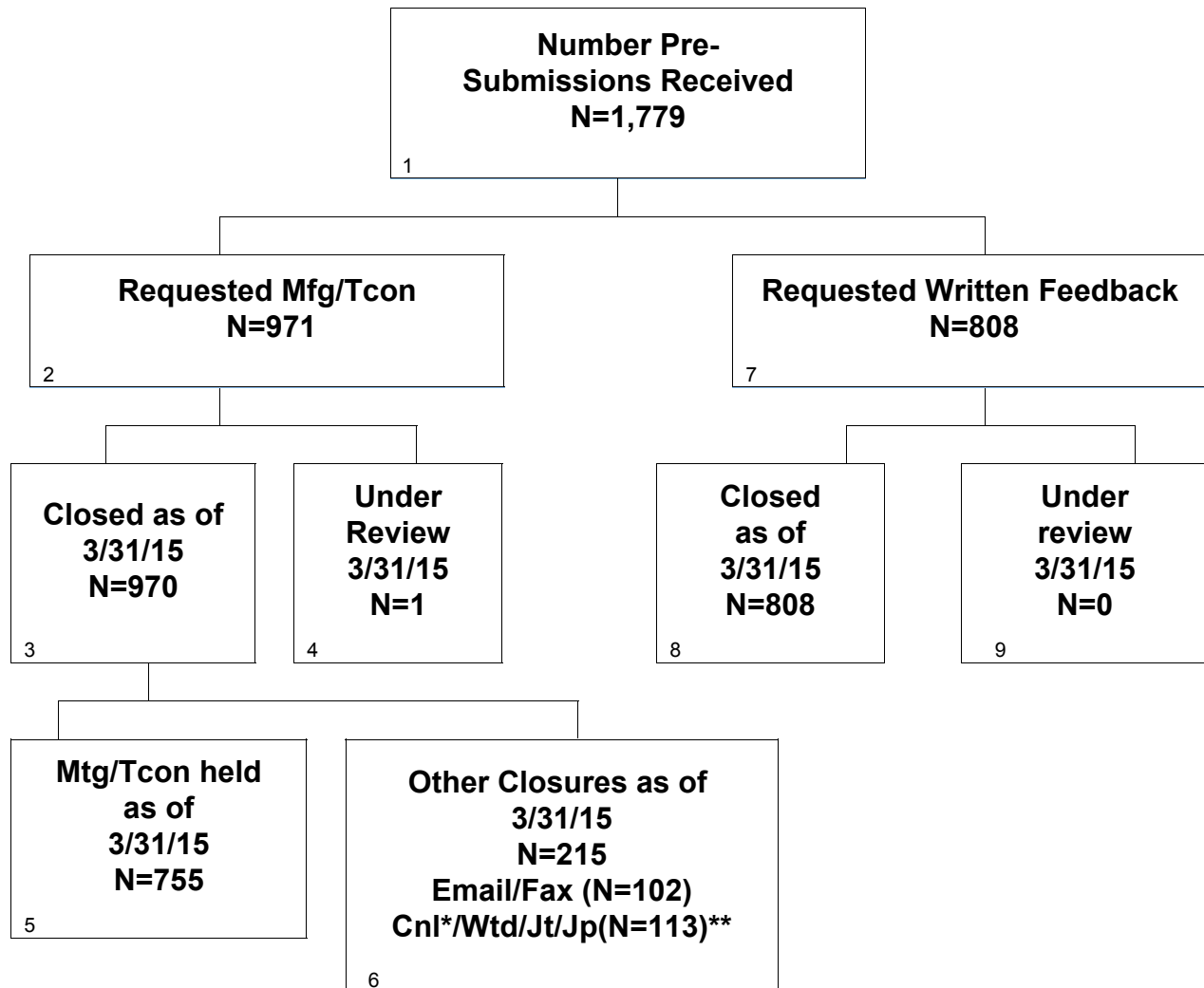
510(k) Annual Metrics and Goals will be reported in the Annual Report.

## **Section 8 Annual Metrics for De Novo Requests**

De Novo Annual Metrics and Goals will be reported in the Annual Report.

