

2nd Quarter FY 2016 Package
MDUFA III (FY 2013-2017) Performance
May 2, 2016

Guidance Development

FDA MDUFA Performance — Actions through March 31, 2015

- Report on decisions goals for 2nd Quarter of FY 2016

Qualitative Update on Finances – 2nd Quarter of FY 2016

- User fee receipts through the 2nd Quarter of FY 2016

CDRH Registration and Listing

- Report on registration and listing

Independent Assessment

- The project was completed by the required due date

CDRH Staff Training Update

- Report on CDRH Staff training

Page intentionally left blank

Medical Device Guidance Documents

(Issued in FY 2016)

January 1, 2016 through March 31, 2016 (Quarter 2)

25. Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices - Guidance for Industry and Food and Drug Administration Staff (3/22/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM452644>
24. Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes - Draft Guidance for Industry and Food and Drug Administration Staff (3/7/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM489111>
23. Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization - Draft Guidance for Industry and Food and Drug Administration Staff (2/29/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020>
22. Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices - Draft Guidance for Industry and Food and Drug Administration Staff (2/12/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM485862>
21. Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays - Guidance for Industry and Food and Drug Administration Staff (2/9/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM221420>
20. Display Devices for Diagnostic Radiology - Draft Guidance for Industry and Food and Drug Administration Staff (2/9/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM484914>
19. List of Highest Priority Devices for Human Factors Review - Draft Guidance for Industry and Food and Drug Administration Staff (2/3/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM484097>
18. Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff (2/3/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259760>
17. Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices - Draft Guidance for Industry and Food and Drug Administration Staff (2/3/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM484092>

16. Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (1/26/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482649>
15. Postmarket Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (1/22/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022>
14. Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile - Guidance for Industry and Food and Drug Administration Staff (1/21/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM109897>
13. Implanted Blood Access Devices for Hemodialysis - Guidance for Industry and Food and Drug Administration Staff (1/21/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM308598>
12. Unique Device Identification: Convenience Kits - Draft Guidance for Industry and Food and Drug Administration Staff (1/4/16)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM479242>

October 1, 2015 thru December 31, 2015 (Quarter 1)

11. Public Notification of Emerging Postmarket Medical Device Signals (Emerging Signals) - Draft Guidance for Industry and Food and Drug Administration Staff (12/31/2015)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm479248.pdf>
10. Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses - Draft Guidance for Industry, Clinicians and Food and Drug Administration Staff (12/29/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm478942.pdf>
9. Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices - Guidance for Industry and Food and Drug Administration Staff (12/15/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm433165.pdf>
8. Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings - Guidance for Industry and Food and Drug Administration Staff (12/09/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm452804.pdf>
7. eCopy Program for Medical Device Submissions - Guidance for Industry and Food and Drug Administration Staff (12/03/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313794.pdf>

6. Class II Special Controls Guideline: In Vitro Diagnostic Devices for *Bacillus* spp. Detection - Draft Guideline for Industry and Food and Drug Administration Staff (11/17/2015)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm470760.pdf>
5. Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (11/02/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm470201.pdf>
4. Class II Special Controls Guideline: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens - Guideline for Industry and Food and Drug Administration Staff (11/02/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm470559.pdf>
3. Homologous Use of Human Cells, Tissue, and Cellular and Tissue-Based Products; Draft guidance for Industry and FDA Staff (10/30/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm469751.pdf>
2. Manufacturing Site Change Supplements: Content and Submission - Draft Guidance for Industry and Food and Drug Administration Staff (10/21/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm467414.pdf>
1. General Considerations for Animal Studies for Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (10/14/15)
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm466358.pdf>

Page intentionally left blank

**Quarterly Update on
Medical Device Performance Goals
----MDUFA III CDRH Performance Data ----
Action through 31 March 2016**

Page intentionally left blank

Table of Contents

Acronyms and Abbreviations-----

Section 1: PMA Originals and Panel Track Supplements-----

PMA Originals and Panel Track Supplements – Center Level-----

PMA Originals and Panel Track Supplements – Office Level

ODE-----

OIR-----

PMA Originals and Panel Track Supplements – Division Level

DAGRID-----

DCD-----

DNPMMD-----

DOD-----

DOED-----

DRGUD-----

DSD-----

DCTD-----

DIHD-----

DMD-----

DMGP-----

DRH-----

Section 2: PMA 180 Day Supplements-----

PMA 180 Day Supplements – Center Level-----

PMA 180 Day Supplements – Office Level

ODE-----

OIR-----

PMA 180 Day Supplements – Division Level

DAGRID-----

DCD-----

DNPMMD-----

DOD-----

DOED-----

DRGUD-----

DSD-----

DCTD-----

DIHD-----

DMD-----

DMGP-----

DRH-----

Section 3: PMA Real Time Supplements-----

PMA Real Time Supplements – Center Level-----

PMA Real Time Supplements – Office Level

ODE-----

OIR-----

PMA Real Time Supplements – Division Level

DAGRID-----
DCD-----
DNPMD-----
DOD-----
DOED-----
DRGUD-----
DSD-----
DCTD-----
DIHD-----
DMD-----
DMGP-----
DRH-----

Section 4: Pre-Market Report Submissions-----

Section 5: PMA Annual Metrics and Goals-----

Section 6: 510(k) MDUFA III Performance -----

510(k) MDUFA III Performance – Center Level-----

510(k) MDUFA III Performance – Office Level

ODE-----

OIR-----

510(k) MDUFA III Performance – Division Level

DAGRID-----
DCD-----
DNPMD-----
DOD-----
DOED-----
DRGUD-----
DSD-----
DCTD-----
DIHD-----
DMD-----
DMGP-----
DRH-----

Section 7: 510(k) Annual General Metrics -----

Section 8: Annual Metrics for De Novo Requests -----

Section 9: Pre-Submissions-----

Pre-Submissions – Center Level-----

Pre-Submissions – Office Level

ODE-----

OIR-----

Pre-Submissions – Division Level

DAGRID-----

DCD-----

DNPMMD-----

DOD-----

DOED-----

DRGUD-----

DSD-----

DCTD-----

DIHD-----

DMD-----

DMGP-----

DRH-----

Section 10: CLIA Waiver Annual Metrics -----

Section 11: Investigational Device Exemptions (IDEs) -----

IDEs – Center Level-----

IDEs – Office Level

ODE-----

OIR-----

IDEs – Division Level

DAGRID-----

DCD-----

DNPMMD-----

DOD-----

DOED-----

DRGUD-----

DSD-----

DCTD-----

DIHD-----

DMD-----

DMGP-----

DRH-----

Appendix A: Variable Definitions-----

Acronyms and Abbreviations

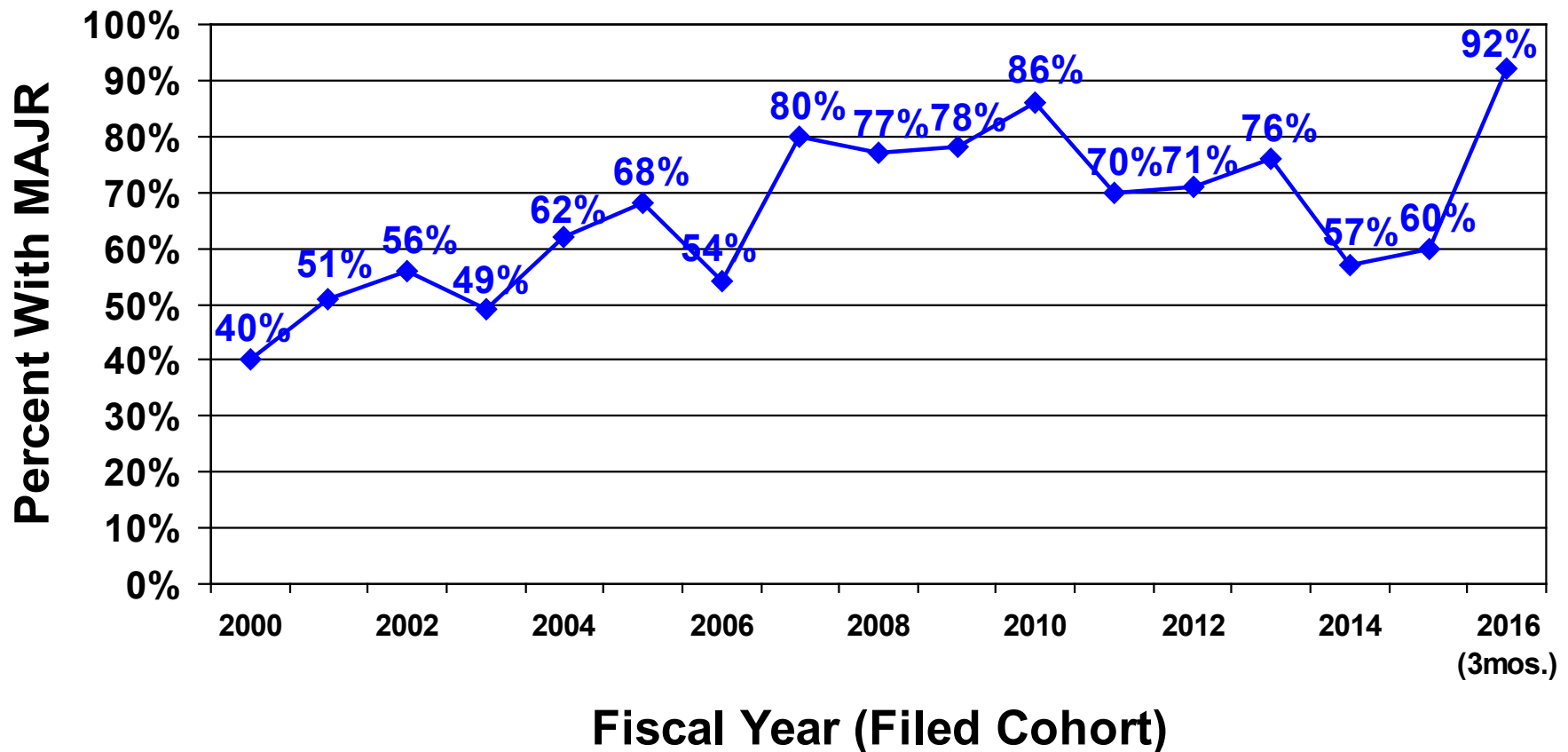
510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Act
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology 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

Q2FY16

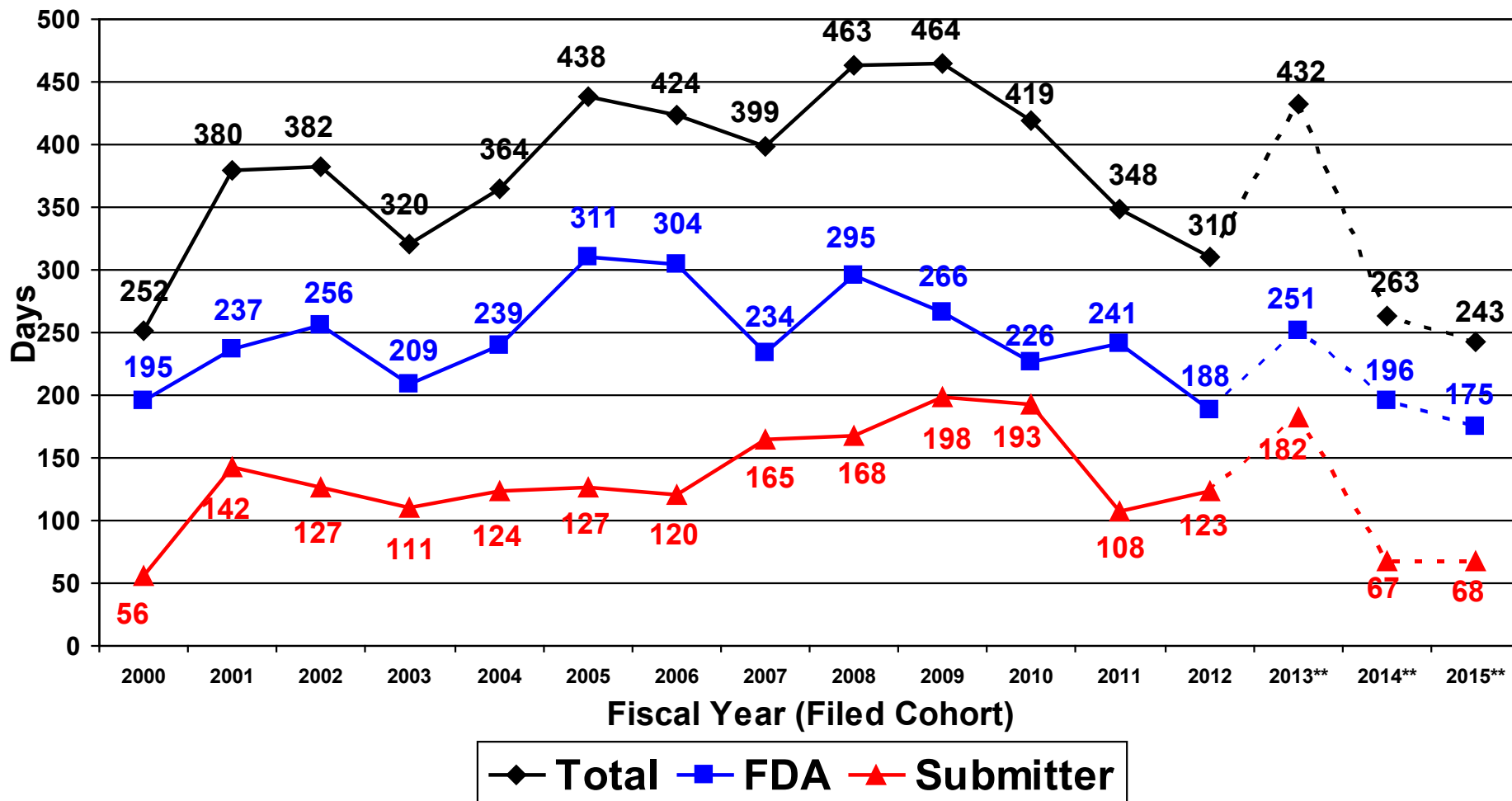
Percent of PMAs With Major Deficiency Letter (MAJR) on 1st FDA Review Cycle*



*Includes original PMAs only; FY 2013 - FY 2015 are receipt cohorts including PMAs filed as of 12/31/2015, prior cohorts are filed cohorts. Data for FY2016 will change.