# CDRH Pre-Submissions - FY 2013

## As of 3/31/15

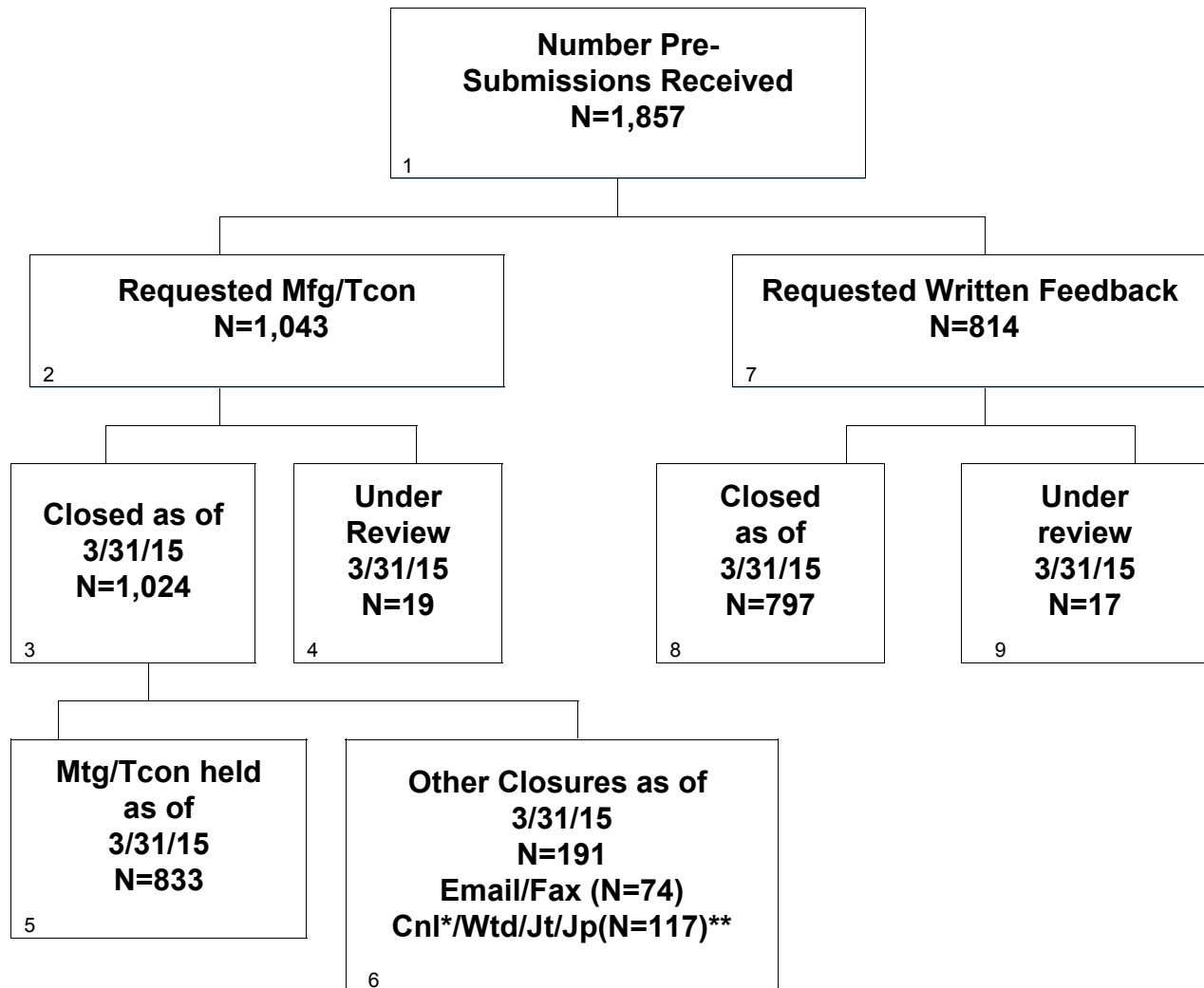


\*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

\*\*Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

# CDRH Pre-Submissions - FY 2014

## As of 3/31/15

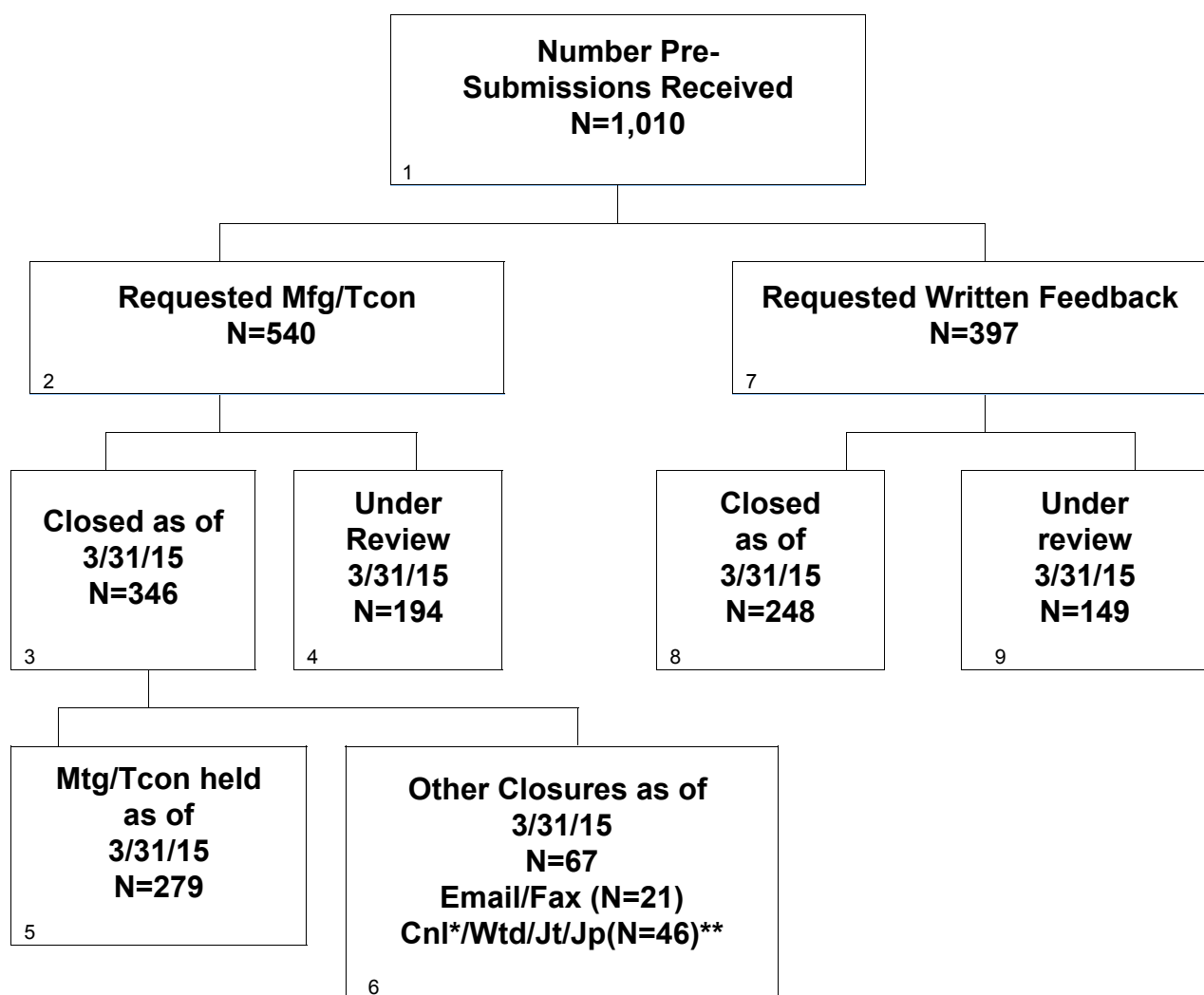


\*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

\*\*Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

# CDRH Pre-Submissions - FY 2015

## As of 3/31/15



\*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

\*\*Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

## Section 9 Pre-Submissions

**Table 9.1 CDRH – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	1,779	1,857	1,010		
Number requesting a meeting or teleconference	971	1,043	540		
Number with meetings or teleconferences held	755	833	279		
Average days to meeting	59.2	64.9	63.6		
20th Percentile days to meeting	38	48	47		
40th Percentile days to meeting	55	62	63		
60th Percentile days to meeting	66	70	70		
80th Percentile days to meeting	77	78	78		
Maximum days to meeting	183	243	126		

## Section 9 Pre-Submission Office Level Metrics

**Table 9.1.ODE - CDRH – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	981	1,140	647		
Number requesting a meeting or teleconference	611	697	355		
Number with meetings or teleconferences held	455	549	171		
Average days to meeting	61.8	67.7	66.9		
20th Percentile days to meeting	40	49	49		
40th Percentile days to meeting	57	63	65		
60th Percentile days to meeting	67	72	73		
80th Percentile days to meeting	79	83	84		
Maximum days to meeting	183	243	126		



**Table 9.1.OIR - CDRH – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	798	717	363		
Number requesting a meeting or teleconference	360	346	185		
Number with meetings or teleconferences held	300	284	108		
Average days to meeting	55.4	59.5	58.2		
20th Percentile days to meeting	37	46	45		
40th Percentile days to meeting	53	60	59		
60th Percentile days to meeting	63	68	69		
80th Percentile days to meeting	71	72	71		
Maximum days to meeting	138	115	112		

## Section 9 Pre-Submission Division Level Metrics

**Table 9.1.DAGRID - ODE - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	156	204	112		
Number requesting a meeting or teleconference	82	110	52		
Number with meetings or teleconferences held	58	82	22		
Average days to meeting	68.3	70.7	69.7		
20th Percentile days to meeting	52	55	51		
40th Percentile days to meeting	65	65	69		
60th Percentile days to meeting	75	75	76		
80th Percentile days to meeting	83	85	84		
Maximum days to meeting	121	149	107		

**Table 9.1.DCD - ODE - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	307	372	177		
Number requesting a meeting or teleconference	214	234	100		
Number with meetings or teleconferences held	173	195	48		
Average days to meeting	56.0	59.0	55.1		
20th Percentile days to meeting	35	44	42		
40th Percentile days to meeting	49	53	51		
60th Percentile days to meeting	62	65	59		
80th Percentile days to meeting	74	73	71		
Maximum days to meeting	134	140	99		

**Table 9.1.DNPMD - ODE - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	78	115	70		
Number requesting a meeting or teleconference	50	72	44		
Number with meetings or teleconferences held	32	48	19		
Average days to meeting	70.3	88.4	78.7		
20th Percentile days to meeting	48	66	68		
40th Percentile days to meeting	63	78	78		
60th Percentile days to meeting	77	90	87		
80th Percentile days to meeting	91	110	100		
Maximum days to meeting	163	243	119		

**Table 9.1.DOD - ODE - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	98	106	67		
Number requesting a meeting or teleconference	61	72	42		
Number with meetings or teleconferences held	39	62	25		
Average days to meeting	60.6	75.3	72.2		
20th Percentile days to meeting	45	62	58		
40th Percentile days to meeting	57	71	72		
60th Percentile days to meeting	69	77	79		
80th Percentile days to meeting	77	89	84		
Maximum days to meeting	129	158	126		

**Table 9.1.DOED - ODE - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	87	73	52		
Number requesting a meeting or teleconference	49	46	28		
Number with meetings or teleconferences held	35	34	12		
Average days to meeting	66.4	75.4	73.1		
20th Percentile days to meeting	53	66	66		
40th Percentile days to meeting	64	69	71		
60th Percentile days to meeting	70	73	77		
80th Percentile days to meeting	83	86	84		
Maximum days to meeting	118	146	91		

**Table 9.1.DRGUD - ODE - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	131	135	87		
Number requesting a meeting or teleconference	76	83	44		
Number with meetings or teleconferences held	60	66	24		
Average days to meeting	60.0	59.8	65.1		
20th Percentile days to meeting	47	44	53		
40th Percentile days to meeting	60	57	65		
60th Percentile days to meeting	67	67	69		
80th Percentile days to meeting	71	75	75		
Maximum days to meeting	132	119	96		

**Table 9.1.DSD - ODE - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	124	135	82		
Number requesting a meeting or teleconference	79	80	45		
Number with meetings or teleconferences held	58	62	21		
Average days to meeting	67.5	71.8	72.6		
20th Percentile days to meeting	41	63	59		
40th Percentile days to meeting	64	69	69		
60th Percentile days to meeting	73	77	75		
80th Percentile days to meeting	85	89	84		
Maximum days to meeting	183	111	125		

**Table 9.1.DCTD - OIR - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	219	178	105		
Number requesting a meeting or teleconference	107	99	62		
Number with meetings or teleconferences held	91	88	39		
Average days to meeting	51.3	57.0	52.6		
20th Percentile days to meeting	36	42	26		
40th Percentile days to meeting	49	55	54		
60th Percentile days to meeting	59	65	65		
80th Percentile days to meeting	68	70	71		
Maximum days to meeting	90	112	97		

**Table 9.1.DIHD - OIR - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	130	127	56		
Number requesting a meeting or teleconference	66	72	25		
Number with meetings or teleconferences held	54	67	18		
Average days to meeting	61.1	65.0	67.1		
20th Percentile days to meeting	41	56	63		
40th Percentile days to meeting	64	67	67		
60th Percentile days to meeting	70	71	69		
80th Percentile days to meeting	81	73	70		
Maximum days to meeting	99	113	92		

**Table 9.1.DMD - OIR - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	234	204	86		
Number requesting a meeting or teleconference	59	48	23		
Number with meetings or teleconferences held	49	28	10		
Average days to meeting	52.6	60.4	66.0		
20th Percentile days to meeting	42	43	56		
40th Percentile days to meeting	51	56	63		
60th Percentile days to meeting	61	68	69		
80th Percentile days to meeting	67	77	72		
Maximum days to meeting	81	91	112		

**Table 9.1.DMGP - OIR - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	145	154	85		
Number requesting a meeting or teleconference	83	90	56		
Number with meetings or teleconferences held	70	69	32		
Average days to meeting	63.0	57.8	57.5		
20th Percentile days to meeting	44	40	46		
40th Percentile days to meeting	56	60	61		
60th Percentile days to meeting	66	68	66		
80th Percentile days to meeting	83	71	71		
Maximum days to meeting	138	115	94		

**Table 9.1.DRH - OIR - Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	70	54	31		
Number requesting a meeting or teleconference	45	37	19		
Number with meetings or teleconferences held	36	32	9		
Average days to meeting	46.7	57.5	58.4		
20th Percentile days to meeting	31	47	47		
40th Percentile days to meeting	43	59	57		
60th Percentile days to meeting	57	68	62		
80th Percentile days to meeting	63	72	68		
Maximum days to meeting	98	107	74		

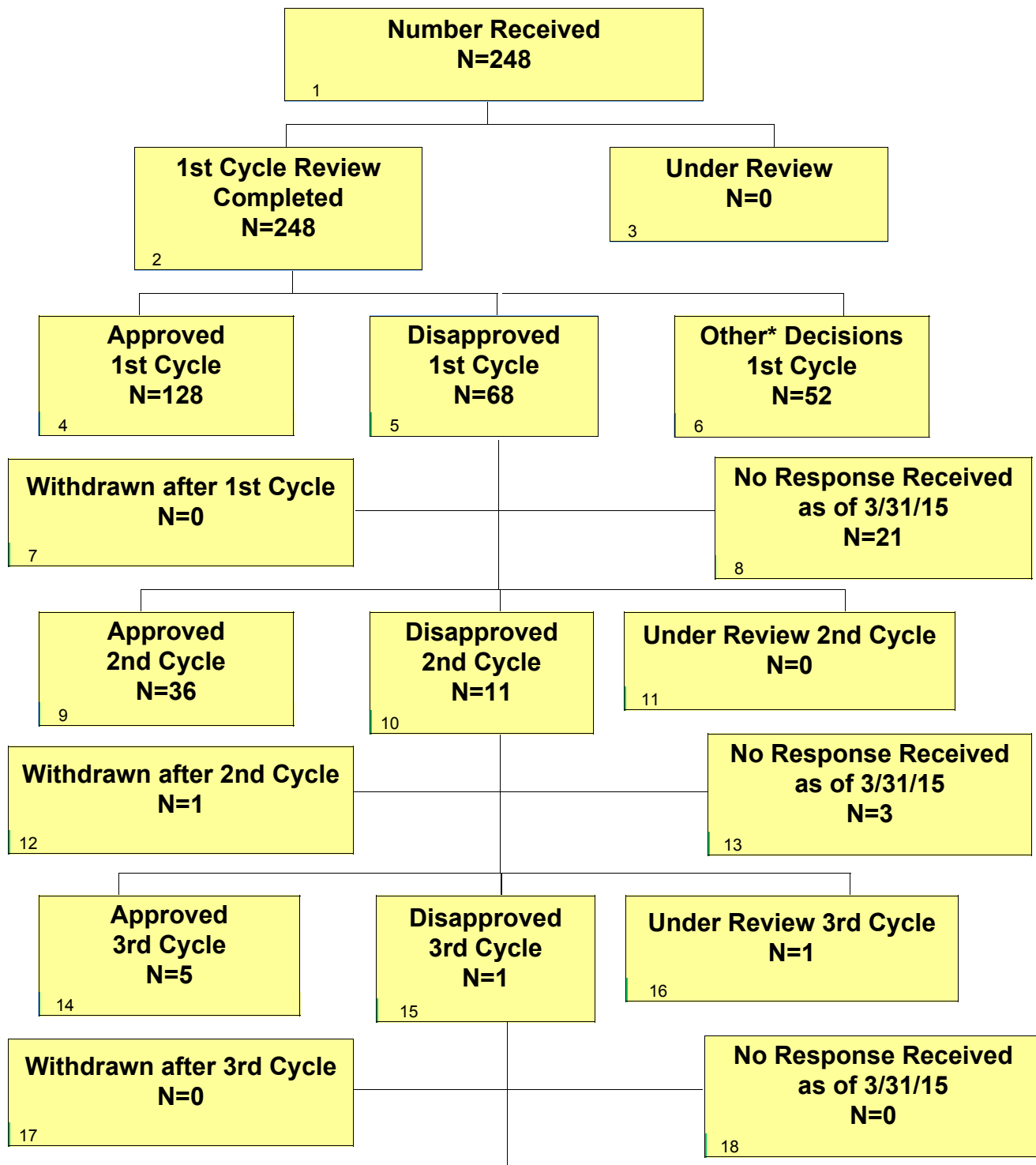


## **Section 10      CLIA Waiver Annual Metrics**

CLIA Waiver Annual Metrics and Goals will be reported in the Annual Report.

# CDRH IDEs - FY 2014

## As of 3/31/15

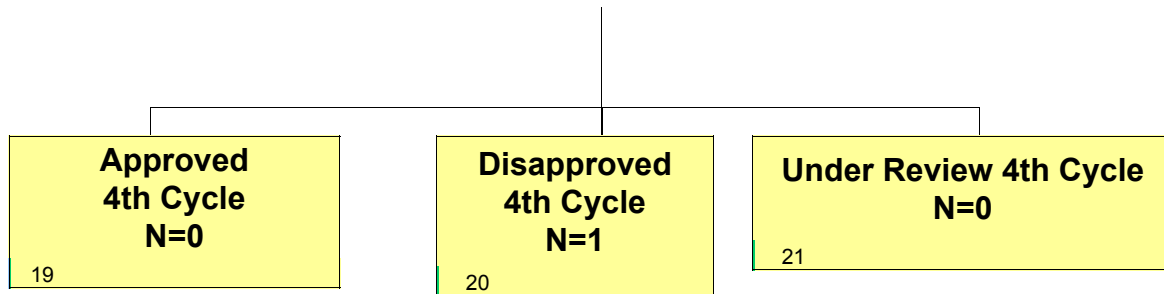


\* Other decisions include withdrawn (N=34), RTA (N=2), nonsignificant risk device (N=10), exempt (N=3), product jurisdiction pending (N=0), or product jurisdiction transferred (N=3).

# CDRH IDEs - FY 2014

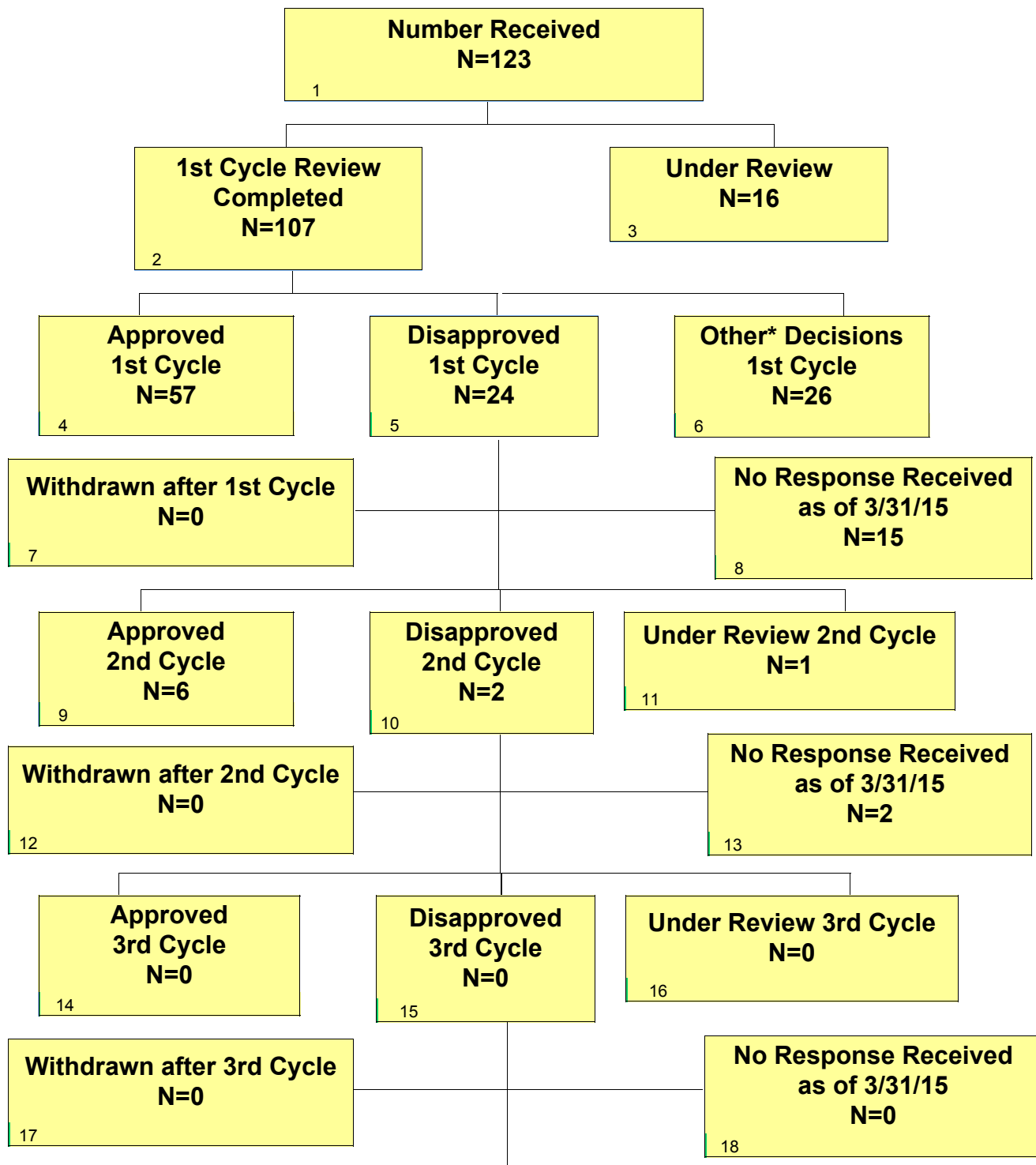
## As of 3/31/15 Continued

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# CDRH IDEs - FY 2015

## As of 3/31/15

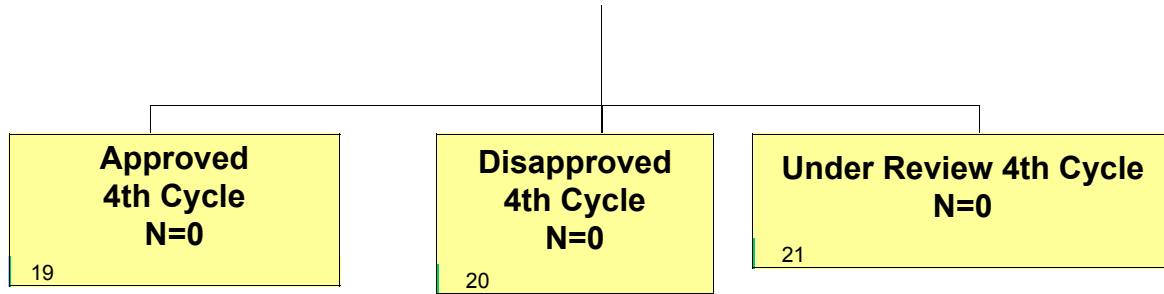


\* Other decisions include withdrawn (N=17), RTA (N=0), nonsignificant risk device (N=6), exempt (N=2), product jurisdiction pending (N=0), or product jurisdiction transferred (N=0).