Average Time to MDUFA Decision: PMAs*

(As of March 31, 2016)

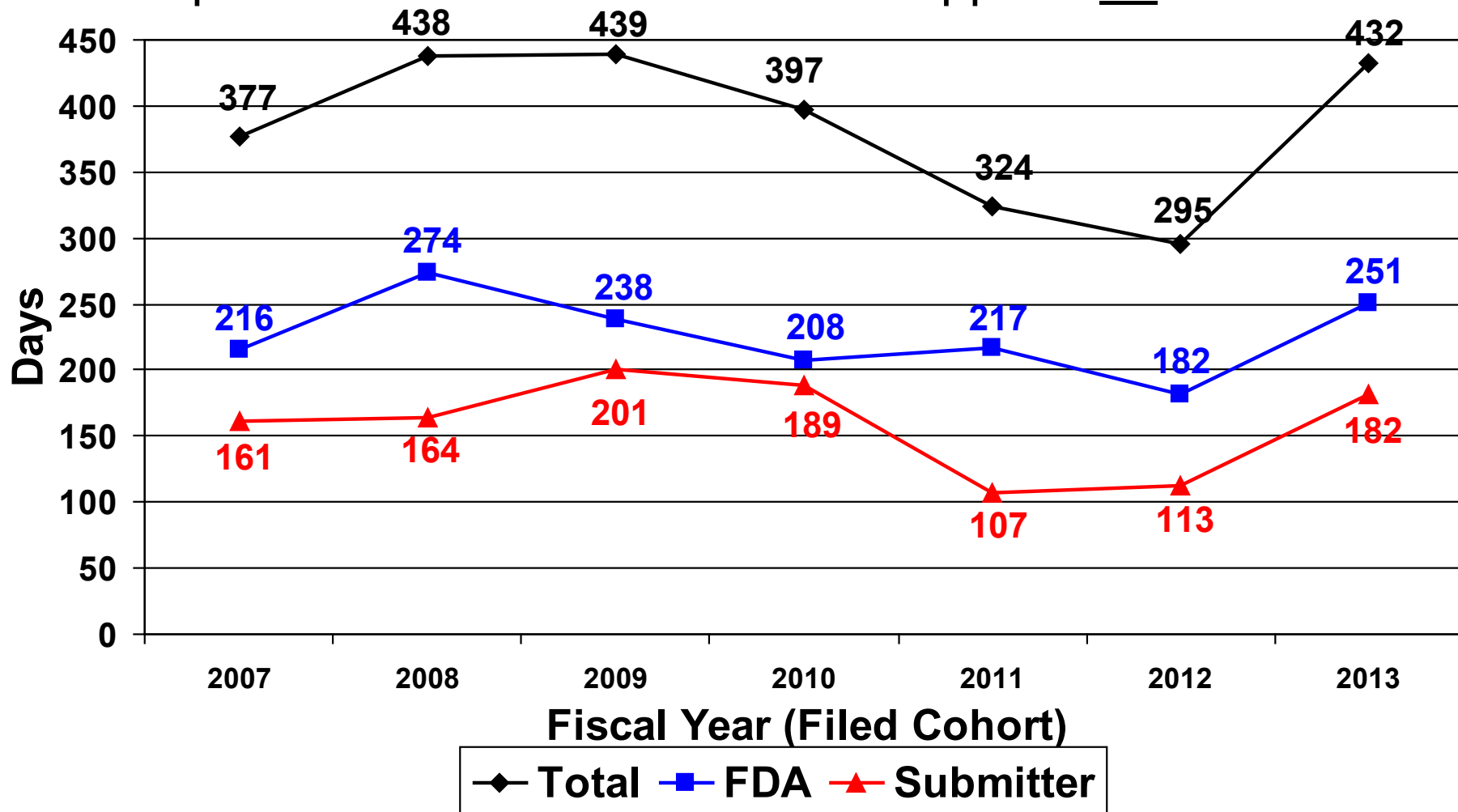


*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 3/31/2016, prior cohorts are filed cohorts; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision:
 FY13 = 97% (28/29); FY14 = 93% (26/28); FY15 = 64% (27/42)

Average Time to MDUFA Decision: PMAs*

- Comparison of Filed Cohorts When Approx. 97% Closed** -



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

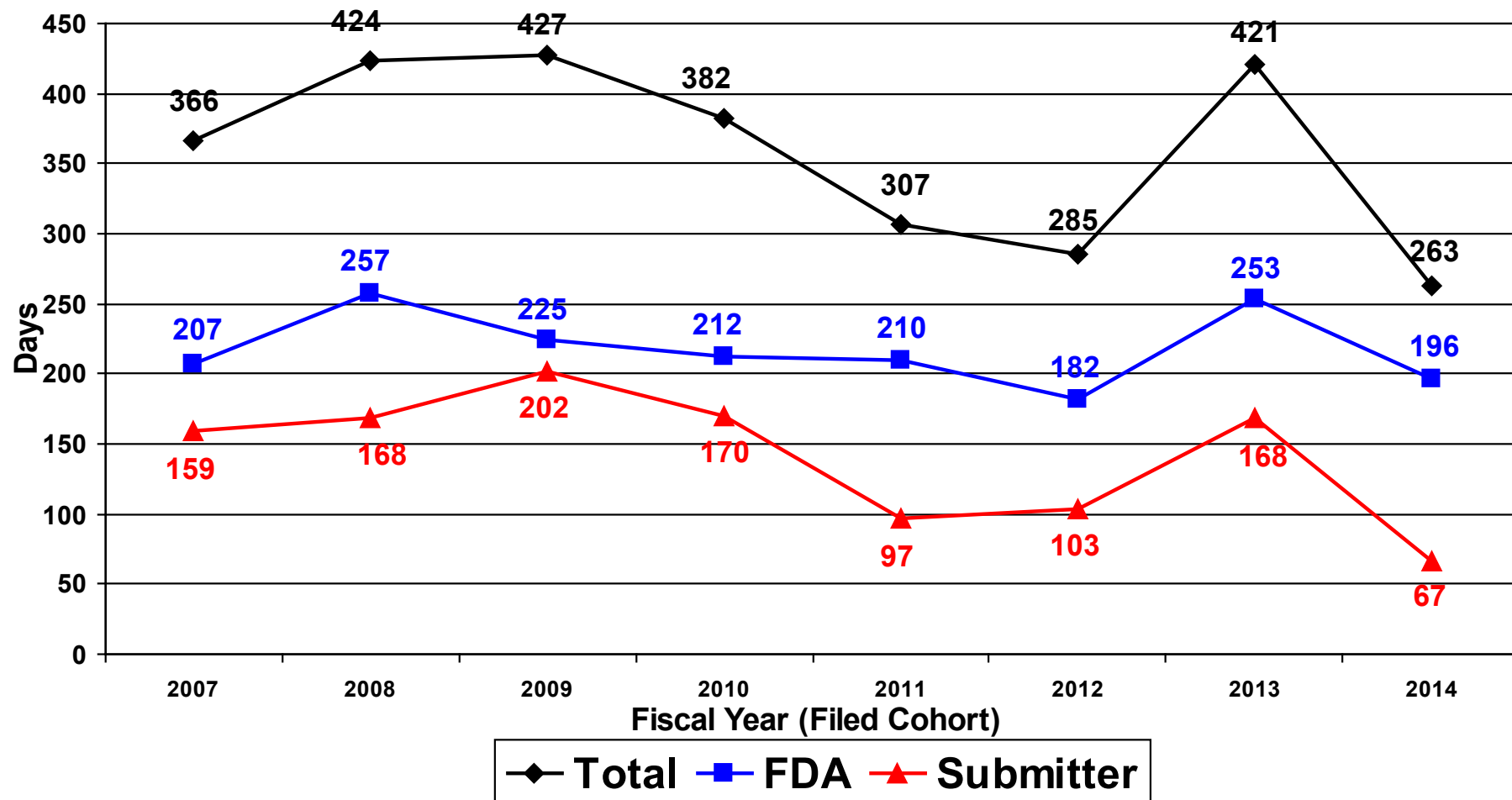
**Proportion of cohort closed (MDUFA decision) in this comparison:

FY07 = 34/35; FY08 = 29/30; FY09 = 31/32; FY10 = 42/43; FY11 = 42/43; FY12 = 23/24; FY13 = 28/29

***FY14 & FY15 cohorts are not yet 97% closed (as of 3/31/2016)

Average Time to MDUFA Decision: PMAs*

- Comparison of Filed Cohorts When Approx. 93% Closed** -



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

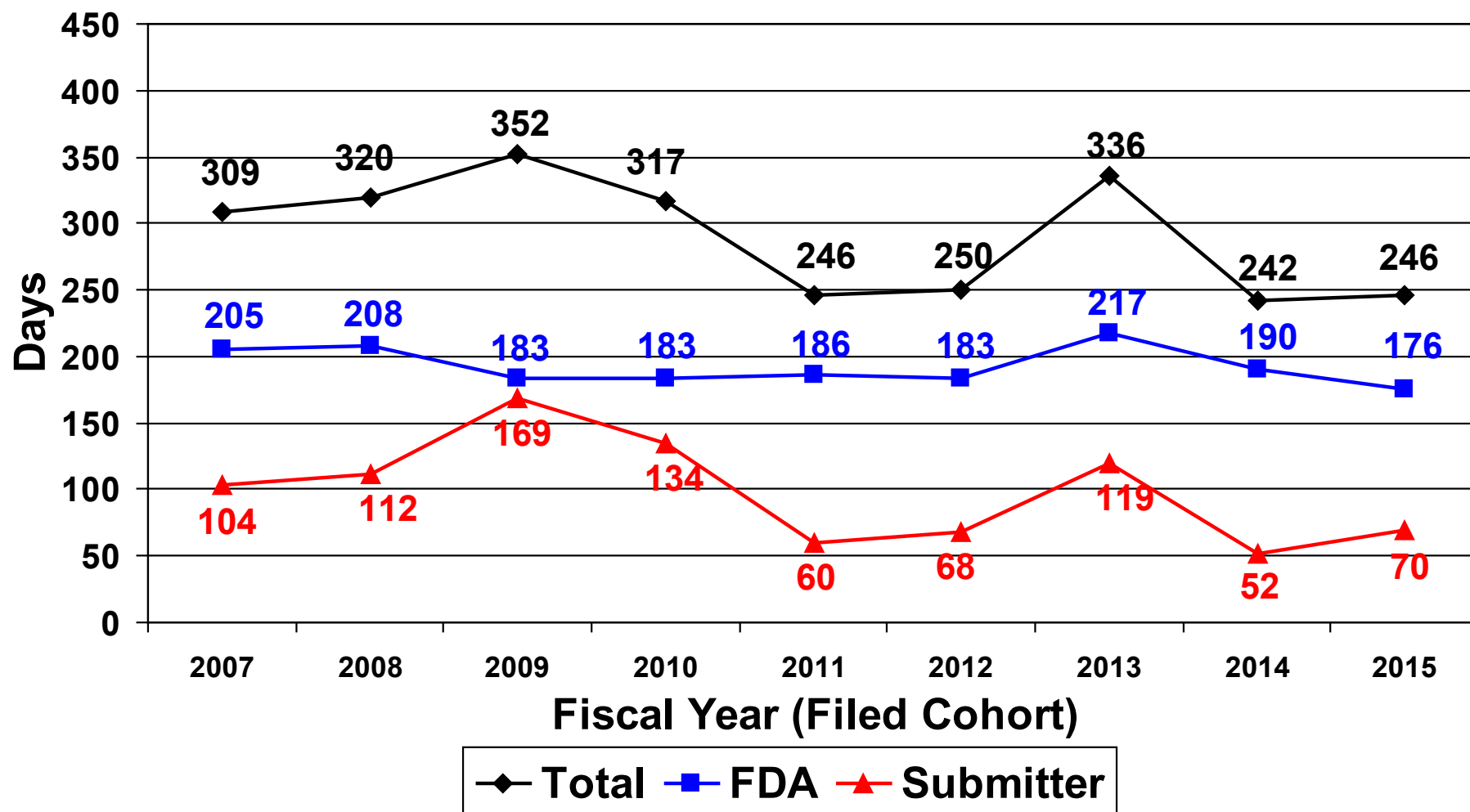
**Proportion of cohort closed (MDUFA decision) in this comparison: FY07 = 33/35; FY08 = 28/30; FY09 = 30/32; FY10 = 40/43; FY11 = 40/43; FY12 = 22/24; FY13 = 27/29; FY14 = 26/28

Page 17 of 360

***FY15 cohort is not yet 93% closed (as of 3/31/2016)

Average Time to MDUFA Decision: PMAs*

- Comparison of Filed Cohorts When Approx. 67% Closed** -



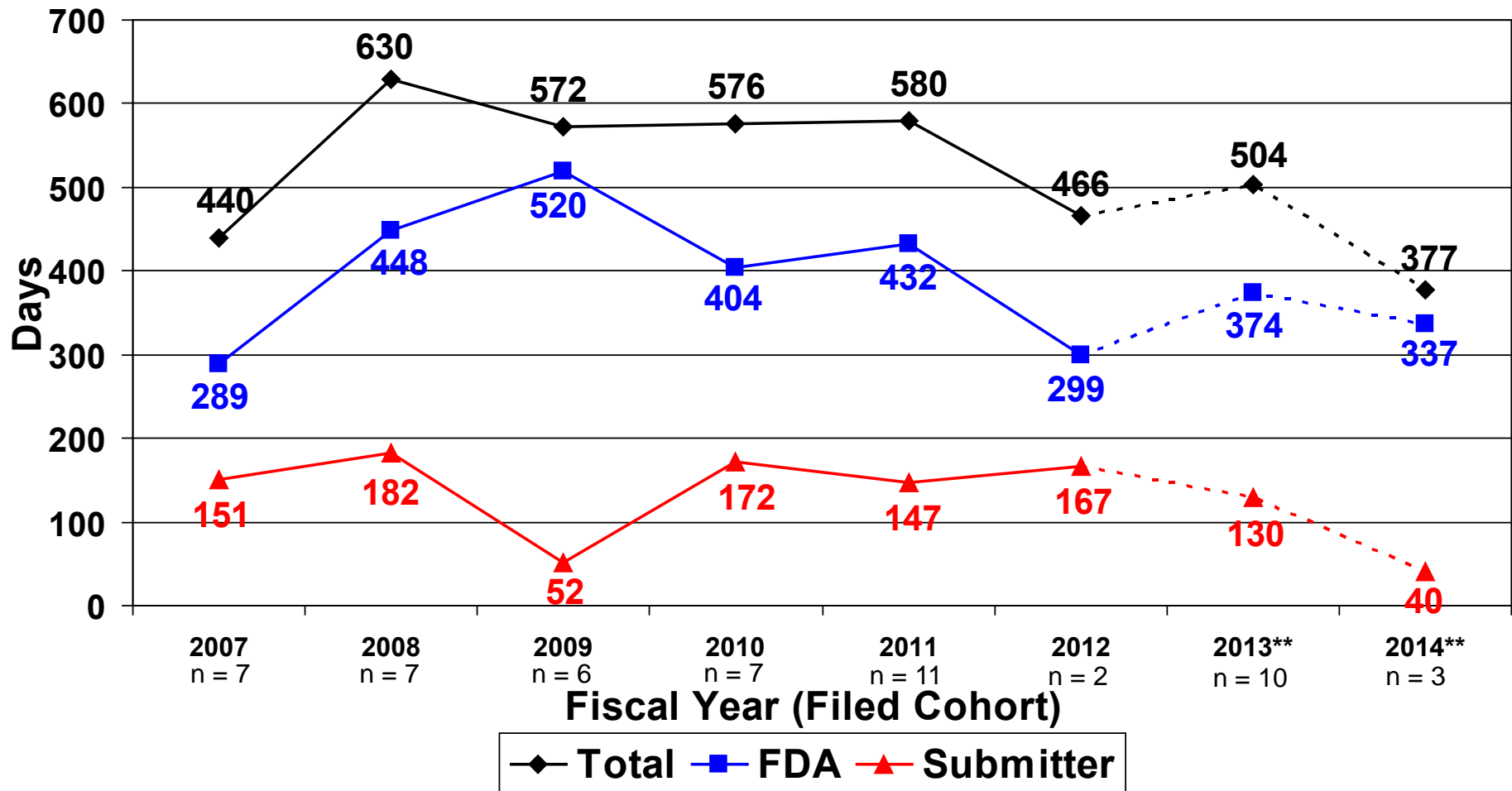
*Includes original PMAs only; times may not add to total due to rounding

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

FY07 = 23/35; FY08 = 20/30; FY09 = 21/32; FY10 = 29/43; FY11 = 29/43; FY12 = 16/24; FY13 = 19/29; FY14 = 19/28; FY15 = 28/42