# CDRH IDEs - FY 2015

## As of 3/31/15 Continued

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## Section 11 IDEs - Center Level Metrics

**Table 11.1 IDE Performance Metrics**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	248	123		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.1		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0.1		

## Section 11 IDEs - Office Level Metrics

**Table 11.1.ODE - CDRH – IDE Performance Metrics**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	188	107		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.1		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0.1		

**Table 11.1.OIR - CDRH – IDE Performance Metrics**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	60	16		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.1	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.1	0		

## Section 11 IDEs - Division Level Metrics

**Table 11.1.DAGRID - ODE - IDE Performance Metrics**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	8	8		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.7	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.7	0		

**Table 11.1.DCD - ODE - IDE Performance Metrics**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	58	26		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.4	1.2		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.4	0.2		

**Table 11.1.DNPMD - ODE - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	35	18		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0		

**Table 11.1.DOD - ODE - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	13	6		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0		

**Table 11.1.DOED - ODE - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	18	11		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.2		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.2		

**Table 11.1.DRGUD - ODE - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	31	23		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.5	1.1		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.5	0		



**Table 11.1.DSD - ODE - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	25	15		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.1		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0		

**Table 11.1.DCTD - OIR - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	29	6		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.0	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0		

**Table 11.1.DIHD - OIR - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	2	2		
Average number of cycles to approval or conditional approval of the IDE	N/A	N/A	N/A		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	N/A	N/A		

**Table 11.1.DMD - OIR - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	1	0		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.0	N/A		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	N/A		

**Table 11.1.DMGP - OIR - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	19	8		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.0	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0		

**Table 11.1.DRH - OIR - IDE Performance Metrics**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>2017</b>
Number of IDEs received	N/A	9	0		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.6	N/A		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.6	N/A		

## **Section 12 Dual (510(k) and CLIA Waiver) Annual Metrics**

Dual (510(k) and CLIA Waiver) Annual Metrics and Goals will be reported in the Annual Report.

## Appendix A      Variable Definitions

### Section 1      PMA Originals and Panel Track Supplements

**Table 1.1 and Tables 1.1.x      PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year (see definition for the Received cohort above).
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number with accepted RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer.
4	Number without RTA Review and > 15 Days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number without RTA Review and <= 15 Days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of submissions not accepted for filing review	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

**Table 1.2 and Tables 1.2.x****PMA Original and Panel Track Supplements – Filing Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year (see definition for the Received cohort above).
2	Number Accepted <sup>#</sup>	Number Received (line 1) that got "RTA Accepted" (RTAA), RTAX, or RTAN decision in the first RTA review cycle entered by reviewer.
3	Number with completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013

**Table 1.3 and Tables 1.3.x****PMA Originals & Panel Track Supplements Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under with no SI past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 1.4 and Tables 1.4.x****PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 1.5 and Tables 1.5.x PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision Past Goal	Number of submissions pending MDUFA III Decision (line 5) past goal. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).



**Table 1.6 and Tables 1.6.x****PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision Past Goal	Number of submissions pending MDUFA III Decision (line 5) past goal. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 1.7 and Tables 1.7.x****PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA III Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.8 and Tables 1.8.x****PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA III Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.9 and Tables 1.9.x****PMA Originals and Panel Track Supplements (without Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable -  
Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

**Table 1.10 and Tables 1.10.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

**Table 1.11 and Tables 1.11.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

**Table 1.12 and Tables 1.12.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

## Section 2 PMA 180 Day Supplements

**Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year. See definition of the received cohort above.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or NON-MDUFA decision but without an SI.
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Supplements filed	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA III Decisions	Supplements received (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMa).
3	MDUFA III Decisions	Supplements received (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	Supplements pending MDUFA III Decision	Number of supplements received (line 1) that do not have a MDUFA III decision or a final decision.
6	Supplements pending MDUFA III Decision Past Goal	Number of supplements pending MDUFA III Decision (line 5) past goal. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 2.3 and Tables 2.3.x****PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable - Definitions**

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

**Table 2.4 and Tables 2.4.x****PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

## Section 3 PMA Real Time Supplements

**Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions**

#	Measure	Description
1	Supplements received	Number of Real Time PMA supplements that were received in this fiscal year. See the Received cohort definition above.
2	Non-MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) within goal.
5	Supplements pending MDUFA III Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA III decision and are not closed with a final decision.
6	Supplements pending MDUFA III Decision Past Goal	Number of supplements pending MDUFA III Decision (line 5) past goal. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – Rate of Not Approvable - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

**Table 3.3 and Tables 3.3.x****Real Time PMA Supplements Performance Metrics – Submissions  
Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).



## Section 5 PMA Annual Metrics and Goals

**Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions**

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non-Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements (No Panel) – Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

**Table 5.2 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number with a decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY closed	Number with a decision (line 2) divided by Number Filed (line 1).

**Table 5.3 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-year Rolling Average Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number with MDUFA decision after trimming the upper and lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA III decision and 5% of submissions with the highest number of Total Days to MDUFA III decision.
3	Three-year Rolling Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

## Section 6    510(k) MDUFA III Performance

**Table 6.1 and Tables 6.1.x    510(k) Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year. See definition for received cohort above. Third party reviews shall be excluded from this table.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	RTA Review not done and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN or RTAS) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	RTA Review not done and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" decision in the first RTA review cycle.
7	Rate of submissions not accepted	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

**Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions with RTA review accepted in this fiscal year (RTAA, RTAX, RTAN, or RTAS.). Third party 510(k) submissions are excluded from SI performance report.
2	510(k) withdrawn or deleted prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made before or on the cutoff date and before any SI action: WD, DD, DE, HD, K4, NR, RC, RD .
3	SI within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI pending within 60 FDA days	Submissions that are under review for not more than 60 FDA days and that do not have an SI.
6	SI pending over 60 FDA days	Submissions that are under review over 60 FDA days and that do not have an SI.
7	510(k)s NSE without SI	Number of 510(k) submissions that are closed with an NSE decision (or with an AN, DN, or ON decision where Date Received does not equal Date Final Decision) and did not have an SI.
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

**Table 6.3 and Tables 6.3.x****510(k) Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of 510(k) submissions accepted in this fiscal year that had an SI. Third party 510(k) submissions shall be excluded from this report.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all 510(k) submissions with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 6.4 and Tables 6.4.x 510(k) MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	510(k)s accepted	Number of 510(k) submissions accepted in this fiscal year. Third party 510(k) shall also be included into this report.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not SE or NSE).
3	MDUFA III Decisions (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA III decision (SE or NSE).
4	MDUFA III Decisions within 90 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA III Decision over 90 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 90 FDA Days	Number of submissions with MDUFA III Decisions within 90 FDA Days (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Average review cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA III Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 6.6 and Tables 6.6.x****510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions - Definitions**

#	Measure	Description
1	Number Accepted	Number of 510(k) submissions accepted in this fiscal year. See definition for Accepted cohort above.
2	Number with MDUFA decision	Number submissions accepted (line 1) that also had a MDUFA decision.
3	Number of SE decisions	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE decisions	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) and closed with Withdrawal (WD) final decision.
6	Number deleted	Number of submissions accepted (line 1) and closed with Delete (DE) final decision.
7	Rate of SE decisions	Number of SE decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of NSE decisions	Number of NSE decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number Received (line 1).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number Received (line 1).

**Table 6.7 and Tables 6.7.x****510(k) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days. Third Party 510(k) submissions shall also be included into this report.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

## Section 7    510(k) Annual General Metrics

**Table 7.1            CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type - Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. Third party 510(k) submissions shall also be included into this count.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.



**Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal - Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. Third-party 510(k) submissions shall also be included into this report.
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA III Decision	Total number of 510(k) submissions accepted (line 1) that had a MDUFA III decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) divided by the total of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA III decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA III Decision (line 4) excluding 2% of submissions with the lowest number of Total Days to MDUFA III decision and 2% of submissions with the highest number of Total Days to MDUFA III decision.
7	Average Total Time to MDUFA III decision	Average Total Time (FDA and Industry) to MDUFA decision. If the cohort is not closed (less than 99% of 510(k) submissions have a decision) "N/A" shall be displayed instead.

## Section 8 Annual Metrics for De Novo Requests

**Table 8.1 CDRH – Annual General Metric Report for *De Novo* Requests - Definitions**

#	Measure	Description
1	Number of <i>De Novo</i> Requests Received	Total number of <i>de novo</i> requests received in this fiscal year as of the report cutoff date.
2	Number of <i>De Novo</i> Requests with Decision	Number of <i>de novo</i> requests received in this fiscal year (line 1) which have also received a final decision as of the report cutoff date.
3	Number of <i>De Novo</i> Requests with Decision Pending	Number <i>de novo</i> requests received in this fiscal year (line 1) which have not received a final decision as of the report cutoff date.
4	Average Number of Days to Decision	Average total number of days to decision (days between <i>De Novo</i> Date Received and <i>De Novo</i> Decision Date) for <i>de novo</i> requests with decision (line 2).

## Section 9 Pre-Submissions

**Table 9.1 and Tables 9.1.x Pre-Submissions Performance Metrics - Definitions**

#	Measure	Description
1	Number of all qualified Pre-Submissions received	Number of all qualified Pre-Submissions received. This include those with a type="pre-sub" either with a meeting request or written feedback requested in the fiscal year.
2	Number requesting a meeting or teleconference	Number of qualified Pre-submission received (line 1) with the Sub-Type of "Pre-Sub Meeting Request".
3	Number with meetings or teleconferences held	Number requesting a meeting or teleconference (line 2) with Actual Meeting Date populated with a value prior to the cutoff date.
4	Days to meeting	Table shall show average days from Date FDA Initial Clock Start to Actual Meeting Date as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for days to meeting days, Industry days, and Total days. The calculation includes meetings where the Actual Meeting Date is greater than the Date FDA Initial Clock Start and the Actual Meeting Date is prior to as of the cutoff date.

## Section 10 CLIA Waiver Annual Metrics

**Table 10.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Withdrawn prior to SI	Number of submissions with MDUFA Decision WTDR within 90 FDA days
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days
5	SI pending within 90 FDA days	Number of submissions that are under review for not more than 90 FDA days and with no SI
6	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no SI
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within 90 FDA days (line 3) divided by the total number of submissions Eligible for SI (line 1), except those withdrawn before an SI was made or due (line 2)

**Table 10.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction –**

## Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications filed in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Table 10.3 CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals – Definitions**

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year, and did not have a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 180 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 180 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 180 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 180 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA III Decisions within 180 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

**Table 10.4 CLIA Waiver (with Panel Review) MDUFA Decision Performance Goals) – Definitions**

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year, and had a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 330 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 330 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

**Table 10.5 CLIA Waiver (without Panel Review) Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 10.6 CLIA Waiver (with Panel Review) Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

## Section 11 IDE Performance Metrics

**Table 11.1 IDE Performance Metrics**

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.

## Section 12 Dual 510(k) and CLIA Waiver Annual Metrics

**Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year
2	Withdrawn prior to SI	Number of submissions that were withdrawn or deleted prior to 90 days
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days
5	SI pending within 90 FDA days	Number of submissions that are under review for not more than 90 FDA days and with no SI
6	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no SI
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within 90 FDA days (line 3) divided by the total number of submissions Eligible for SI (line 1), except those withdrawn before an SI was made or due (line 2)

**Table 12.2 Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications filed in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).



**Table 12.3 Dual 510(k) and CLIA Waiver (without panel review) MDUFA Decision Performance Goals – Definitions**

#	Measure	Description
1	Dual 510(k) and CLIA Waiver Applications accepted	Number of Dual 510(k) and CLIA Waiver by Applications that were filed in this fiscal year, and did not have a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 210 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 210 FDA days
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision over 210 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 210 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 210 FDA Days	Number of submissions with MDUFA III Decisions within 210 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

**Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA Decision Performance Goals – Definitions**

#	Measure	Description
1	Dual 510(k) and CLIA Waiver Applications accepted	Number of Dual 510(k) and CLIA Waiver by Applications that were filed in this fiscal year, and had a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 210 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 210 FDA days
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

**Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Quarterly Update on  
Medical Device Performance Goals  
----MDUFA III CBER Performance Data ----  
Action through 31 March 2015**

## Section 1 PMA Original and Panel Track Supplements - Center Level

**Table 1.1 CBER – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	6	0		
Closed before RTA action	0	0	0		
Number Accepted	1	6	0		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of submissions not accepted for filing review	0.0%	0.0%	0.0%		
Completed RTF	0	0	0		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0.0%	0.0%	0.0%		

**Table 1.2 CBER – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	1	6	0		
SI within 90 FDA days	0	6	0		
SI over 90 FDA days	1	0	0		
SI pending within 90 FDA days	0	0	0		
SI pending over 90 FDA days	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent within 90 FDA days	0.0%	100.0%	0.0%		

**Table 1.3 CBER – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1	6	0		
Average number of FDA days to Substantive Interaction	101	88	0		
20th Percentile FDA days to Substantive Interaction	101	87	0		
40th Percentile FDA days to Substantive Interaction	101	88	0		
60th Percentile FDA days to Substantive Interaction	101	88	0		
80th Percentile FDA days to Substantive Interaction	101	90	0		
Maximum FDA days to Substantive Interaction	101	90	0		

**Table 1.4 CBER – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	0	6	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	4	0		
MDUFA III Decisions within 180 FDA Days	0	4	0		
PMAs pending MDUFA III Decision	0	2	0		
PMAs pending MDUFA III Decision over 180 FDA days	0	0	0		
Current Performance Percent within 180 FDA Days	0.0%	100.0%	0.0%		

**Table 1.5 CBER – PMA Originals & Panel-Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	0	0		
MDUFA III Decisions within 320 FDA Days	1	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision over 320 FDA days	0	0	0		
Current Performance Percent within 320 FDA Days	100.0%	0.0%	0.0%		

**Table 1.6 CBER – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	4	0		
<b>Average FDA days to MDUFA III decision</b>	<b>0</b>	<b>175</b>	<b>0</b>		
20th Percentile FDA days to MDUFA III decision	0	170	0		
40th Percentile FDA days to MDUFA III decision	0	172	0		
60th Percentile FDA days to MDUFA III decision	0	177	0		
80th Percentile FDA days to MDUFA III decision	0	180	0		
Maximum FDA days to MDUFA III decision	0	180	0		
<b>Average Industry days to MDUFA III decision</b>	<b>0</b>	<b>55</b>	<b>0</b>		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	41	0		
80th Percentile Industry days to MDUFA III decision	0	178	0		
Maximum Industry days to MDUFA III decision	0	178	0		
<b>Average Total days to MDUFA III decision</b>	<b>0</b>	<b>230</b>	<b>0</b>		
20th Percentile Total days to MDUFA III decision	0	170	0		
40th Percentile Total days to MDUFA III decision	0	172	0		
60th Percentile Total days to MDUFA III decision	0	218	0		
80th Percentile Total days to MDUFA III decision	0	358	0		
Maximum Total days to MDUFA III decision	0	358	0		



**Table 1.7 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	0	0		
<b>Average FDA days to MDUFA III decision</b>	<b>303</b>	<b>0</b>	<b>0</b>		
20th Percentile FDA days to MDUFA III decision	303	0	0		
40th Percentile FDA days to MDUFA III decision	303	0	0		
60th Percentile FDA days to MDUFA III decision	303	0	0		
80th Percentile FDA days to MDUFA III decision	303	0	0		
Maximum FDA days to MDUFA III decision	303	0	0		
<b>Average Industry days to MDUFA III decision</b>	<b>41</b>	<b>0</b>	<b>0</b>		
20th Percentile Industry days to MDUFA III decision	41	0	0		
40th Percentile Industry days to MDUFA III decision	41	0	0		
60th Percentile Industry days to MDUFA III decision	41	0	0		
80th Percentile Industry days to MDUFA III decision	41	0	0		
Maximum Industry days to MDUFA III decision	41	0	0		
<b>Average Total days to MDUFA III decision</b>	<b>344</b>	<b>0</b>	<b>0</b>		
20th Percentile Total days to MDUFA III decision	344	0	0		
40th Percentile Total days to MDUFA III decision	344	0	0		
60th Percentile Total days to MDUFA III decision	344	0	0		
80th Percentile Total days to MDUFA III decision	344	0	0		
Maximum Total days to MDUFA III decision	344	0	0		

**Table 1.8 CBER – PMA Originals and Panel Track Supplements (without Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	6	0		
Number with MDUFA decision	0	4	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0.0%	0.0%	0.0%		
Rate of Not Approvable	0.0%	0.0%	0.0%		

**Table 1.9 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0	0		
Number with MDUFA decision	1	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0.0%	0.0%	0.0%		
Rate of Not Approvable	0.0%	0.0%	0.0%		

**Table 1.10 CBER – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

**Table 1.11 CBER – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	0	0	0		

## Section 2 PMA 180 Day Supplements - Center Level

**Table 2.1 CBER – PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	2	1	0		
SI within 90 FDA days	2	1	0		
SI over 90 FDA days	0	0	0		
SI pending within 90 FDA days	0	0	0		
SI pending over 90 FDA days	0	0	0		
Closed without SI	1	0	0		
Current SI Performance Percent within 90 FDA days	100.0%	100.0%	0.0%		

**Table 2.2 CBER – PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	3	1	0		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	2	1	0		
MDUFA III Decisions within 180 FDA Days	2	1	0		
Supplements pending MDUFA III Decision	0	0	0		
Supplements pending MDUFA III Decision over 180 FDA days	0	0	0		
Current Performance Percent within 180 FDA Days	100.0%	100.0%	0.0%		

**Table 2.3 CBER – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	1	0		
Number with MDUFA decision	2	1	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.0%	0.0%	0.0%		

**Table 2.4 CBER – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

### Section 3 PMA Real Time Supplements - Center Level Metrics

**Table 3.1 CBER – Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	3	2	3		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	3	2	0		
MDUFA III Decisions within 90 FDA Days	3	2	0		
Supplements pending MDUFA III Decision	0	0	3		
Supplements pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	100.0%	100.0%	0.0%		

**Table 3.2 CBER – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	2	3		
Number with MDUFA decision	3	2	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.0%	0.0%	0.0%		

**Table 3.3 CBER – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

## Section 6 510(k) Center Level Metrics

**Table 6.1 CBER – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	57	27		
Closed before RTA action	1	4	0		
Number Accepted	40	48	21		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	2		
Number Not Accepted	19	9	4		
Rate of submissions not accepted for review	32.2%	15.8%	16.0%		

**Table 6.2 CBER – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	47	48	21		
SI within 60 FDA days	41	47	18		
SI over 60 FDA days	6	1	1		
SI pending within 60 FDA days	0	0	2		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	87.2%	97.9%	95.0%		

**Table 6.3 CBER – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	47	48	19		
Average number of FDA days to Substantive Interaction	49	49	51		
20th Percentile FDA days to Substantive Interaction	30	34	34		
40th Percentile FDA days to Substantive Interaction	46	54	57		
60th Percentile FDA days to Substantive Interaction	58	56	59		
80th Percentile FDA days to Substantive Interaction	59	60	60		
Maximum FDA days to Substantive Interaction	90	90	62		

**Table 6.4 CBER – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>91% within 90 FDA days</b>	<b>93% within 90 FDA days</b>	<b>95% within 90 FDA days</b>	<b>95% within 90 FDA days</b>	<b>95% within 90 FDA days</b>
510(k)s accepted	47	48	21		
Non-MDUFA III Decisions	8	1	0		
MDUFA III Decisions (SE/NSE)	39	35	10		
MDUFA III Decisions within 90 FDA Days	37	35	10		
510(k)s pending MDUFA III Decision	0	12	11		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	94.9%	100.0%	100.0%		

**Table 6.5 CBER – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.69	1.37	1.30		
Number with MDUFA III decision	39	35	10		
<b>Average FDA days to MDUFA III decision</b>	71	62	74		
20th Percentile FDA days to MDUFA III decision	30	28	59		
40th Percentile FDA days to MDUFA III decision	81	60	76		
60th Percentile FDA days to MDUFA III decision	87	79	79		
80th Percentile FDA days to MDUFA III decision	89	88	84		
Maximum FDA days to MDUFA III decision	94	90	90		
<b>Average Industry days to MDUFA III decision</b>	76	26	10		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	19	0	0		
60th Percentile Industry days to MDUFA III decision	83	0	0		
80th Percentile Industry days to MDUFA III decision	150	44	24		
Maximum Industry days to MDUFA III decision	370	187	47		
<b>Average Total days to MDUFA III decision</b>	147	88	84		
20th Percentile Total days to MDUFA III decision	30	31	59		
40th Percentile Total days to MDUFA III decision	108	63	49		
60th Percentile Total days to MDUFA III decision	171	85	80		
80th Percentile Total days to MDUFA III decision	244	126	99		
Maximum Total days to MDUFA III decision	460	275	136		