Average Time to MDUFA Decision: PMAs With Panel Review*

(As of March 31, 2016)

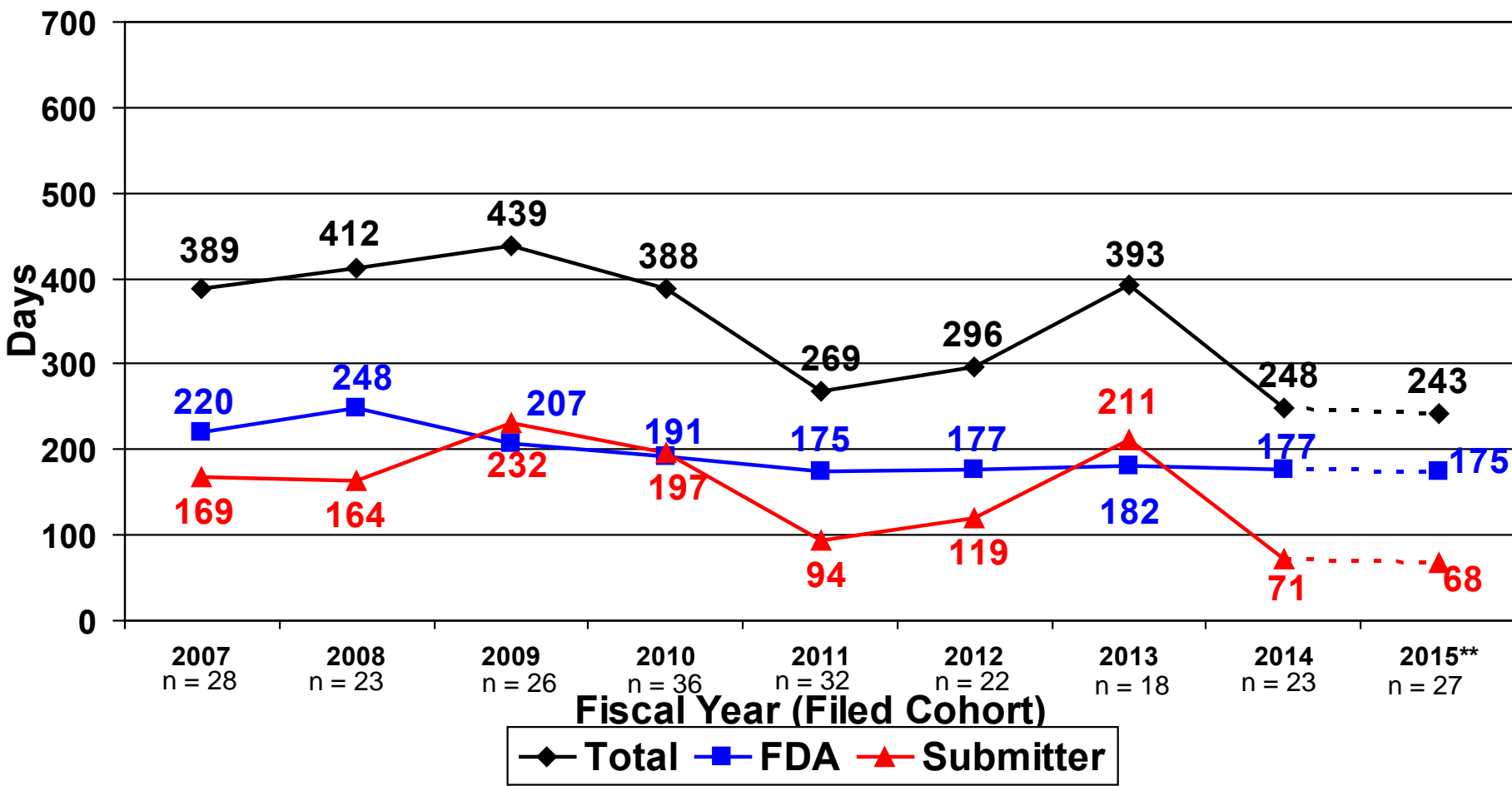


*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 3/31/2016, prior cohorts are filed cohorts; times may not add to total due to rounding;

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY13 = 91% (10/11) and FY14 = 60% (3/5)

Average Time to MDUFA Decision: PMAs Without Panel Review*

(As of March 31, 2016)

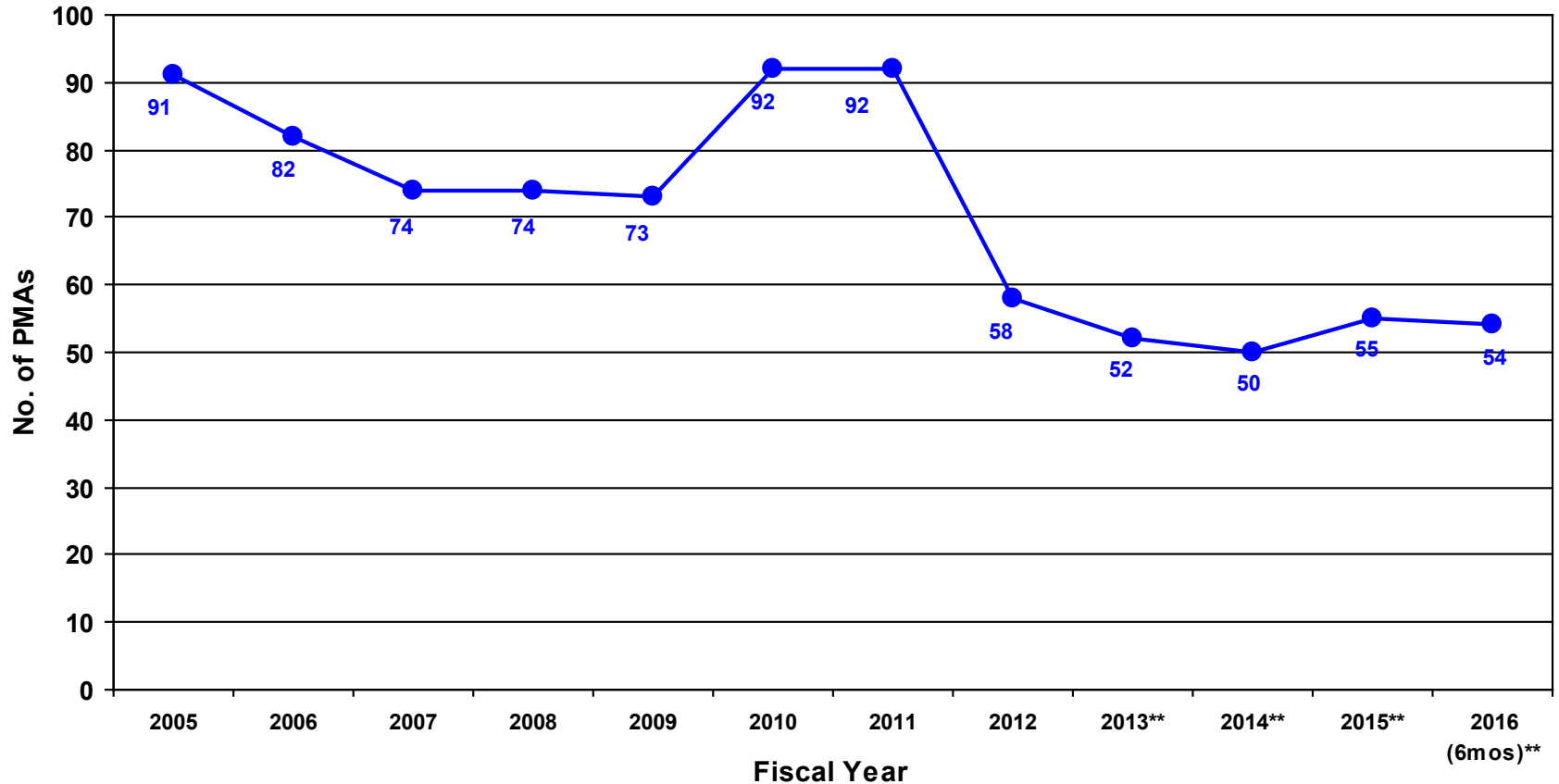


*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 3/31/2016, prior cohorts are filed cohorts; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY15 = now 71% (27/38)

Page 20 of 360

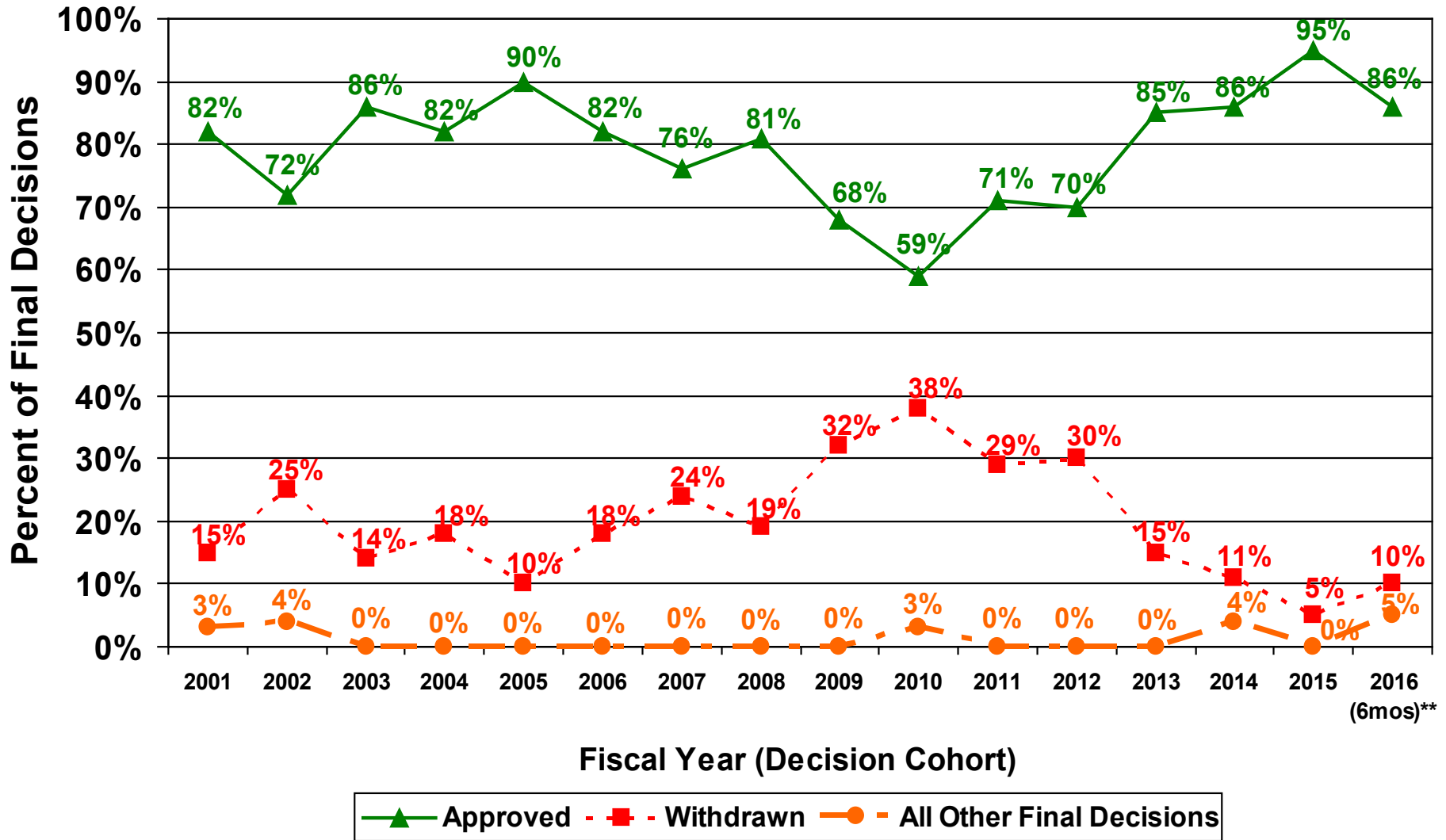
PMAs Pending* at End of Year



***Original PMAs under review or on hold**

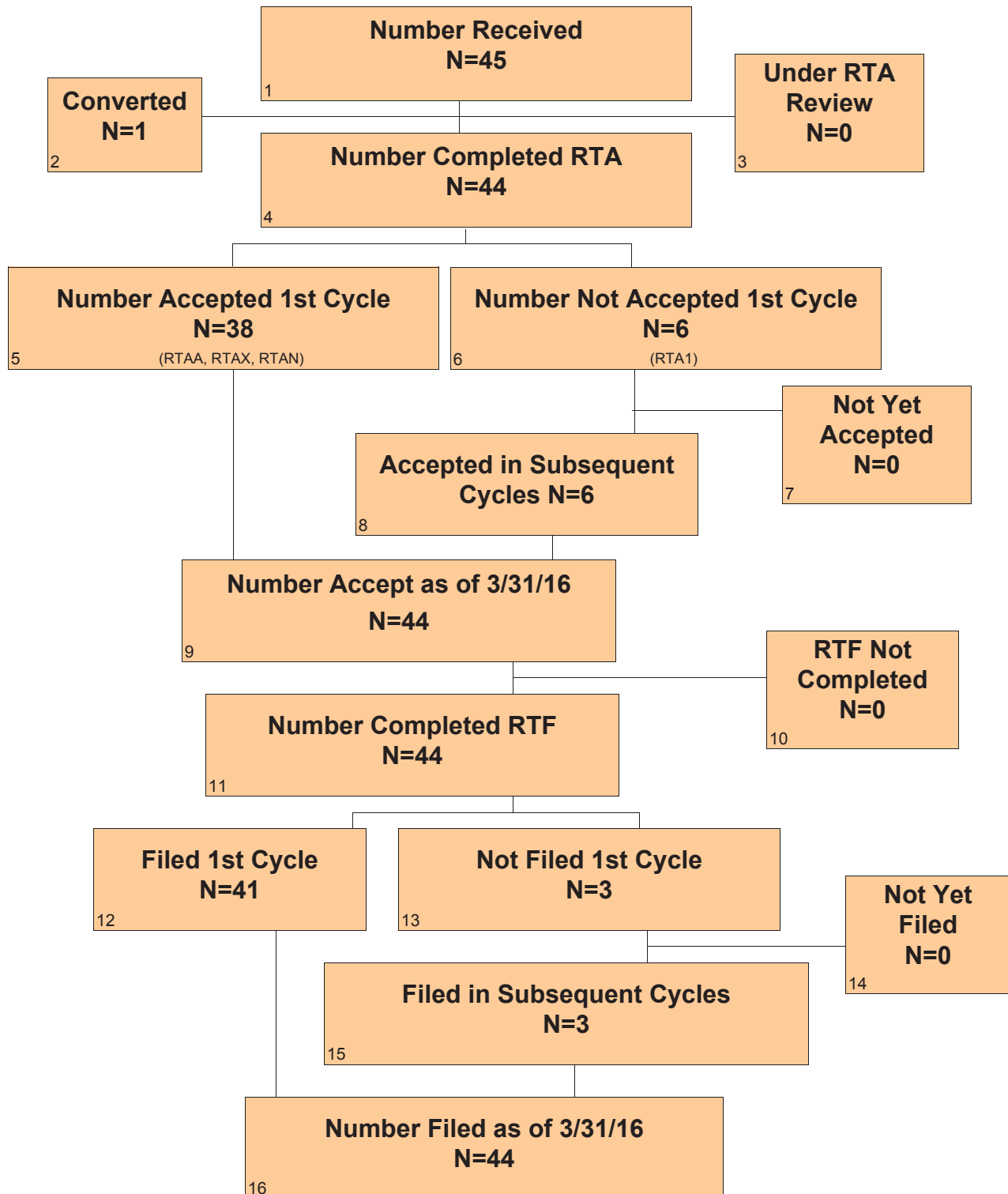
****Excludes FY 2013 - FY 2016 receipts that were not accepted for review at quarter end; FY 2015 increase reflects increase in filed PMAs (42 PMAs compared to 24, 29, and 28 for FY 2012 – FY 2014, respectively)**

Percent of PMAs Approved*

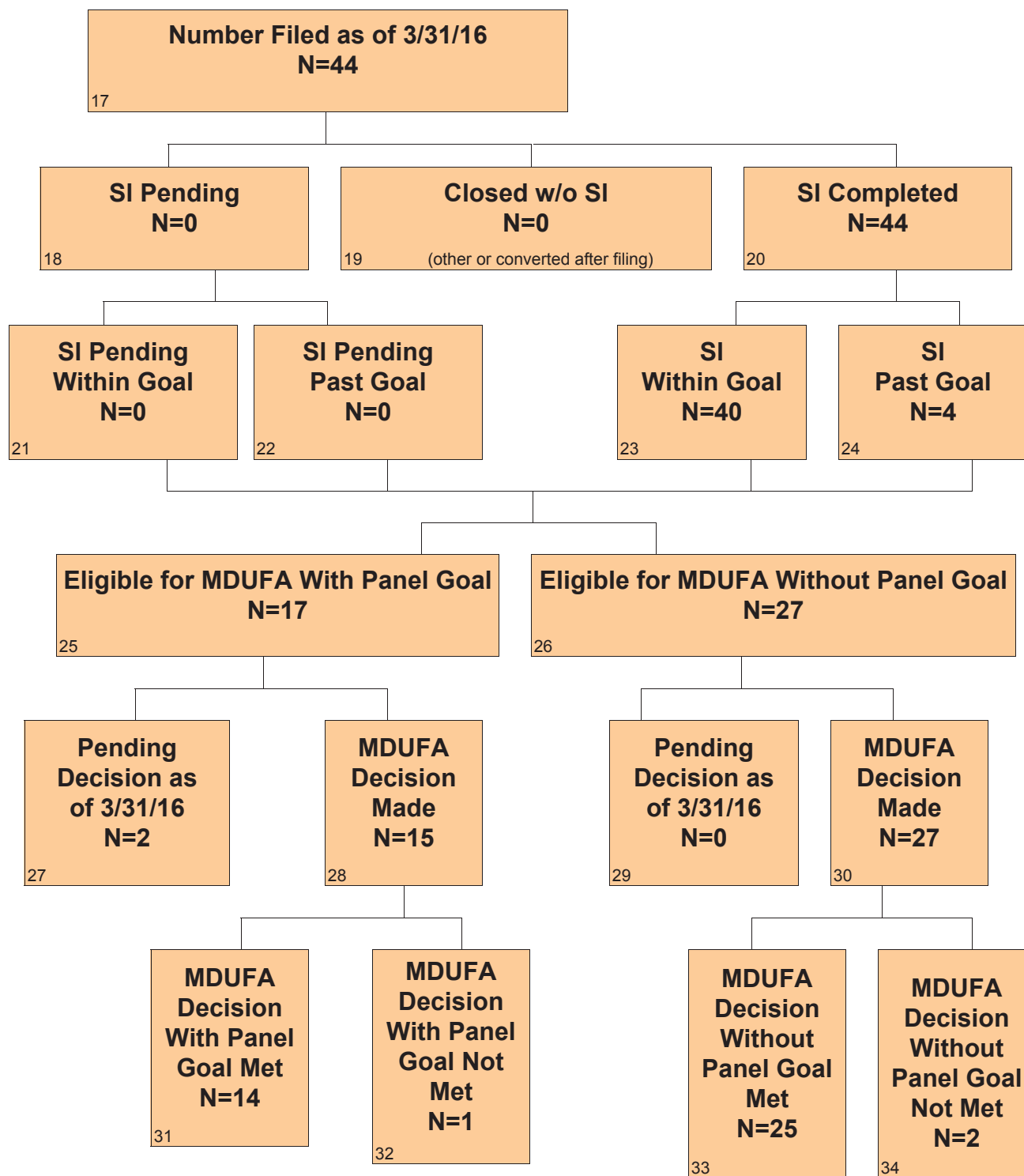


*Based on original PMAs that were accepted for filing as of 3/31/2016; percentages may not add to 100% due to rounding. Note FY15 previously showed 3% withdrawn and now shows 5% withdrawn due to a change in data entry.

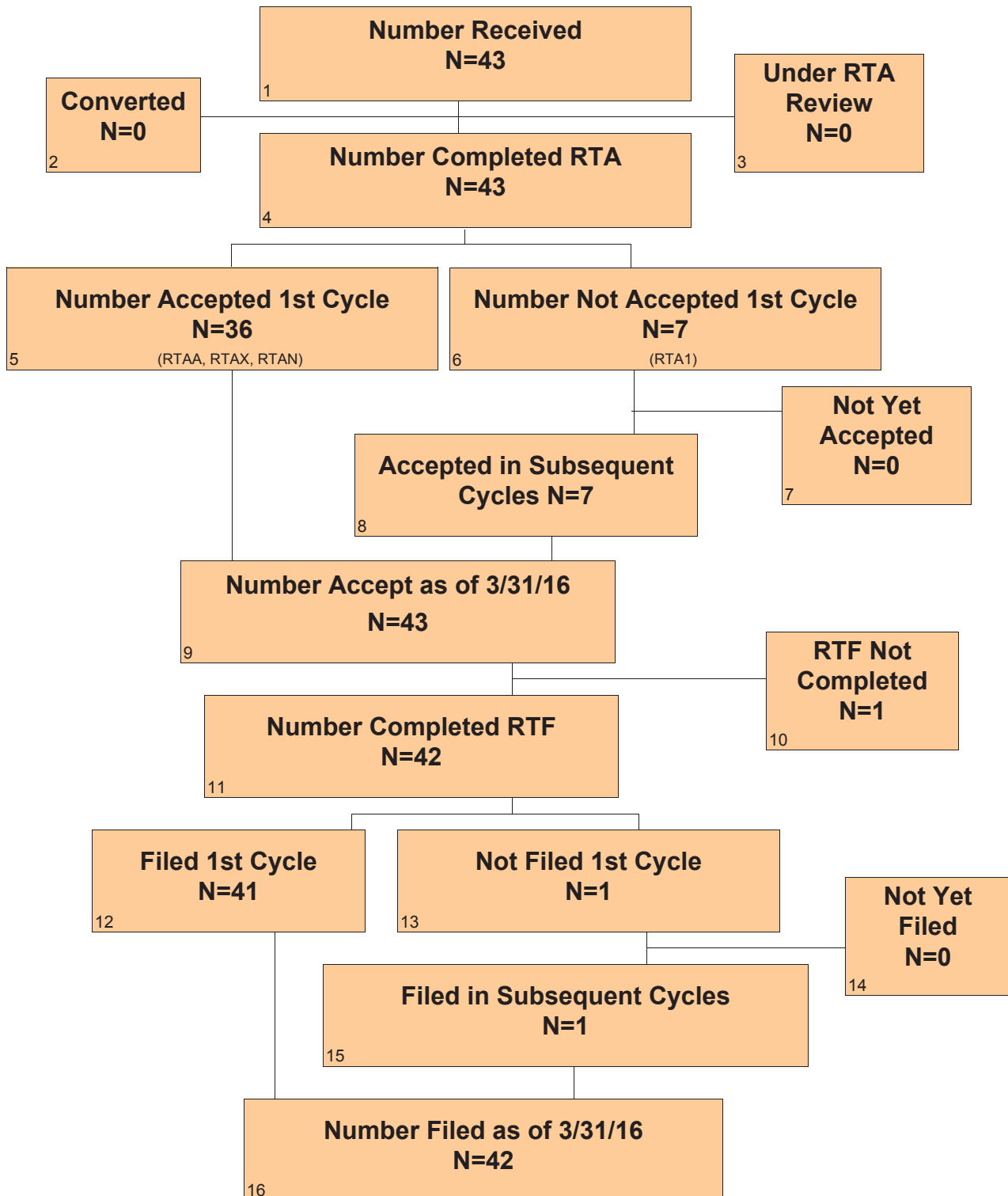
CDRH PMA Original and Panel Track Supplements - FY 2013 As of 3/31/16



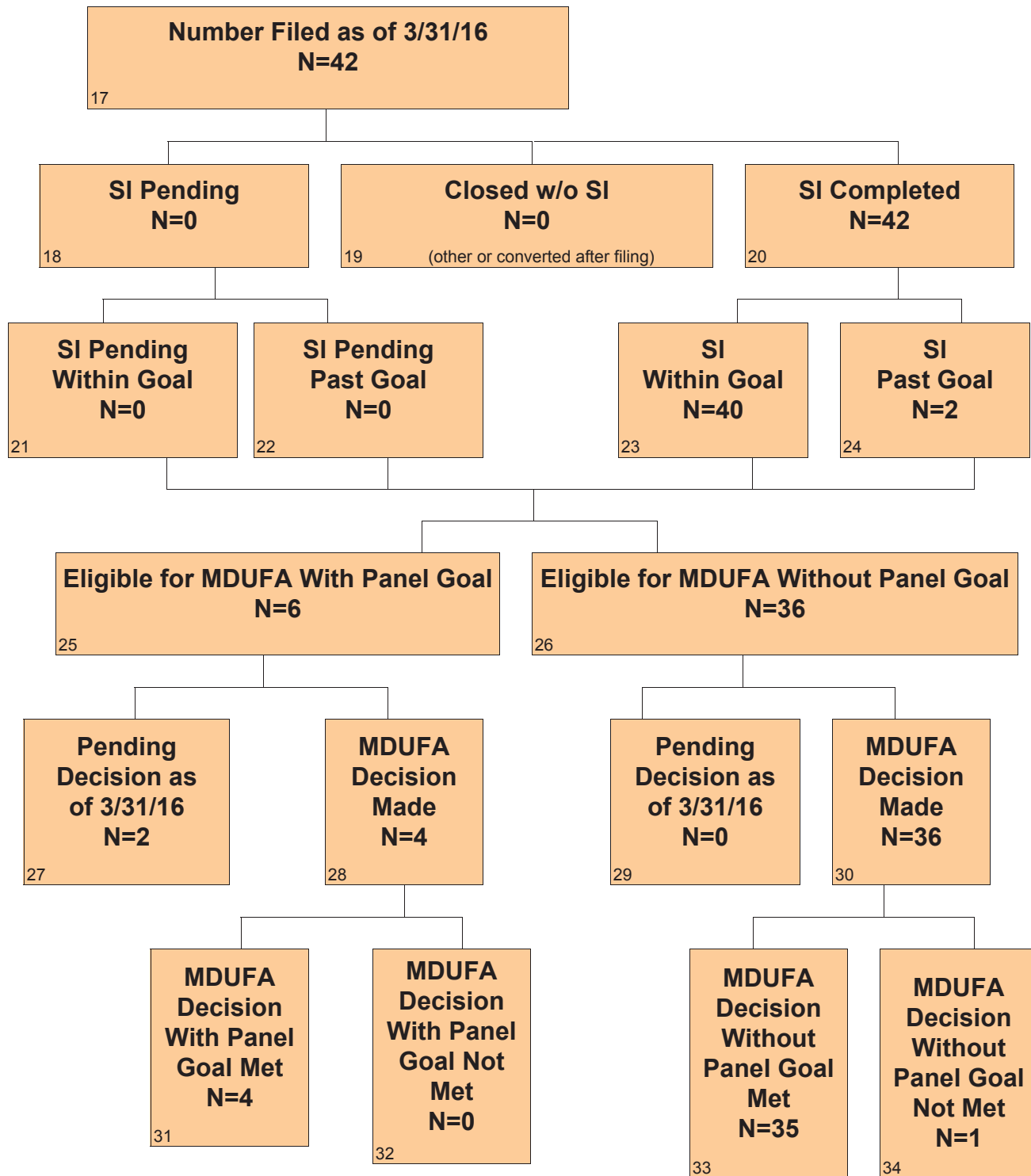
CDRH PMA Original and Panel Track Supplements - FY 2013 As of 3/31/16 Continued



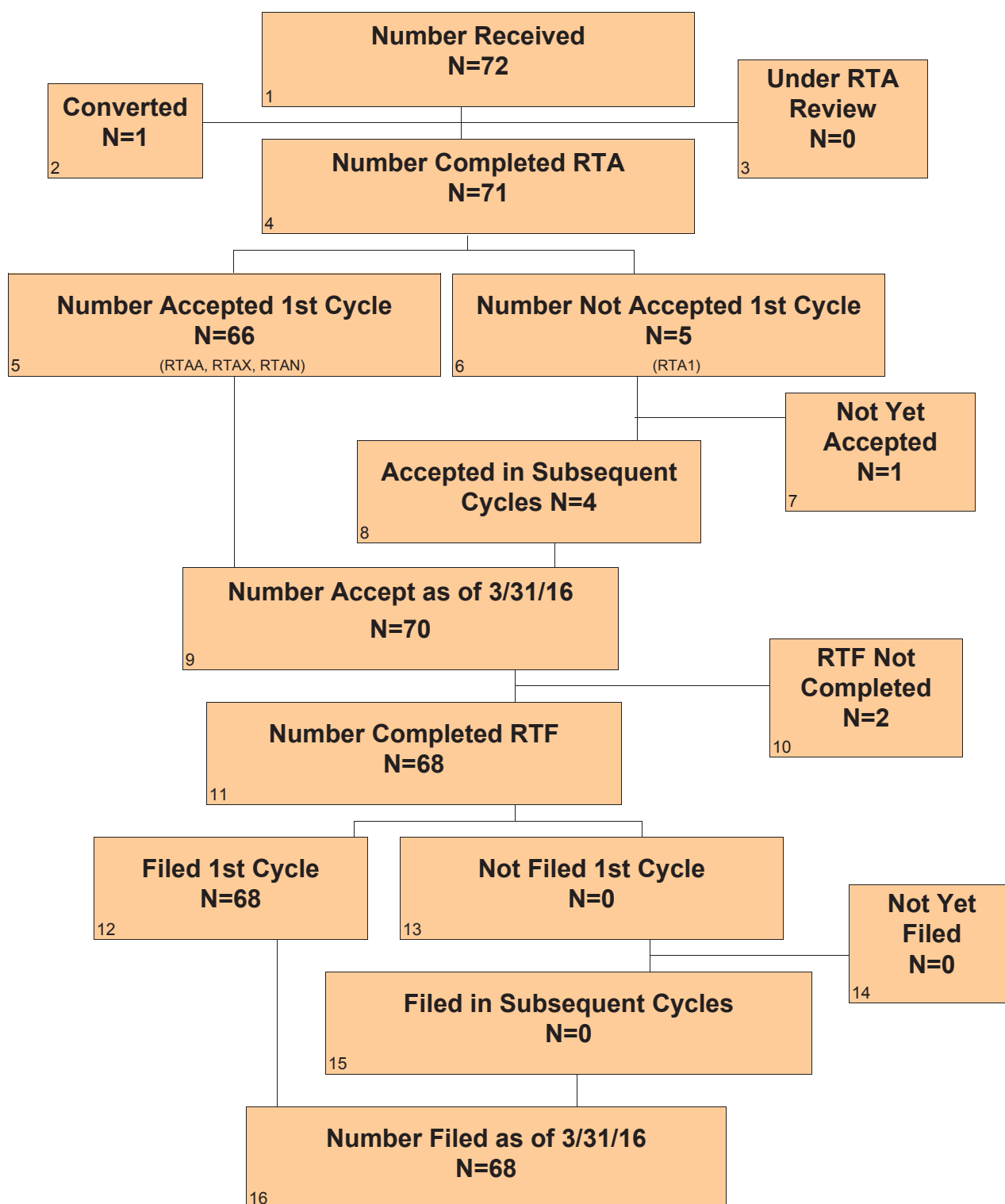
CDRH PMA Original and Panel Track Supplements - FY 2014 As of 3/31/16