**Table 6.6 CBER – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	47	48	21		
Number with MDUFA decision	39	35	10		
Number of SE decisions	36	33	9		
Number of NSE decisions	3	2	1		
Number of Withdrawals	8	1	0		
Number deleted	0	0	0		
Rate of SE decisions	92.3%	94.0%	90.0%		
Rate of NSE decisions	7.7%	6.0%	10.0%		
Rate of Withdrawals	17.0%	2.1%	0.0%		
Rate of Deleted	0.0%	0.0%	0.0%		

**Table 6.7 CBER – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0		
Mean FDA days for submissions that missed goal	94	0	0		
Mean industry days for submissions that missed goal	150	0	0		

## Section 9 Pre-Submissions

### Section 9 Pre-Submission Center Level Metrics

**Table 9.1 CBER – Pre-Submission Center Level Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	44	57	24		
Number requesting a meeting or teleconference	34	46	21		
Number with meetings or teleconferences granted	29	41	19		
Number with meeting granted and industry cancelled	13	7	3		
Number with meeting granted and FDA cancelled	0	1	0		
Number with meeting granted and pending within timeframe	0	0	10		
Number with meeting granted and pending outside timeframe	0	0	0		
Number with meetings or teleconferences held	15	33	6		
Average days to meeting	65	68	65		
20th Percentile days to meeting	55	44	40		
40th Percentile days to meeting	58	62	79		
60th Percentile days to meeting	61	78	83		
80th Percentile days to meeting	70	92	86		
Maximum days to meeting	122	132	87		

**BLAs****CBER – Annual General Metric Report for BLAs**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard BLAs Filed	9	10	2		
Number of Standard BLA First Actions less than or equal to 10 months	9	3	0		
Number of Standard BLA First Actions greater than 10 months	0	0	0		
Number of Standard BLAs Pending	0	7	2		
Number of Priority BLA Filed	0	0	0		
Number of Priority BLA First Actions less than or equal to 10 months	0	0	0		
Number of Priority BLA First Actions greater than 10 months	0	0	0		
Number of Priority BLAs Pending	0	0	0		

**BLA Efficacy Supplements****CBER – Annual General Metric Report for BLA Efficacy Supplements**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard Efficacy Supplements Filed	0	17	0		
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0	10	0		
Number of Standard Efficacy Supplements First Actions greater than 10 months	0	0	0		
Number of Standard Efficacy Supplements Pending	0	7	0		
Number of Priority Efficacy Supplements Filed	0	0	0		
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0	0	0		
Number of Priority Efficacy Supplements First Actions greater than 10 months	0	0	0		
Number of Priority Efficacy Supplements Pending	0	0	0		

**BLA Prior Approval Manufacturing Supplements**  
**CBER – Annual General Metric Report for BLA PAS Supplements**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard PAS Supplements Filed	20	6	6		
Number of Standard PAS Supplements First Actions less than or equal to 4months	20	6	4		
Number of Standard PAS Supplements First Actions greater than 4 months	0	0	0		
Number of Standard PAS Supplements Pending	0	0	2		

**BLA/BLA Resubmissions**  
**CBER – Annual General Metric Report for BLA/BLA Resubmissions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Class 1 Resubmissions Received	10	6	1		
Number of Class 1 Resubmission Actions less than or equal to 2 months	10	6	1		
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0		
Number of Class 1 Resbumssions Pending	0	0	0		
Number of Class 2 Resubmissions Received	0	2	0		
Number of Class 2 Resubmission Actions less than or equal to 6 months	0	2	0		
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0		
Number of Class 2 Resubmissions Pending	0	0	0		

<b>FY 2015 Medical Device User Fee Collections</b> <b>as of March 31, 2015</b> <sup>/1, 2</sup> <b>Excludes Unearned Fees</b>					
	<b>Receipts</b>	<b>Refunds</b>	<b>Net</b>	<b>Authorized</b>	<b>% of Authorized</b>
Registration Fees	\$84,655,516	\$218,678	\$84,436,838		
Application Fees	\$19,333,470	\$406,801	\$18,926,670		
<b>Total</b>	<b>\$103,988,986</b>	<b>\$625,479</b>	<b>\$103,363,508</b>	<b>\$131,195,000</b>	<b>79%</b>

<b>Medical Device User Fee Collection History</b> <sup>/3</sup>					
MD I	<b>FY 2003</b>	<b>FY 2004</b>	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>
	\$21,620,549	\$26,281,779	\$31,676,833	\$34,469,732	\$27,798,431
MD II	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
	\$47,703,148	\$56,937,803	\$63,400,607	\$69,541,787	\$65,158,728
MD III	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	\$99,954,122	\$120,285,271	\$103,363,508		

**Notes:**

/1 Figures are based on Q2 data; subject to revision.

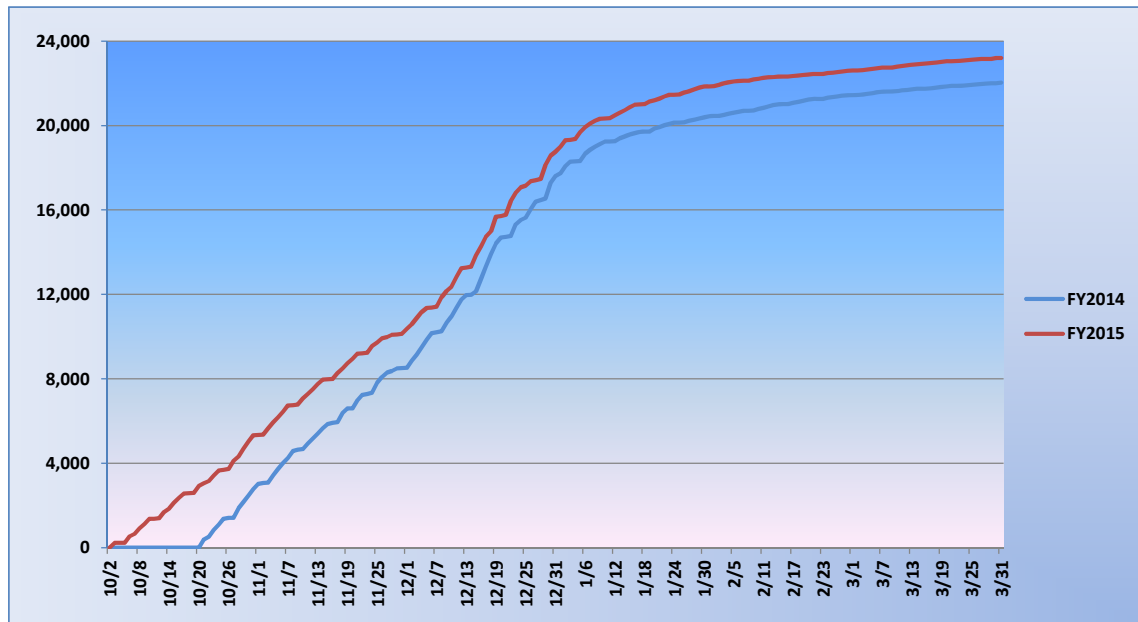
/2 Collections in this section are attributed to the authorized revenue ceiling for the Cohort Year

/3 Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year

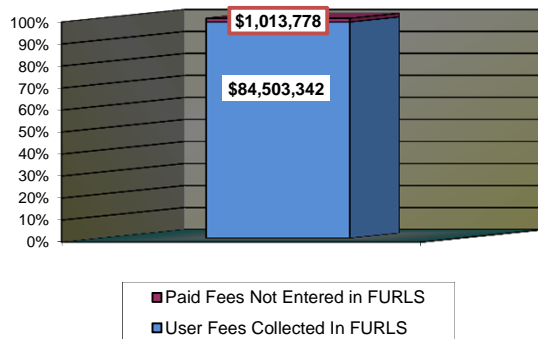
## MDUFA III, Registrations, Second Quarter Summary FY2015

Registrations by Type	FY15 End of 2nd Quarter Active			FY14 Year End Active Totals			Progress by Est Type
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,658	8,293	13,951	5,751	8,580	14,331	97.35%
Contract Manufacturer	886	1,115	2,001	894	1,113	2,007	99.70%
Contract Sterilizer	74	121	195	76	114	190	102.63%
Specification Developer	1,537	402	1,939	1,659	406	2,065	93.90%
Reprocessor of Single Use Devices	22	0	22	26	1	27	81.48%
U.S. Manufacturer of Export Only Devices	121	0	121	129	0	129	93.80%
Repackager/Relabeler	1,070	167	1,237	1,173	171	1,344	92.04%
Remanufacturer	20	13	33	23	17	40	82.50%
Foreign Exporter/Private Label Distributor	0	583	583	0	619	619	94.18%
Initial Importer	2,987	0	2,987	3,303	0	3,303	90.43%
Unknown	7	6	13	9	8	17	76.47%
<b>Total:</b>	<b>12,382</b>	<b>10,700</b>	<b>23,082</b>	<b>13,043</b>	<b>11,029</b>	<b>24,072</b>	<b>95.89%</b>

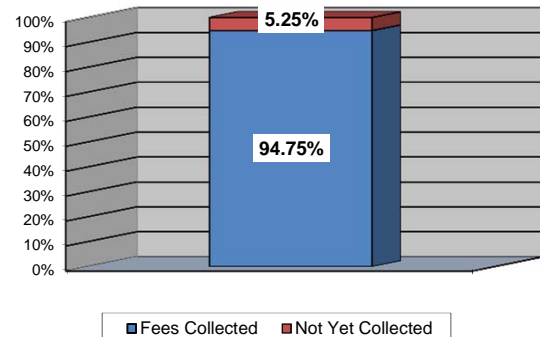
**Registration Progress - FY2014 Versus FY2015**



**User Fees Collected Versus User Fees Paid in Dollars**



**User Fee Progress - Percent Collected Versus Projections**  
Goals: \$89,188,452 fees or 24,462 Registrations



# MDUFA III Quarterly Performance Update

## Independent Assessment of Medical Device Review Process

2nd Quarter FY 2015 Status – April 21, 2015

### Objectives

Pursuant to the Performance Goals and Procedures adopted under the 2012 Medical Device User Fee Amendments (MDUFA III), FDA agreed to participate with the device industry in a comprehensive assessment of the process for the review of device applications.