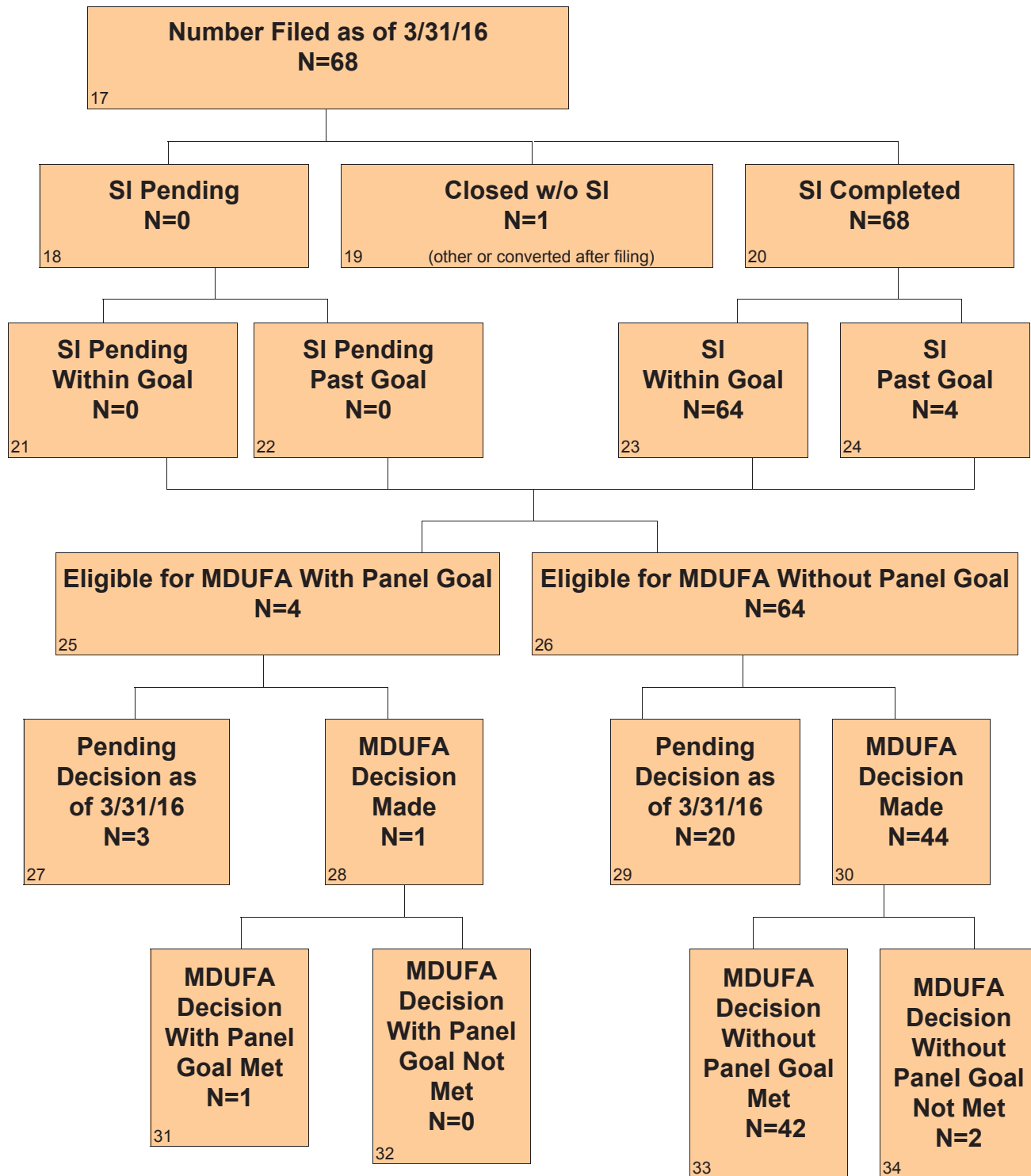
CDRH PMA Original and Panel Track Supplements - FY 2014 As of 3/31/16 Continued



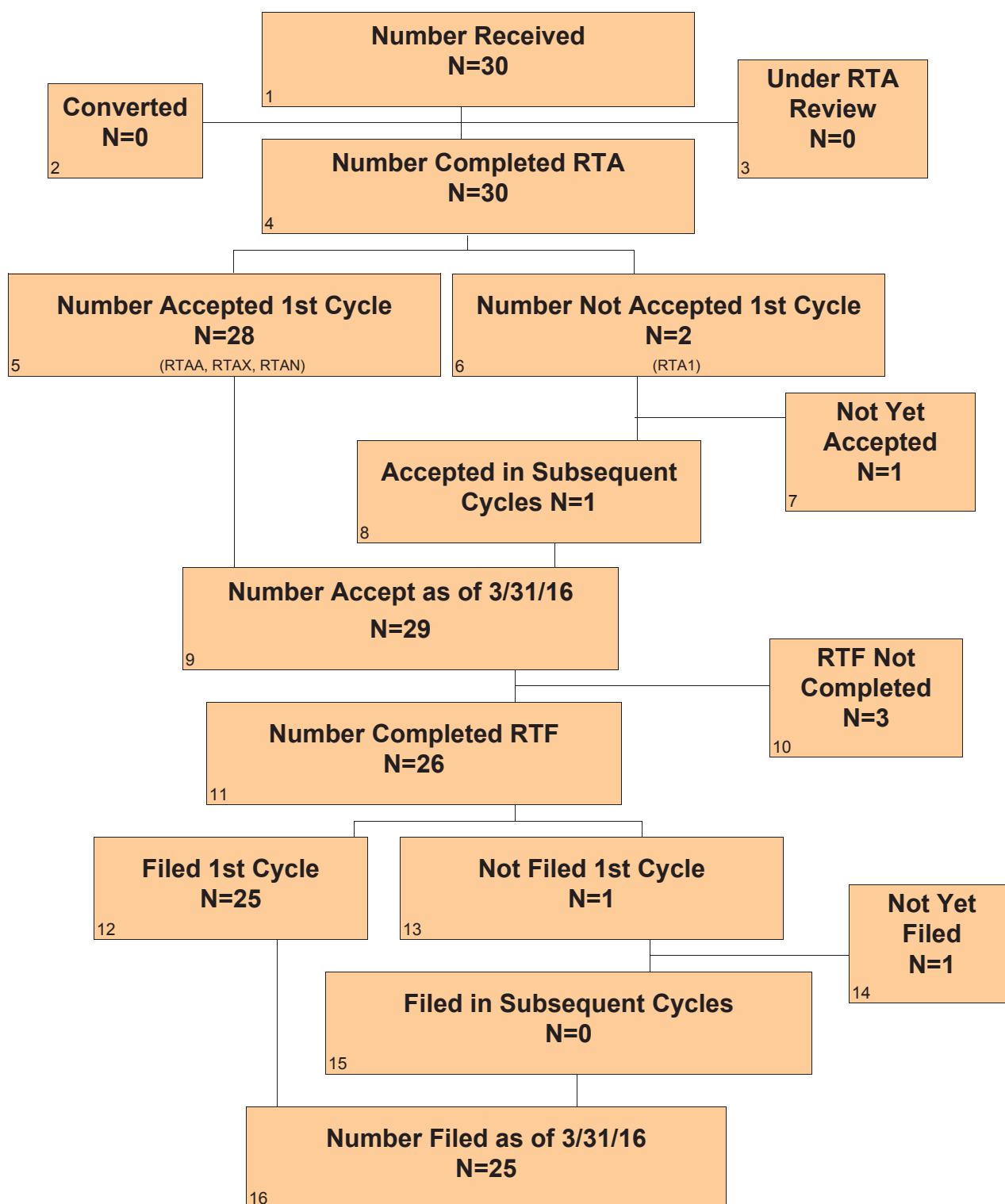
CDRH PMA Original and Panel Track Supplements - FY 2015 As of 3/31/16



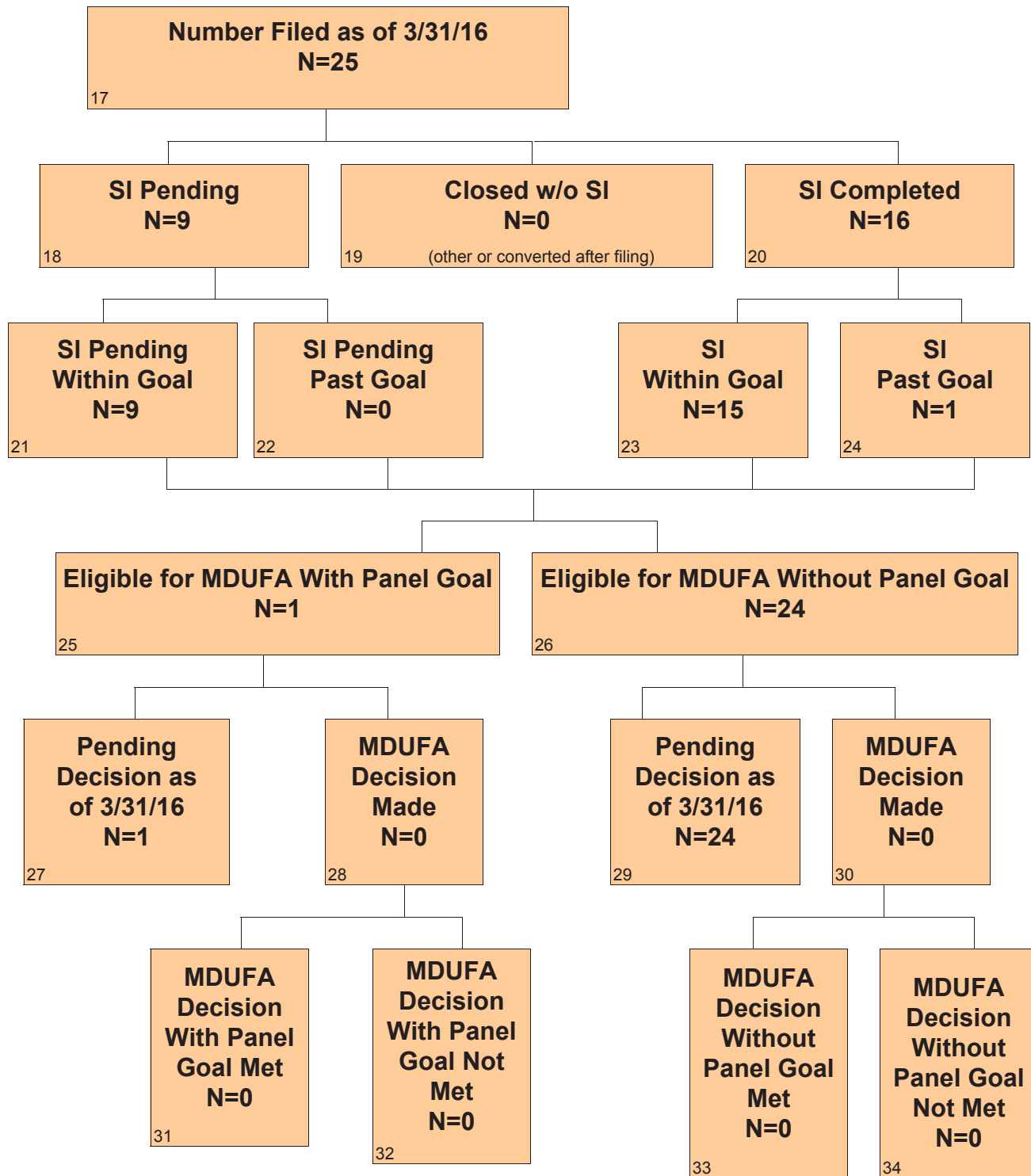
CDRH PMA Original and Panel Track Supplements - FY 2015 As of 3/31/16 Continued



CDRH PMA Original and Panel Track Supplements - FY 2016 As of 3/31/16



CDRH PMA Original and Panel Track Supplements - FY 2016 As of 3/31/16 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	72	30	
Closed before RTA action	1	0	1	0	
Number with accepted RTA review	27	35	64	28	
Number without a RTA Review and > 15 Days since Date Received	1	1	2	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	6	7	5	2	
Rate of submissions not accepted for filing review	17.6%	16.3%	7%	6.7%	

*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	72	30	
Number Accepted	38	36	66	28	
Completed RTF	44	42	68	26	
Number Not Filed	3	1	0	1	
Rate of submissions Not Filed	6.8%	2.4%	0%	3.8%	

Table 1.3 CDRH – 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	44	42	68	25	
SI Goal Met	40	40	64	15	
SI Goal Not Met	4	2	4	1	
SI Pending Within Goal	0	0	0	9	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	90.9%	95.2%	94.1%	93.8%	

Table 1.4 CDRH – 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	44	42	68	16	
Average number of FDA days to Substantive Interaction	109.73	90.02	91.75	89.94	
20th Percentile FDA days to Substantive Interaction	86	87	85	83	
40th Percentile FDA days to Substantive Interaction	88	88	88	88	
60th Percentile FDA days to Substantive Interaction	90	89	90	90	
80th Percentile FDA days to Substantive Interaction	90	90	90	90	
Maximum FDA days to Substantive Interaction	1031	136	168	163	

Table 1.5 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
Number of PMAs filed	27	36	64	24	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	27	36	44	0	
MDUFA III Decisions Goal Met	25	35	42	0	
PMAs pending MDUFA III Decision	0	0	20	24	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	92.6%	97.2%	95.5%	N/A	

Table 1.6 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
Number of PMAs filed	17	6	4	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	15	4	1	0	
MDUFA III Decisions Goal Met	14	4	1	0	
PMAs pending MDUFA III Decision	2	2	3	1	
PMAs pending MDUFA III Decision Past Goal	1	0	0	0	
Current Performance Percent Goal Met	87.5%	100%	100%	N/A	

**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	27	36	44	0	
Average FDA days to MDUFA III decision	208.81	175.81	173.82	0	
20th Percentile FDA days to MDUFA III decision	175	176	168	0	
40th Percentile FDA days to MDUFA III decision	178	179	177	0	
60th Percentile FDA days to MDUFA III decision	180	179	179	0	
80th Percentile FDA days to MDUFA III decision	180	180	180	0	
Maximum FDA days to MDUFA III decision	1031	359	256	0	
Average Industry days to MDUFA III decision	163.81	48.72	53.68	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	80	0	0	0	
60th Percentile Industry days to MDUFA III decision	116	44	56	0	
80th Percentile Industry days to MDUFA III decision	337	88	98	0	
Maximum Industry days to MDUFA III decision	563	238	263	0	
Average Total days to MDUFA III decision	372.63	224.51	227.50	0	
20th Percentile Total days to MDUFA III decision	181	179	177	0	
40th Percentile Total days to MDUFA III decision	253	180	180	0	
60th Percentile Total days to MDUFA III decision	345	234	231	0	
80th Percentile Total days to MDUFA III decision	538	283	277	0	
Maximum Total days to MDUFA III decision	1031	418	442	0	

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	15	4	1	0	
Average FDA days to MDUFA III decision	339.60	332.75	206.00	0	
20th Percentile FDA days to MDUFA III decision	276	316	206	0	
40th Percentile FDA days to MDUFA III decision	314	318	206	0	
60th Percentile FDA days to MDUFA III decision	316	320	206	0	
80th Percentile FDA days to MDUFA III decision	360	344	206	0	
Maximum FDA days to MDUFA III decision	668	379	206	0	
Average Industry days to MDUFA III decision	98.87	74.75	119.00	0	
20th Percentile Industry days to MDUFA III decision	0	12	119	0	
40th Percentile Industry days to MDUFA III decision	17	36	119	0	
60th Percentile Industry days to MDUFA III decision	119	85	119	0	
80th Percentile Industry days to MDUFA III decision	187	132	119	0	
Maximum Industry days to MDUFA III decision	295	178	119	0	
Average Total days to MDUFA III decision	438.47	407.50	325	0	
20th Percentile Total days to MDUFA III decision	312	367	325	0	
40th Percentile Total days to MDUFA III decision	338	402	325	0	
60th Percentile Total days to MDUFA III decision	454	412	325	0	
80th Percentile Total days to MDUFA III decision	577	448	325	0	
Maximum Total days to MDUFA III decision	805	498	325	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	27	36	64	24	
Number with MDUFA decision	27	36	44	0	
Number of Withdrawals	1	1	0	0	
Number of Not Approvable	4	2	7	0	
Rate of Withdrawals	3.7%	2.8%	0%	N/A	
Rate of Not Approvable	14.8%	5.6%	15.9%	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	17	6	4	1	
Number with MDUFA decision	15	4	1	0	
Number of Withdrawals	1	0	1	0	
Number of Not Approvable	3	0	0	0	
Rate of Withdrawals	6.7%	0%	100%	N/A	
Rate of Not Approvable	20%	0%	0%	N/A	

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	1	2	0	
Mean FDA days for submissions that missed goal	661	201	189	0	
Mean industry days for submissions that missed goal	57	43	44	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	2	0	0	0	
Mean FDA days for submissions that missed goal	579	0	0	0	
Mean industry days for submissions that missed goal	362	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	55	19	
Closed before RTA action	1	0	1	0	
Number with accepted RTA review	20	30	47	17	
Number without a RTA Review and > 15 Days since Date Received	1	1	2	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	6	6	5	2	
Rate of submissions not accepted for filing review	22.2%	16.2%	9.3%	10.5%	

*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	55	19	
Number Accepted	28	31	49	17	
Completed RTF	34	36	51	16	
Number Not Filed	3	1	0	1	
Rate of submissions Not Filed	8.8%	2.8%	0%	6.3%	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	34	36	51	15	
SI Goal Met	31	34	48	8	
SI Goal Not Met	3	2	3	0	
SI Pending Within Goal	0	0	0	7	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	91.2%	94.4%	94.1%	100%	

Table 1.4 ODE - CDRH – 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	34	36	51	8	
Average number of FDA days to Substantive Interaction	115.88	90.64	94.31	98.88	
20th Percentile FDA days to Substantive Interaction	86	87	86	90	
40th Percentile FDA days to Substantive Interaction	88	88	88	90	
60th Percentile FDA days to Substantive Interaction	89	89	89	90	
80th Percentile FDA days to Substantive Interaction	90	90	90	90	
Maximum FDA days to Substantive Interaction	1031	136	168	163	

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	21	30	47	14	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	21	30	30	0	
MDUFA III Decisions Goal Met	19	29	28	0	
PMAs pending MDUFA III Decision	0	0	17	14	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	90.5%	96.7%	93.3%	N/A	

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	13	6	4	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	11	4	1	0	
MDUFA III Decisions Goal Met	10	4	1	0	
PMAs pending MDUFA III Decision	2	2	3	1	
PMAs pending MDUFA III Decision Past Goal	1	0	0	0	
Current Performance Percent Goal Met	83.3%	100%	100%	N/A	

**Table 1.7 ODE - 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	21	30	30	0	
Average FDA days to MDUFA III decision	225.05	178.30	183.03	0	
20th Percentile FDA days to MDUFA III decision	177	175	177	0	
40th Percentile FDA days to MDUFA III decision	180	179	179	0	
60th Percentile FDA days to MDUFA III decision	180	179	180	0	
80th Percentile FDA days to MDUFA III decision	180	180	180	0	
Maximum FDA days to MDUFA III decision	1031	359	256	0	
Average Industry days to MDUFA III decision	167.29	43.00	59.13	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	68	0	0	0	
60th Percentile Industry days to MDUFA III decision	113	43	55	0	
80th Percentile Industry days to MDUFA III decision	356	79	123	0	
Maximum Industry days to MDUFA III decision	563	168	263	0	
Average Total days to MDUFA III decision	392.33	221.30	242.17	0	
20th Percentile Total days to MDUFA III decision	180	179	178	0	
40th Percentile Total days to MDUFA III decision	260	180	180	0	
60th Percentile Total days to MDUFA III decision	397	228	237	0	
80th Percentile Total days to MDUFA III decision	540	261	309	0	
Maximum Total days to MDUFA III decision	1031	392	442	0	

**Table 1.8 ODE - 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	11	4	1	0	
Average FDA days to MDUFA III decision	359.18	332.75	206	0	
20th Percentile FDA days to MDUFA III decision	290	316	206	0	
40th Percentile FDA days to MDUFA III decision	315	318	206	0	
60th Percentile FDA days to MDUFA III decision	316	320	206	0	
80th Percentile FDA days to MDUFA III decision	501	344	206	0	
Maximum FDA days to MDUFA III decision	668	379	206	0	
Average Industry days to MDUFA III decision	108.09	74.75	119	0	
20th Percentile Industry days to MDUFA III decision	0	12	119	0	
40th Percentile Industry days to MDUFA III decision	28	36	119	0	
60th Percentile Industry days to MDUFA III decision	141	85	119	0	
80th Percentile Industry days to MDUFA III decision	186	132	119	0	
Maximum Industry days to MDUFA III decision	295	178	119	0	
Average Total days to MDUFA III decision	467.27	407.50	325	0	
20th Percentile Total days to MDUFA III decision	316	367	325	0	
40th Percentile Total days to MDUFA III decision	348	402	325	0	
60th Percentile Total days to MDUFA III decision	490	412	325	0	
80th Percentile Total days to MDUFA III decision	610	448	325	0	
Maximum Total days to MDUFA III decision	805	498	325	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	21	30	47	14	
Number with MDUFA decision	21	30	30	0	
Number of Withdrawals	1	1	0	0	
Number of Not Approvable	3	2	6	0	
Rate of Withdrawals	4.8%	3.3%	0%	N/A	
Rate of Not Approvable	14.3%	6.7%	20%	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	13	6	4	1	
Number with MDUFA decision	11	4	1	0	
Number of Withdrawals	1	0	1	0	
Number of Not Approvable	2	0	0	0	
Rate of Withdrawals	9.1%	0%	100%	N/A	
Rate of Not Approvable	18.2%	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	1	2	0	
Mean FDA days for submissions that missed goal	661	201	189	0	
Mean industry days for submissions that missed goal	57	43	44	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	2	0	0	0	
Mean FDA days for submissions that missed goal	579	0	0	0	
Mean industry days for submissions that missed goal	362	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	17	11	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	7	5	17	11	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	1	0	0	
Rate of submissions not accepted for filing review	0%	16.7%	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.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	17	11	
Number Accepted	10	5	17	11	
Completed RTF	10	6	17	10	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	0%	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
Substantive Interaction (SI) Goals:	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	6	17	10	
SI Goal Met	9	6	16	7	
SI Goal Not Met	1	0	1	1	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	90%	100%	94.1%	87.5%	

Table 1.4 OIR - CDRH – 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	10	6	17	8	
Average number of FDA days to Substantive Interaction	88.80	86.33	84.06	81	
20th Percentile FDA days to Substantive Interaction	86	85	84	80	
40th Percentile FDA days to Substantive Interaction	90	86	87	83	
60th Percentile FDA days to Substantive Interaction	90	87	90	85	
80th Percentile FDA days to Substantive Interaction	90	88	90	88	
Maximum FDA days to Substantive Interaction	112	89	91	94	

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	17	10	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	6	6	14	0	
MDUFA III Decisions Goal Met	6	6	14	0	
PMAs pending MDUFA III Decision	0	0	3	10	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	4	0	0	0	
MDUFA III Decisions Goal Met	4	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	N/A	N/A	

**Table 1.7 OIR - 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	6	6	14	0	
Average FDA days to MDUFA III decision	152	163.33	154.07	0	
20th Percentile FDA days to MDUFA III decision	116	177	125	0	
40th Percentile FDA days to MDUFA III decision	167	179	165	0	
60th Percentile FDA days to MDUFA III decision	174	179	173	0	
80th Percentile FDA days to MDUFA III decision	177	179	176	0	
Maximum FDA days to MDUFA III decision	179	180	180	0	
Average Industry days to MDUFA III decision	151.67	77.33	42	0	
20th Percentile Industry days to MDUFA III decision	81	0	0	0	
40th Percentile Industry days to MDUFA III decision	107	0	4	0	
60th Percentile Industry days to MDUFA III decision	118	106	54	0	
80th Percentile Industry days to MDUFA III decision	133	120	80	0	
Maximum Industry days to MDUFA III decision	400	238	140	0	
Average Total days to MDUFA III decision	303.67	240.67	196.07	0	
20th Percentile Total days to MDUFA III decision	217	179	171	0	
40th Percentile Total days to MDUFA III decision	248	179	177	0	
60th Percentile Total days to MDUFA III decision	284	283	193	0	
80th Percentile Total days to MDUFA III decision	307	299	221	0	
Maximum Total days to MDUFA III decision	579	418	315	0	

**Table 1.8 OIR - 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	4	0	0	0	
Average FDA days to MDUFA III decision	285.75	0	0	0	
20th Percentile FDA days to MDUFA III decision	261	0	0	0	
40th Percentile FDA days to MDUFA III decision	301	0	0	0	
60th Percentile FDA days to MDUFA III decision	311	0	0	0	
80th Percentile FDA days to MDUFA III decision	319	0	0	0	
Maximum FDA days to MDUFA III decision	325	0	0	0	
Average Industry days to MDUFA III decision	73.50	0	0	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	21	0	0	0	
60th Percentile Industry days to MDUFA III decision	84	0	0	0	
80th Percentile Industry days to MDUFA III decision	139	0	0	0	
Maximum Industry days to MDUFA III decision	189	0	0	0	
Average Total days to MDUFA III decision	359.25	0	0	0	
20th Percentile Total days to MDUFA III decision	261	0	0	0	
40th Percentile Total days to MDUFA III decision	324	0	0	0	
60th Percentile Total days to MDUFA III decision	403	0	0	0	
80th Percentile Total days to MDUFA III decision	460	0	0	0	
Maximum Total days to MDUFA III decision	504	0	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	17	10	
Number with MDUFA decision	6	6	14	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	1	0	1	0	
Rate of Withdrawals	0%	0%	0%	N/A	
Rate of Not Approvable	16.7%	0%	7%	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	0	
Number with MDUFA decision	4	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	1	0	0	0	
Rate of Withdrawals	0%	N/A	N/A	N/A	
Rate of Not Approvable	25%	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	2	0	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	0	1	2	0	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	1	0	0	0	
Rate of submissions not accepted for filing review	100%	0%	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.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	2	0	
Number Accepted	1	1	2	0	
Completed RTF	2	1	2	0	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	0%	0%	0%	N/A	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	2	0	
SI Goal Met	2	1	2	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	100%	N/A	

Table 1.4.DAGRID - ODE – 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	2	1	2	0	
Average number of FDA days to Substantive Interaction	85	87	128	0	
20th Percentile FDA days to Substantive Interaction	84	87	104	0	
40th Percentile FDA days to Substantive Interaction	85	87	120	0	
60th Percentile FDA days to Substantive Interaction	85	87	136	0	
80th Percentile FDA days to Substantive Interaction	86	87	152	0	
Maximum FDA days to Substantive Interaction	87	87	168	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	2	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	1	1	0	
MDUFA III Decisions Goal Met	1	1	1	0	
PMAs pending MDUFA III Decision	0	0	1	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions Goal Met	1	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	N/A	N/A	

Table 1.7.DAGRID - ODE – 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	1	1	1	0	
Average FDA days to MDUFA III decision	180	179	256	0	
20th Percentile FDA days to MDUFA III decision	180	179	256	0	
40th Percentile FDA days to MDUFA III decision	180	179	256	0	
60th Percentile FDA days to MDUFA III decision	180	179	256	0	
80th Percentile FDA days to MDUFA III decision	180	179	256	0	
Maximum FDA days to MDUFA III decision	180	179	256	0	
Average Industry days to MDUFA III decision	360	0	182	0	
20th Percentile Industry days to MDUFA III decision	360	0	182	0	
40th Percentile Industry days to MDUFA III decision	360	0	182	0	
60th Percentile Industry days to MDUFA III decision	360	0	182	0	
80th Percentile Industry days to MDUFA III decision	360	0	182	0	
Maximum Industry days to MDUFA III decision	360	0	182	0	
Average Total days to MDUFA III decision	540	179	438	0	
20th Percentile Total days to MDUFA III decision	540	179	438	0	
40th Percentile Total days to MDUFA III decision	540	179	438	0	
60th Percentile Total days to MDUFA III decision	540	179	438	0	
80th Percentile Total days to MDUFA III decision	540	179	438	0	
Maximum Total days to MDUFA III decision	540	179	438	0	

**Table 1.8.DAGRID - ODE – 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	0	
Average FDA days to MDUFA III decision	320	0	0	0	
20th Percentile FDA days to MDUFA III decision	320	0	0	0	
40th Percentile FDA days to MDUFA III decision	320	0	0	0	
60th Percentile FDA days to MDUFA III decision	320	0	0	0	
80th Percentile FDA days to MDUFA III decision	320	0	0	0	
Maximum FDA days to MDUFA III decision	320	0	0	0	
Average Industry days to MDUFA III decision	28	0	0	0	
20th Percentile Industry days to MDUFA III decision	28	0	0	0	
40th Percentile Industry days to MDUFA III decision	28	0	0	0	
60th Percentile Industry days to MDUFA III decision	28	0	0	0	
80th Percentile Industry days to MDUFA III decision	28	0	0	0	
Maximum Industry days to MDUFA III decision	28	0	0	0	
Average Total days to MDUFA III decision	348	0	0	0	
20th Percentile Total days to MDUFA III decision	348	0	0	0	
40th Percentile Total days to MDUFA III decision	348	0	0	0	
60th Percentile Total days to MDUFA III decision	348	0	0	0	
80th Percentile Total days to MDUFA III decision	348	0	0	0	
Maximum Total days to MDUFA III decision	348	0	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	2	0	
Number with MDUFA decision	1	1	1	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	1	0	
Rate of Withdrawals	0%	0%	0%	N/A	
Rate of Not Approvable	0%	0%	100%	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	0	
Number with MDUFA decision	1	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	N/A	N/A	N/A	
Rate of Not Approvable	0%	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	28	12	
Closed before RTA action	1	0	1	0	
Number with accepted RTA review	15	15	25	11	
Number without a RTA Review and > 15 Days since Date Received	1	1	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	1	2	1	
Rate of submissions not accepted for filing review	0%	5.9%	7.4%	8.3%	

*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	28	12	
Number Accepted	19	16	25	11	
Completed RTF	19	17	27	9	
Number Not Filed	0	0	0	1	
Rate of submissions Not Filed	0%	0%	0%	11.1%	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	19	17	27	8	
SI Goal Met	17	16	26	4	
SI Goal Not Met	2	1	1	0	
SI Pending Within Goal	0	0	0	4	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	89.5%	94.1%	96.3%	100%	