This requirement is to conduct a comprehensive assessment of FDA premarket review processes for medical devices and to identify opportunities for improvement that will significantly impact the review of device premarket applications. Primary objectives include:

#### Phase 1:

- Identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards
- In-depth analyses of the elements of the review process in order to identify best practices and opportunities for improvement, including root cause analyses of selected significant factors
- Assessment of resource allocation to premarket device reviews across FDA
- Development of implementation plans for selected recommendations
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results

#### Phase 2:

- Evaluation of the implementation of selected recommendations

### Timeline

Milestone	Planned	Status
<b>FY 2013</b>		
Publish Federal Register notice	December 2012	Completed December 2012
Award contract	May 2013	Completed June 2013
Contract kickoff meeting between FDA and contractor	June 2013	Completed July 2013
Final workplan for Phase 1	July 2013	Completed August 2013
<b>FY 2014</b>		
Report on preliminary findings and high-priority recommendations	December 2013	Completed December 2013
Implementation plan for high-priority recommendations	June 2014	Completed June 2014
Final report on complete findings and recommendations	June 2014	Completed June 2014

Milestone	Planned	Status
<b>FY 2015</b>		
Phase 2 kickoff meeting between FDA and contractor	October 2014	Completed October 2014
Final workplan for Phase 2	November 2014	Completed November 2014
Implementation plan for final recommendations	December 2014	Completed December 2014
<b>FY 2016</b>		
Final evaluation report	February 1, 2016	On schedule

**Progress to-date:**

- Established Project Advisory Group (PAG) – Kickoff Meeting held July 12, 2012
- Established Technical Advisory Group (TAG) – 1<sup>st</sup> Meeting held September 12, 2012
- Drafted Assessment Statement of Work for FDA clearance – October 11, 2012
- Published SOW for industry and public comment – December 18, 2012
- Spoke with industry representatives regarding SOW feedback – January 29, 2013
- Received comments from Federal Register notice – February 4, 2013
- Finalized SOW based on feedback from Federal Register notice – March 25, 2013
- Issued request for proposal – April 19, 2013
- Awarded task order to Booz Allen Hamilton (BAH) – June 11, 2013
- Held kick-off meeting – July 1, 2013
- Received draft workplan – July 19, 2013
- Final workplan – August 2, 2013
- Focus group with Medical Device Industry representatives – August 17, 2013
- Report on preliminary findings and high-priority recommendations – December 11, 2013
- BAH meeting with Medical Device Industry representatives – January 17, 2014
- BAH benchmarking discussions with U.S. Patent and Trademark Office – February 2014
- Final report on complete findings and recommendations – June 11, 2014
- Implementation plan for high-priority recommendations – June 11, 2014
- Award of Phase 2 of contract – July 25, 2014
- Kick off Meeting for Phase 2 – October 2, 2014
- Final workplan for Phase 2 of assessment – November 14, 2014
- FDA implementation plan for final recommendations – December 11, 2014

**Progress from 2nd Quarter FY 2015:**

- Phase 2 kickoff meeting with Industry – January 2015
- FDA TAG meeting – January 2015
- BAH Presented Phase 1 assessment findings at the 2 day MDMA-FDA Forum – March 2015
- BAH continues to meet with FDA implementation project teams – Ongoing
- Refined preliminary SMART analysis on FDA's Implementation Plan for Priority and Final Recommendations – Ongoing



**Planned Progress in 3rd Quarter FY 2015:**

- Contractual progress reports and updates from BAH assessment team – Ongoing
- Meetings with Industry and FDA TAG – May 8, 2015

# **Center for Devices and Radiological Health Internal Training Summary Report**

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**Q2 FY15**

October 2014 – March 2015

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Prepared by: The Division of Employee Training and Development (DETD)

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As of: 4/30/2015

FDA continues to invest in internal and external training opportunities supporting the medical device review process. The Division of Employee Training and Development (DETD - formerly Staff College) is CDRH's internal resource for scientific, regulatory and, leadership training, career development programs, and customized learning opportunities. We help further the Center's mission of regulating medical devices and radiation-emitting products by championing employee growth across the Center's eight Offices. Our approach to improving performance combines classroom, experiential, and online learning with mentoring, self-study initiatives, and specialty programs. We are committed to providing CDRH employees with the knowledge and skills needed to maximize their organizational and individual potential.

Table X provides a summary of internal training conducted in CDRH between October 1, 2014 and March 31, 2015. DETD offered 260 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and program activities.

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**Table X - FY15 CDRH Internal Training Conducted Between:**

**Internal Training Conducted Between: *October 1, 2014 – March 31, 2015***

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
<b>Regulatory and Law (LAW) Training</b>	MDUFA III	6	146	343
	ELP	8	113	1360
	Other LAW	56	1279	5801
<i>LAW Subtotal:</i>		<i>71</i>	<i>1555</i>	<i>7776</i>
<b>Leadership Education and Development (LED) Training</b>	LEAD	19	346	1167
	Other LED	13	243	1411
<i>LED Subtotal:</i>		<i>32</i>	<i>589</i>	<i>2578</i>
<b>Professional Development (PRO) Training</b>	New Employee Orientation (NEO)	2	53	371
	Other PRO	60	1295	9012
<i>PRO Subtotal:</i>		<i>62</i>	<i>1348</i>	<i>9383</i>
<b>Science (SCI) Training</b>	All SCI	82	1961	7316
<b>*Center-Specific Information Technology (CIT) Training</b>	All CIT	13	63	41
<b>Grand Total:</b>		<b>260</b>	<b>5516</b>	<b>27094</b>

\* CIT is a new category that was added to Table X as of Q2FY15.

## Premarket Reviewer Training - RCP

### Reviewer Certification Program Description:

The development of new employees is vital to CDRH's mission. The Reviewer Certification Program (RCP) is intended for all new review staff in the offices of Device Evaluation (ODE) and In Vitro Diagnostics and Radiological Health (OIR). The RCP is a 10-month program consisting of training which addresses the basic core competencies required for completing the premarket review process.

The program components include:

- 38 courses totaling 140 hours of training,
- Practical activities and Hands-on exercises,
- A Submission Review Audit Process and;
- Knowledge Assessments.

### RCP Training Completed Between: *October 2014 – March 2015*

Category	Total Learning Events	Total Participants	Total Completions	Total Training Hours	Examples of Training Conducted
RCP	59	115	1518	8150	<ul style="list-style-type: none"> <li>• Basic Food and Drug Law</li> <li>• How to Write Effective Pre-market Consulting Reviews</li> <li>• Freedom of Information (FOI) Training</li> </ul>

### RCP Training by Cohort, Completed Between: *October 2014 – March 2015*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
<b>Fall 2014 Cohort 1</b> <i>October 2014 – December 2014</i>	7	26	ODE	18	171	1331
			OIR	11	176	958
<b>Fall 2014 Cohort 2</b> <i>October 2014 – December 2014</i>	9	26	ODE	24	304	1690
			OIR	13	211	1128
<b>Spring 2015 Cohort 1</b> <i>January 2015 – March 2015</i>	9	26	ODE	21	237	1346
			OIR	4	79	329
<b>Spring 2015 Cohort 2</b> <i>January 2015 – March 2015</i>	8	26	ODE	20	253	1072
			OIR	4	87	296
<b>Total:</b>	<b>33</b>	<b>26*</b>	<b>-</b>	<b>115</b>	<b>1518</b>	<b>8150</b>

\* The same online modules were offered to each cohort listed above.

## Premarket Reviewer Training - ELP

### **Experiential Learning Program Description:**

CDRH offers an innovative learning opportunity for new and experienced review staff. The Experiential Learning Program (ELP) is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the pre-market review of the resulting medical devices. The program fosters the premarket reviewers' understanding of how medical devices are developed, clinically tested, manufactured, and utilized.

### **ELP Training Completed Between:** *October 2014 – March 2015*

Office	# of Site Visits	# of Attendees	Total Training Hours	Focus Area
ODE	7	96	1088	<ul style="list-style-type: none"><li>• Endosseous Implants</li><li>• Refractive lasers</li><li>• Electrophysiology catheters for diagnostic and therapeutic indications</li><li>• Hemodialysis used in the home environment</li></ul>
OIR	1	17	272	<ul style="list-style-type: none"><li>• Good manufacturing practices under regulation 820</li></ul>
Total	8	113	1360	-

## **Premarket Reviewer Training – BAH Recommendation Update**

### **BAH Independent Assessment Training Recommendation Update: Q2FY15**

#### **Evaluation of IT Infrastructure and Workload Tools**

The Office of Communication and Education (OCE) is collaborating with the Offices of Device Evaluation (ODE) and Invitro Diagnostics and Radiological Health (OIR) to develop training for CDRH's three primary premarket IT systems: CTS, DocMan and Image2000+. Delivered in an online format; the training will be evaluated using Kirkpatrick's Level 1 and 2 evaluation. Training will be provided for all premarket review staff during Summer 2015.

#### **Evaluation of Training Programs**

The Office of Communication and Education is continuing the effort to implement Kirkpatrick's evaluation Levels 1-4. Specifically, OCE has implemented a revised Level 1 evaluation, and has modified the Level 2 evaluation data collection process for the Reviewer Certification Program. OCE has been working with ODE and OIR to determine the process for conducting the Level 3 and 4 training evaluation processes.