Table 1.4.DCD - ODE – 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	19	17	27	4	
Average number of FDA days to Substantive Interaction	137.95	87.71	92.04	107.75	
20th Percentile FDA days to Substantive Interaction	85	87	85	89	
40th Percentile FDA days to Substantive Interaction	88	88	88	90	
60th Percentile FDA days to Substantive Interaction	90	89	89	90	
80th Percentile FDA days to Substantive Interaction	90	90	90	119	
Maximum FDA days to Substantive Interaction	1031	91	145	163	

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	15	16	25	7	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	15	16	19	0	
MDUFA III Decisions Goal Met	13	15	17	0	
PMAs pending MDUFA III Decision	0	0	6	7	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	86.7%	93.8%	89%	N/A	

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	4	1	2	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	3	1	0	0	
MDUFA III Decisions Goal Met	2	1	0	0	
PMAs pending MDUFA III Decision	1	0	2	1	
PMAs pending MDUFA III Decision Past Goal	1	0	0	0	
Current Performance Percent Goal Met	50%	100%	N/A	N/A	

**Table 1.7.DCD - ODE – 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	15	16	19	0	
Average FDA days to MDUFA III decision	243.60	174.25	178.95	0	
20th Percentile FDA days to MDUFA III decision	177	177	178	0	
40th Percentile FDA days to MDUFA III decision	180	178	179	0	
60th Percentile FDA days to MDUFA III decision	180	179	180	0	
80th Percentile FDA days to MDUFA III decision	259	180	180	0	
Maximum FDA days to MDUFA III decision	1031	201	232	0	
Average Industry days to MDUFA III decision	154.67	29.31	59.74	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	48	0	9	0	
60th Percentile Industry days to MDUFA III decision	110	0	48	0	
80th Percentile Industry days to MDUFA III decision	464	43	101	0	
Maximum Industry days to MDUFA III decision	563	161	263	0	
Average Total days to MDUFA III decision	398.27	203.56	238.68	0	
20th Percentile Total days to MDUFA III decision	222	179	179	0	
40th Percentile Total days to MDUFA III decision	281	179	224	0	
60th Percentile Total days to MDUFA III decision	391	180	233	0	
80th Percentile Total days to MDUFA III decision	714	244	280	0	
Maximum Total days to MDUFA III decision	1031	338	442	0	

Table 1.8.DCD - ODE – 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	3	1	0	0	
Average FDA days to MDUFA III decision	433.33	318	0	0	
20th Percentile FDA days to MDUFA III decision	316	318	0	0	
40th Percentile FDA days to MDUFA III decision	316	318	0	0	
60th Percentile FDA days to MDUFA III decision	386	318	0	0	
80th Percentile FDA days to MDUFA III decision	527	318	0	0	
Maximum FDA days to MDUFA III decision	668	318	0	0	
Average Industry days to MDUFA III decision	0	0	0	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	0	0	0	0	
80th Percentile Industry days to MDUFA III decision	0	0	0	0	
Maximum Industry days to MDUFA III decision	0	0	0	0	
Average Total days to MDUFA III decision	433.33	318	0	0	
20th Percentile Total days to MDUFA III decision	316	318	0	0	
40th Percentile Total days to MDUFA III decision	316	318	0	0	
60th Percentile Total days to MDUFA III decision	386	318	0	0	
80th Percentile Total days to MDUFA III decision	527	318	0	0	
Maximum Total days to MDUFA III decision	668	318	0	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	15	16	25	7	
Number with MDUFA decision	15	16	19	0	
Number of Withdrawals	1	0	0	0	
Number of Not Approvable	2	0	4	0	
Rate of Withdrawals	6.7%	0%	0%	N/A	
Rate of Not Approvable	13.3%	0%	21.1%	N/A	

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	4	1	2	1	
Number with MDUFA decision	3	1	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	0%	N/A	N/A	
Rate of Not Approvable	0%	0%	N/A	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	1	2	0	
Mean FDA days for submissions that missed goal	661	201	189	0	
Mean industry days for submissions that missed goal	57	43	44	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	2	0	0	0	
Mean FDA days for submissions that missed goal	579	0	0	0	
Mean industry days for submissions that missed goal	362	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	4	1	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	0	2	4	1	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	1	1	0	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	4	1	
Number Accepted	0	2	4	1	
Completed RTF	1	3	4	1	
Number Not Filed	0	1	0	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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	3	4	1	
SI Goal Met	0	2	4	1	
SI Goal Not Met	1	1	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	0%	66.7%	100%	100%	

Table 1.4.DNPMD - ODE – 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	3	4	1	
Average number of FDA days to Substantive Interaction	92	90.33	108.25	90	
20th Percentile FDA days to Substantive Interaction	92	90	89	90	
40th Percentile FDA days to Substantive Interaction	92	90	90	90	
60th Percentile FDA days to Substantive Interaction	92	90	90	90	
80th Percentile FDA days to Substantive Interaction	92	91	120	90	
Maximum FDA days to Substantive Interaction	92	91	166	90	

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	4	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	3	3	0	
MDUFA III Decisions Goal Met	1	3	3	0	
PMAs pending MDUFA III Decision	0	0	1	1	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions Goal Met	0	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	3	3	0	
Average FDA days to MDUFA III decision	180	182.33	199.33	0	
20th Percentile FDA days to MDUFA III decision	180	178	170	0	
40th Percentile FDA days to MDUFA III decision	180	179	175	0	
60th Percentile FDA days to MDUFA III decision	180	182	194	0	
80th Percentile FDA days to MDUFA III decision	180	186	225	0	
Maximum FDA days to MDUFA III decision	180	190	256	0	
Average Industry days to MDUFA III decision	0	91.67	45.33	0	
20th Percentile Industry days to MDUFA III decision	0	48	6	0	
40th Percentile Industry days to MDUFA III decision	0	69	11	0	
60th Percentile Industry days to MDUFA III decision	0	97	36	0	
80th Percentile Industry days to MDUFA III decision	0	132	79	0	
Maximum Industry days to MDUFA III decision	0	168	122	0	
Average Total days to MDUFA III decision	180	274	244.67	0	
20th Percentile Total days to MDUFA III decision	180	227	178	0	
40th Percentile Total days to MDUFA III decision	180	246	178	0	
60th Percentile Total days to MDUFA III decision	180	276	218	0	
80th Percentile Total days to MDUFA III decision	180	317	298	0	
Maximum Total days to MDUFA III decision	180	358	378	0	

Table 1.8.DNPMD - ODE – 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	0	0	0	0	
Average FDA days to MDUFA III decision	0	0	0	0	
20th Percentile FDA days to MDUFA III decision	0	0	0	0	
40th Percentile FDA days to MDUFA III decision	0	0	0	0	
60th Percentile FDA days to MDUFA III decision	0	0	0	0	
80th Percentile FDA days to MDUFA III decision	0	0	0	0	
Maximum FDA days to MDUFA III decision	0	0	0	0	
Average Industry days to MDUFA III decision	0	0	0	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	0	0	0	0	
80th Percentile Industry days to MDUFA III decision	0	0	0	0	
Maximum Industry days to MDUFA III decision	0	0	0	0	
Average Total days to MDUFA III decision	0	0	0	0	
20th Percentile Total days to MDUFA III decision	0	0	0	0	
40th Percentile Total days to MDUFA III decision	0	0	0	0	
60th Percentile Total days to MDUFA III decision	0	0	0	0	
80th Percentile Total days to MDUFA III decision	0	0	0	0	
Maximum Total days to MDUFA III decision	0	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	4	1	
Number with MDUFA decision	1	3	3	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	0%	0%	N/A	
Rate of Not Approvable	0%	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	0	
Number with MDUFA decision	0	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	7	0	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	0	4	5	0	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	2	0	
Rate of submissions not accepted for filing review	N/A	N/A	28.6%	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.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	7	0	
Number Accepted	2	4	5	0	
Completed RTF	2	4	6	0	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	0%	0%	0%	N/A	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	6	0	
SI Goal Met	2	4	5	0	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	83.3%	N/A	

Table 1.4.DOD - ODE – 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	2	4	6	0	
Average number of FDA days to Substantive Interaction	86	100	89.33	0	
20th Percentile FDA days to Substantive Interaction	86	89	88	0	
40th Percentile FDA days to Substantive Interaction	86	89	88	0	
60th Percentile FDA days to Substantive Interaction	86	90	90	0	
80th Percentile FDA days to Substantive Interaction	86	107	90	0	
Maximum FDA days to Substantive Interaction	86	133	96	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	2	5	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	2	2	0	
MDUFA III Decisions Goal Met	1	2	2	0	
PMAs pending MDUFA III Decision	0	0	3	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	2	1	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	1	0	0	
MDUFA III Decisions Goal Met	1	1	0	0	
PMAs pending MDUFA III Decision	0	1	1	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	2	2	0	
Average FDA days to MDUFA III decision	175	179.50	171.50	0	
20th Percentile FDA days to MDUFA III decision	175	179	167	0	
40th Percentile FDA days to MDUFA III decision	175	179	170	0	
60th Percentile FDA days to MDUFA III decision	175	180	173	0	
80th Percentile FDA days to MDUFA III decision	175	180	176	0	
Maximum FDA days to MDUFA III decision	175	180	179	0	
Average Industry days to MDUFA III decision	356	79	0	0	
20th Percentile Industry days to MDUFA III decision	356	78	0	0	
40th Percentile Industry days to MDUFA III decision	356	79	0	0	
60th Percentile Industry days to MDUFA III decision	356	79	0	0	
80th Percentile Industry days to MDUFA III decision	356	80	0	0	
Maximum Industry days to MDUFA III decision	356	81	0	0	
Average Total days to MDUFA III decision	531	258.50	171.50	0	
20th Percentile Total days to MDUFA III decision	531	258	167	0	
40th Percentile Total days to MDUFA III decision	531	258	170	0	
60th Percentile Total days to MDUFA III decision	531	259	173	0	
80th Percentile Total days to MDUFA III decision	531	259	176	0	
Maximum Total days to MDUFA III decision	531	260	179	0	

Table 1.8.DOD - ODE – 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	1	0	0	
Average FDA days to MDUFA III decision	219	314	0	0	
20th Percentile FDA days to MDUFA III decision	219	314	0	0	
40th Percentile FDA days to MDUFA III decision	219	314	0	0	
60th Percentile FDA days to MDUFA III decision	219	314	0	0	
80th Percentile FDA days to MDUFA III decision	219	314	0	0	
Maximum FDA days to MDUFA III decision	219	314	0	0	
Average Industry days to MDUFA III decision	186	101	0	0	
20th Percentile Industry days to MDUFA III decision	186	101	0	0	
40th Percentile Industry days to MDUFA III decision	186	101	0	0	
60th Percentile Industry days to MDUFA III decision	186	101	0	0	
80th Percentile Industry days to MDUFA III decision	186	101	0	0	
Maximum Industry days to MDUFA III decision	186	101	0	0	
Average Total days to MDUFA III decision	405	415	0	0	
20th Percentile Total days to MDUFA III decision	405	415	0	0	
40th Percentile Total days to MDUFA III decision	405	415	0	0	
60th Percentile Total days to MDUFA III decision	405	415	0	0	
80th Percentile Total days to MDUFA III decision	405	415	0	0	
Maximum Total days to MDUFA III decision	405	415	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	2	5	0	
Number with MDUFA decision	1	2	2	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	1	1	0	0	
Rate of Withdrawals	0%	0%	0%	N/A	
Rate of Not Approvable	100%	50%	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	2	1	0	
Number with MDUFA decision	1	1	0	0	
Number of Withdrawals	1	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	100%	0%	N/A	N/A	
Rate of Not Approvable	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	5	4	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	4	1	5	4	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	1	0	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	5	4	
Number Accepted	5	1	5	4	
Completed RTF	6	1	5	4	
Number Not Filed	1	0	0	0	
Rate of submissions Not Filed	16.7%	0%	0%	0%	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	6	1	5	4	
SI Goal Met	6	1	4	3	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	80.0%	100%	

Table 1.4.DOED - ODE – 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	6	1	5	3	
Average number of FDA days to Substantive Interaction	88.50	81	87.40	90	
20th Percentile FDA days to Substantive Interaction	88	81	86	90	
40th Percentile FDA days to Substantive Interaction	88	81	88	90	
60th Percentile FDA days to Substantive Interaction	89	81	88	90	
80th Percentile FDA days to Substantive Interaction	90	81	90	90	
Maximum FDA days to Substantive Interaction	90	81	93	90	

Table 1.5.DOED - 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	2	1	5	4	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	2	1	2	0	
MDUFA III Decisions Goal Met	2	1	2	0	
PMAs pending MDUFA III Decision	0	0	3	4	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

Table 1.6.DOED - 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	4	0	0	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	3	0	0	0	
MDUFA III Decisions Goal Met	3	0	0	0	
PMAs pending MDUFA III Decision	1	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	N/A	N/A	

**Table 1.7.DOED - ODE – 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	2	1	2	0	
Average FDA days to MDUFA III decision	178.50	170	178.50	0	
20th Percentile FDA days to MDUFA III decision	178	170	178	0	
40th Percentile FDA days to MDUFA III decision	178	170	178	0	
60th Percentile FDA days to MDUFA III decision	179	170	179	0	
80th Percentile FDA days to MDUFA III decision	179	170	179	0	
Maximum FDA days to MDUFA III decision	180	170	180	0	
Average Industry days to MDUFA III decision	108.50	0	0	0	
20th Percentile Industry days to MDUFA III decision	43	0	0	0	
40th Percentile Industry days to MDUFA III decision	87	0	0	0	
60th Percentile Industry days to MDUFA III decision	130	0	0	0	
80th Percentile Industry days to MDUFA III decision	174	0	0	0	
Maximum Industry days to MDUFA III decision	217	0	0	0	
Average Total days to MDUFA III decision	287	170	178.50	0	
20th Percentile Total days to MDUFA III decision	221	170	178	0	
40th Percentile Total days to MDUFA III decision	265	170	178	0	
60th Percentile Total days to MDUFA III decision	309	170	179	0	
80th Percentile Total days to MDUFA III decision	353	170	179	0	
Maximum Total days to MDUFA III decision	397	170	180	0	

**Table 1.8.DOED - ODE – 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	3	0	0	0	
Average FDA days to MDUFA III decision	328	0	0	0	
20th Percentile FDA days to MDUFA III decision	225	0	0	0	
40th Percentile FDA days to MDUFA III decision	268	0	0	0	
60th Percentile FDA days to MDUFA III decision	334	0	0	0	
80th Percentile FDA days to MDUFA III decision	423	0	0	0	
Maximum FDA days to MDUFA III decision	512	0	0	0	
Average Industry days to MDUFA III decision	144.67	0	0	0	
20th Percentile Industry days to MDUFA III decision	56	0	0	0	
40th Percentile Industry days to MDUFA III decision	113	0	0	0	
60th Percentile Industry days to MDUFA III decision	171	0	0	0	
80th Percentile Industry days to MDUFA III decision	232	0	0	0	
Maximum Industry days to MDUFA III decision	293	0	0	0	
Average Total days to MDUFA III decision	472.67	0	0	0	
20th Percentile Total days to MDUFA III decision	303	0	0	0	
40th Percentile Total days to MDUFA III decision	316	0	0	0	
60th Percentile Total days to MDUFA III decision	419	0	0	0	
80th Percentile Total days to MDUFA III decision	612	0	0	0	
Maximum Total days to MDUFA III decision	805	0	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	5	4	
Number with MDUFA decision	2	1	2	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	0%	0%	N/A	
Rate of Not Approvable	0%	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	0	
Number with MDUFA decision	3	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	N/A	N/A	N/A	
Rate of Not Approvable	0%	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	2	0	0	0	
Mean FDA days for submissions that missed goal	520	0	0	0	
Mean industry days for submissions that missed goal	246	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	3	1	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	1	3	2	1	
Number without a RTA Review and > 15 Days since Date Received	0	0	1	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	3	2	0	0	
Rate of submissions not accepted for filing review	75%	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	3	1	
Number Accepted	1	3	3	1	
Completed RTF	4	5	2	1	
Number Not Filed	2	0	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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	4	5	2	1	
SI Goal Met	4	5	2	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	100%	N/A	