#### **Promotion of Informal Training**

The Office of Communication and Education has a senior reviewer onboard who is responsible for collecting data regarding internal training conducted by the Premarket Offices. The Office is also working to standardize the process for collecting informal training data conducted in the Center.



## Leadership Training - LEAD

### Leadership Enhancement and Development (LEAD) Program Description:

The LEAD Program is a Mandatory Supervisory Training Program targeting all CDRH Supervisors, Managers and Non-Bargaining Unit Team Leaders. The LEAD curriculum supports the CDRH Management Competencies and addresses the supervisory training requirements as mandated in 5 CFR 412.

### LEAD Training Completed Between: *October 2014 – March 2015*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	19	346	1167	<ul style="list-style-type: none"> <li>• Building Strong Customer Relations</li> <li>• Critical Thinking for Better Decision Making</li> <li>• Nonverbal Communication for Managers</li> </ul>

### LEAD Training for ODE and OIR Completed Between: *October 2014 – March 2015*

Office	Total # of Managers/Supervisors	# of Training Participants	Training Hours Completed	Training Hours Required	% of Required Training Hours Completed
ODE	64	44	282	1600	18%
OIR	36	23	107	1056	10%
<b>Total:</b>	<b>100</b>	<b>67</b>	<b>389</b>	<b>2656</b>	<b>15%</b>

## Leadership Training - LRP

### Leadership Readiness Program (LRP) Description:

The Leadership Readiness Program (LRP) is a one-year learning opportunity for employees considering a supervisory career path. The program facilitates learning in the areas of mentoring, self-study, classroom-based courses, and other practical activities. The target audiences for this program are highly motivated non-managers at the GS 12, 13, and non-supervisory 14 levels or equivalent Commissioned Corps Officers rank with a minimum of two years of FDA experience. Participants are selected for the one-year cohort program through a competitive process. They remain in their current position and participate in the LRP as a collateral activity.

### LRP Participant Data:

LRP Program Year	Office	# of Enrolled Participants	# of Participant Completions
<b>2006 - 2007</b>	OIVD	3	3
	ODE	13	12
<b>2008 - 2009</b>	OIVD	3	3
	ODE	10	10
	Other	17	16
<b>2010 - 2011</b>	OIVD	3	3
	ODE	9	8
	Other	8	8
<b>2012 - 2013</b>	OIR	3	3
	ODE	6	6
	Other	11	11
<b>2014 - 2015</b>	OIR	2	-
	ODE	6	-
	Other	12	-
<b>Total:</b>		<b>106</b>	<b>83</b>

### **CDRH Training Courses by Category:**

The following section contains a sampling of DETD courses that occurred during FY15.

#### **Regulatory and Law (LAW) Training:**

Basic Food and Drug Law	This interactive course is designed to provide CDRH employees with a focused, in-depth knowledge of the Food, Drug and Cosmetic Act and court precedents that govern the Agency's activities.
Benefit-Risk Guidance – Online	This online course outlines the factors to consider when making benefit-risk determinations in medical device Premarket Approval (PMA) application and De novo petitions.
FOI for Reviewers – Online	This course provides an overview of the Freedom of Information Act (FOIA) and provides additional information regarding the exemptions that apply when interacting with industry, consumers, and other domestic and foreign government agencies.
How to Write Deficiencies in Four-Part Harmony	This course provides staff with instruction regarding how to write deficiencies that are clear, concise and in the appropriate format. Through instructor- and coach-led lecture and interactive exercises, participants explore use of the 4-Part Harmony as addressed in the Guidance document.
How to Write Effective Pre-market Consulting Reviews	High quality consulting reviews are essential for communicating and documenting the pre-market review of medical devices. This course is led by experienced reviewers who describe the content required in pre-market consulting reviews and share best practices.
Humanitarian Use Devices and Humanitarian Device Exemption	This half-day seminar provides information on the Humanitarian Use Device (HUD) designation process and Humanitarian Device Exemption (HDE) review requirements, including an update on changes in legislation and guidance documents related to HUDs/HDEs in the FDA Safety and Innovation Act (FDASIA).
Mastering Technical Writing: A Plain Writing Workshop	This class teaches participants the basic elements of plain writing and how to use them to write succinct, well-written technical documents. The class is based on best practices used by professional writers and features interactive exercises and peer feedback.
Investigational Device Exemption (IDE) Overview- Online	This course describes what an IDE is, how to obtain it, and how to address it in AIMS.

MDUFA III - Module 1: 510(k)s webcast – Online	Module 1: 510(k)s provides Center staff with an overview of the MDUFA III changes to the 510(k) program with respect to Refuse to Accept (RTA), Substantive Interaction (SI) Communication, Interactive Review (IR), MDUFA Performance Goals, and Missed MDUFA Decision (MMD) Communication.
MDUFA III - Module 2: PMAs webcast – Online	Module 2: PMAs provides Center staff with an overview of the MDUFA III changes to the PMA program with respect to Refuse to Accept (RTA), Refuse to File (RTF), Substantive Interaction (SI) Communication, Interactive Review (IR), MDUFA Performance Goals, and Missed MDUFA Decision (MMD) Communication.
MDUFA III - Module 3: Pre-Submissions webcast – Online	Module 3: Pre-Submissions provides Center staff with training on the draft Pre-Submission guidance document and MDUFA III commitments, including a description of the types of Pre-Submissions and the tracking process.
MDUFA III - Module 4: Electronic Workload Management webcast – Online	Module 4: Electronic Workload Management Enhancements provides Center staff with instruction on the new eCopy program, the DocMan/Alfresco management tool, digital signatures and the Center Tracking System (CTS) Dashboards.
MDUFA III - Module 5: CLIA Waivers webcast – Online	Module 5: CLIA Waivers provides Center staff with instruction on the new program and processing procedures, Substantive Interactive (SI) Communication, and MDUFA Performance Goals.
Signal Management Program - Online	This module provides an overview of the Signal Management Program (SMP), which is a Center-wide program for finding, reporting, and resolving signals associated with marketed medical devices. Viewers will discover why CDRH has a consistent, systematic approach to handling signals and how their contribution can impact medical device safety.

### **Leadership Education and Development (LED) Training:**

LEAD: CDRH Customer Service Training	Customer service is one of CDRH's 2014-2015 Strategic Priorities. Providing excellent customer service improves our interactions with stakeholders and colleagues and supports better regulatory outcomes, which improves public health. As part of this strategic priority implementation, CDRH has adopted Standards of Excellence.
LEAD: CDRH Manager Orientation Program	To provide managers with detailed resources to access professional development and HR information for themselves as well as the employees they supervise.

LEAD: Crucial Conversations	This course teaches participants the skills and tools necessary for stepping up to and holding conversations that occur when stakes are high, opinions differ, and emotions run strong.
LEAD: The Successful Mentor	This workshop provides the participants with a learning experience that will enable them to maximize the mentoring experience.
LEAD: Time Management for Leaders	This training provides managers with the skills needed to monitor where their time goes, set priorities, manage tasks, and distinguish urgent from important activities in order to achieve their goals.

### Professional Development (PRO) Training:

Briefing and Public Speaking Skills	This workshop will review a systematic approach to planning and delivering effective, focused presentations to small or large groups. It will cover techniques for establishing objectives, remaining on target, and responding to difficult questions or challenges.
Critical Thinking and Problem Solving	This one-day workshop develops critical thinking skills for practical everyday use. Participants learn to assist work teams in understanding complex problems, methods for evaluating the possibilities of various decisions and increase their productivity and confidence for the constructive resolution of problems.
Critical TOP Thinking	This training provides an overview and tools for Thought Optimized Processing (TOP) Thinking. Participants will learn how to get more accomplished in a better and pragmatic way while maintaining precision and accuracy. Instruction will also address the ability to think creatively and critically and ensure that reasoning is objective.
Emotional Intelligence	This training provides participants with a proven set of skills in four areas of competency: self-awareness, self-management, social awareness, and social adeptness.
Event-Driven Leadership	This class supports organizational leadership in developing the competencies to deal with ongoing changes and events that impact the professional environment.
Influencing Others for High Impact	This seminar focuses on the skills and strategies necessary to increase the likelihood that others will say "yes". Instruction includes the opportunity to translate theory into practice.

Sparkling Creativity and Innovation	This class offers strategies and techniques to help the participant harness innovative thinking, find solutions to problems and enhance their own and others' ability to think more clearly and make better decisions.
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### Science (SCI) Training:

Basics of Flow Cytometry	Flow cytometry is used as a powerful technique in many fields, including diagnosis of hematological malignancy, detection of minimal residual disease (MRD), determination of CD4/CD8 ratio in HIV, and nanotechnology.
Basics of Human Factors Engineering and Device Design	Human factors engineering is a discipline that blends engineering design with human psychology, kinesiology, and biomechanics. The goal is to apply knowledge of human cognition and physical limitations to the design of systems, such as tools, tasks, devices, software, work areas, etc.
CDRH Laboratory Waste Management – online	This course gives an overview of the requirements for waste handling in CDRH laboratories, as well as a brief description of Emergency Procedures for the laboratory. These requirements are in place to establish regulatory compliance with entities such as EPA, Maryland Department of the Environment (MDE), and Montgomery County.
Distinguishing Medical Device Recalls from Medical Device Enhancements	This course provides CDRH staff with instruction on the distinctions between medical device recalls and medical device enhancements.
Regenerative Medicine Series	The Regenerative Medicine Seminar Series offers a variety of thought-provoking seminars that examine restoration and function of the human form within the context of translational research involving medical devices and biologics.

### Center-Specific IT (CIT) Training

Center Ad Hoc Reporting Systems (CARS): Overview	This course provides the participants with a functional overview of the system, a survey of the TPLC universe, and examples of office-specific foundational reports.
Learning about SharePoint	This training provides participants with a basic overview of SharePoint, examples of how it is used in CDRH and how to find additional resources. The relationship between SharePoint and Knowledge Management is also discussed.