Table 1.4.DRGUD - ODE – 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	4	5	2	0	
Average number of FDA days to Substantive Interaction	88.50	97.80	122	0	
20th Percentile FDA days to Substantive Interaction	88	88	100	0	
40th Percentile FDA days to Substantive Interaction	88	88	115	0	
60th Percentile FDA days to Substantive Interaction	88	89	129	0	
80th Percentile FDA days to Substantive Interaction	89	99	144	0	
Maximum FDA days to Substantive Interaction	90	136	158	0	

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	4	1	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	4	0	0	
MDUFA III Decisions Goal Met	1	4	0	0	
PMAs pending MDUFA III Decision	0	0	1	1	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	N/A	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	1	1	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	3	0	1	0	
MDUFA III Decisions Goal Met	3	0	1	0	
PMAs pending MDUFA III Decision	0	1	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	100%	N/A	

Table 1.7.DRGUD - ODE – 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	1	4	0	0	
Average FDA days to MDUFA III decision	180	193.20	0	0	
20th Percentile FDA days to MDUFA III decision	180	124	0	0	
40th Percentile FDA days to MDUFA III decision	180	154	0	0	
60th Percentile FDA days to MDUFA III decision	180	174	0	0	
80th Percentile FDA days to MDUFA III decision	180	252	0	0	
Maximum FDA days to MDUFA III decision	180	359	0	0	
Average Industry days to MDUFA III decision	260	60.25	0	0	
20th Percentile Industry days to MDUFA III decision	260	20	0	0	
40th Percentile Industry days to MDUFA III decision	260	40	0	0	
60th Percentile Industry days to MDUFA III decision	260	61	0	0	
80th Percentile Industry days to MDUFA III decision	260	97	0	0	
Maximum Industry days to MDUFA III decision	260	140	0	0	
Average Total days to MDUFA III decision	440	253.75	0	0	
20th Percentile Total days to MDUFA III decision	440	184	0	0	
40th Percentile Total days to MDUFA III decision	440	256	0	0	
60th Percentile Total days to MDUFA III decision	440	280	0	0	
80th Percentile Total days to MDUFA III decision	440	330	0	0	
Maximum Total days to MDUFA III decision	440	392	0	0	

Table 1.8.DRGUD - ODE – 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	3	0	1	0	
Average FDA days to MDUFA III decision	376	0	206	0	
20th Percentile FDA days to MDUFA III decision	313	0	206	0	
40th Percentile FDA days to MDUFA III decision	314	0	206	0	
60th Percentile FDA days to MDUFA III decision	352	0	206	0	
80th Percentile FDA days to MDUFA III decision	427	0	206	0	
Maximum FDA days to MDUFA III decision	501	0	206	0	
Average Industry days to MDUFA III decision	180.33	0	119	0	
20th Percentile Industry days to MDUFA III decision	112	0	119	0	
40th Percentile Industry days to MDUFA III decision	156	0	119	0	
60th Percentile Industry days to MDUFA III decision	201	0	119	0	
80th Percentile Industry days to MDUFA III decision	248	0	119	0	
Maximum Industry days to MDUFA III decision	295	0	119	0	
Average Total days to MDUFA III decision	556.33	0	325	0	
20th Percentile Total days to MDUFA III decision	522	0	325	0	
40th Percentile Total days to MDUFA III decision	553	0	325	0	
60th Percentile Total days to MDUFA III decision	577	0	325	0	
80th Percentile Total days to MDUFA III decision	594	0	325	0	
Maximum Total days to MDUFA III decision	610	0	325	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	4	1	1	
Number with MDUFA decision	1	4	0	0	
Number of Withdrawals	0	1	0	0	
Number of Not Approvable	0	1	0	0	
Rate of Withdrawals	0%	25%	N/A	N/A	
Rate of Not Approvable	0%	25%	N/A	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	1	1	0	
Number with MDUFA decision	3	0	1	0	
Number of Withdrawals	0	0	1	0	
Number of Not Approvable	2	0	0	0	
Rate of Withdrawals	0%	N/A	100%	N/A	
Rate of Not Approvable	66.7%	N/A	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	1	0	0	0	
Mean FDA days for submissions that missed goal	501	0	0	0	
Mean industry days for submissions that missed goal	68	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	6	1	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	0	4	4	0	
Number without a RTA Review and > 15 Days since Date Received	0	0	1	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	2	1	1	
Rate of submissions not accepted for filing review	N/A	33.3%	16.7%	100%	

*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	6	1	
Number Accepted	0	4	5	0	
Completed RTF	0	5	5	1	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	N/A	0%	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
Substantive Interaction (SI) Goals:	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	0	5	5	1	
SI Goal Met	0	5	5	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	N/A	100%	100%	N/A	

Table 1.4.DSD - ODE – 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	0	5	5	0	
Average number of FDA days to Substantive Interaction	0	88.80	85.60	0	
20th Percentile FDA days to Substantive Interaction	0	88	82	0	
40th Percentile FDA days to Substantive Interaction	0	90	85	0	
60th Percentile FDA days to Substantive Interaction	0	90	87	0	
80th Percentile FDA days to Substantive Interaction	0	90	88	0	
Maximum FDA days to Substantive Interaction	0	90	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	5	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	0	3	3	0	
MDUFA III Decisions Goal Met	0	3	3	0	
PMAs pending MDUFA III Decision	0	0	2	1	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	100%	100%	N/A	

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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	0	2	0	0	
MDUFA III Decisions Goal Met	0	2	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	100%	N/A	N/A	

**Table 1.7.DSD - ODE – 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	0	3	3	0	
Average FDA days to MDUFA III decision	0	177.33	179.00	0	
20th Percentile FDA days to MDUFA III decision	0	175	178	0	
40th Percentile FDA days to MDUFA III decision	0	178	179	0	
60th Percentile FDA days to MDUFA III decision	0	179	180	0	
80th Percentile FDA days to MDUFA III decision	0	180	180	0	
Maximum FDA days to MDUFA III decision	0	180	180	0	
Average Industry days to MDUFA III decision	0	49	107	0	
20th Percentile Industry days to MDUFA III decision	0	46	77	0	
40th Percentile Industry days to MDUFA III decision	0	47	88	0	
60th Percentile Industry days to MDUFA III decision	0	49	107	0	
80th Percentile Industry days to MDUFA III decision	0	52	134	0	
Maximum Industry days to MDUFA III decision	0	55	162	0	
Average Total days to MDUFA III decision	0	226.33	286	0	
20th Percentile Total days to MDUFA III decision	0	222	257	0	
40th Percentile Total days to MDUFA III decision	0	223	268	0	
60th Percentile Total days to MDUFA III decision	0	226	286	0	
80th Percentile Total days to MDUFA III decision	0	230	313	0	
Maximum Total days to MDUFA III decision	0	234	339	0	

Table 1.8.DSD - ODE – 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	0	2	0	0	
Average FDA days to MDUFA III decision	0	349.50	0	0	
20th Percentile FDA days to MDUFA III decision	0	332	0	0	
40th Percentile FDA days to MDUFA III decision	0	344	0	0	
60th Percentile FDA days to MDUFA III decision	0	355	0	0	
80th Percentile FDA days to MDUFA III decision	0	367	0	0	
Maximum FDA days to MDUFA III decision	0	379	0	0	
Average Industry days to MDUFA III decision	0	99	0	0	
20th Percentile Industry days to MDUFA III decision	0	52	0	0	
40th Percentile Industry days to MDUFA III decision	0	83	0	0	
60th Percentile Industry days to MDUFA III decision	0	115	0	0	
80th Percentile Industry days to MDUFA III decision	0	146	0	0	
Maximum Industry days to MDUFA III decision	0	178	0	0	
Average Total days to MDUFA III decision	0	448.50	0	0	
20th Percentile Total days to MDUFA III decision	0	419	0	0	
40th Percentile Total days to MDUFA III decision	0	439	0	0	
60th Percentile Total days to MDUFA III decision	0	458	0	0	
80th Percentile Total days to MDUFA III decision	0	478	0	0	
Maximum Total days to MDUFA III decision	0	498	0	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	5	1	
Number with MDUFA decision	0	3	3	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	1	0	
Rate of Withdrawals	N/A	0%	0%	N/A	
Rate of Not Approvable	N/A	0%	33.3%	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	0	
Number with MDUFA decision	0	2	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	N/A	0%	N/A	N/A	
Rate of Not Approvable	N/A	0%	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	8	1	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	2	2	8	1	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	0	0	
Rate of submissions not accepted for filing review	0%	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	8	1	
Number Accepted	2	2	8	1	
Completed RTF	2	2	8	0	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	0%	0%	0%	N/A	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	2	8	0	
SI Goal Met	2	2	8	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	100%	N/A	

Table 1.4.DCTD - OIR – 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	2	2	8	0	
Average number of FDA days to Substantive Interaction	90	88	80.25	0	
20th Percentile FDA days to Substantive Interaction	90	87	71	0	
40th Percentile FDA days to Substantive Interaction	90	88	85	0	
60th Percentile FDA days to Substantive Interaction	90	88	86	0	
80th Percentile FDA days to Substantive Interaction	90	89	89	0	
Maximum FDA days to Substantive Interaction	90	89	90	0	

Table 1.5.DCTD - 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	2	2	8	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	2	2	5	0	
MDUFA III Decisions Goal Met	2	2	5	0	
PMAs pending MDUFA III Decision	0	0	3	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

Table 1.6.DCTD - 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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions Goal Met	0	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	2	2	5	0	
Average FDA days to MDUFA III decision	176.50	179.50	177.40	0	
20th Percentile FDA days to MDUFA III decision	175	179	176	0	
40th Percentile FDA days to MDUFA III decision	176	179	177	0	
60th Percentile FDA days to MDUFA III decision	177	180	178	0	
80th Percentile FDA days to MDUFA III decision	178	180	179	0	
Maximum FDA days to MDUFA III decision	179	180	180	0	
Average Industry days to MDUFA III decision	266.50	119	53.20	0	
20th Percentile Industry days to MDUFA III decision	186	48	0	0	
40th Percentile Industry days to MDUFA III decision	240	95	13	0	
60th Percentile Industry days to MDUFA III decision	293	143	55	0	
80th Percentile Industry days to MDUFA III decision	347	190	112	0	
Maximum Industry days to MDUFA III decision	400	238	140	0	
Average Total days to MDUFA III decision	443	298.50	230.60	0	
20th Percentile Total days to MDUFA III decision	361	227	179	0	
40th Percentile Total days to MDUFA III decision	416	275	190	0	
60th Percentile Total days to MDUFA III decision	470	322	232	0	
80th Percentile Total days to MDUFA III decision	525	370	290	0	
Maximum Total days to MDUFA III decision	579	418	315	0	

Table 1.8.DCTD - OIR – 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	0	0	0	0	
Average FDA days to MDUFA III decision	0	0	0	0	
20th Percentile FDA days to MDUFA III decision	0	0	0	0	
40th Percentile FDA days to MDUFA III decision	0	0	0	0	
60th Percentile FDA days to MDUFA III decision	0	0	0	0	
80th Percentile FDA days to MDUFA III decision	0	0	0	0	
Maximum FDA days to MDUFA III decision	0	0	0	0	
Average Industry days to MDUFA III decision	0	0	0	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	0	0	0	0	
80th Percentile Industry days to MDUFA III decision	0	0	0	0	
Maximum Industry days to MDUFA III decision	0	0	0	0	
Average Total days to MDUFA III decision	0	0	0	0	
20th Percentile Total days to MDUFA III decision	0	0	0	0	
40th Percentile Total days to MDUFA III decision	0	0	0	0	
60th Percentile Total days to MDUFA III decision	0	0	0	0	
80th Percentile Total days to MDUFA III decision	0	0	0	0	
Maximum Total days to MDUFA III decision	0	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	8	0	
Number with MDUFA decision	2	2	5	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	1	0	
Rate of Withdrawals	0%	0%	0%	N/A	
Rate of Not Approvable	0%	0%	20%	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	0	
Number with MDUFA decision	0	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	0	0	0	0	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	0	0	
Rate of submissions not accepted for filing review	N/A	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	0	
Number Accepted	0	0	0	0	
Completed RTF	0	0	0	0	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	N/A	N/A	N/A	N/A	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	0	0	0	0	
SI Goal Met	0	0	0	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	N/A	N/A	N/A	N/A	

Table 1.4.DIHD - OIR – 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	0	0	0	0	
Average number of FDA days to Substantive Interaction	0	0	0	0	
20th Percentile FDA days to Substantive Interaction	0	0	0	0	
40th Percentile FDA days to Substantive Interaction	0	0	0	0	
60th Percentile FDA days to Substantive Interaction	0	0	0	0	
80th Percentile FDA days to Substantive Interaction	0	0	0	0	
Maximum FDA days to Substantive Interaction	0	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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions Goal Met	0	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions Goal Met	0	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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**

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

**Table 1.8.DIHD - OIR – 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	0	0	0	0	
Average FDA days to MDUFA III decision	0	0	0	0	
20th Percentile FDA days to MDUFA III decision	0	0	0	0	
40th Percentile FDA days to MDUFA III decision	0	0	0	0	
60th Percentile FDA days to MDUFA III decision	0	0	0	0	
80th Percentile FDA days to MDUFA III decision	0	0	0	0	
Maximum FDA days to MDUFA III decision	0	0	0	0	
Average Industry days to MDUFA III decision	0	0	0	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	0	0	0	0	
80th Percentile Industry days to MDUFA III decision	0	0	0	0	
Maximum Industry days to MDUFA III decision	0	0	0	0	
Average Total days to MDUFA III decision	0	0	0	0	
20th Percentile Total days to MDUFA III decision	0	0	0	0	
40th Percentile Total days to MDUFA III decision	0	0	0	0	
60th Percentile Total days to MDUFA III decision	0	0	0	0	
80th Percentile Total days to MDUFA III decision	0	0	0	0	
Maximum Total days to MDUFA III decision	0	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	0	
Number with MDUFA decision	0	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Number with MDUFA decision	0	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	3	3	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	2	1	3	3	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	0	0	
Rate of submissions not accepted for filing review	0%	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	3	3	
Number Accepted	2	1	3	3	
Completed RTF	2	1	3	3	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	0%	0%	0%	0%	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	3	3	
SI Goal Met	2	1	2	2	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	66.7%	100%	

Table 1.4.DMD - OIR – 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	2	1	3	2	
Average number of FDA days to Substantive Interaction	86	83	88.67	83	
20th Percentile FDA days to Substantive Interaction	86	83	87	83	
40th Percentile FDA days to Substantive Interaction	86	83	88	83	
60th Percentile FDA days to Substantive Interaction	86	83	89	83	
80th Percentile FDA days to Substantive Interaction	86	83	90	83	
Maximum FDA days to Substantive Interaction	86	83	91	83	

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	3	3	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	1	3	0	
MDUFA III Decisions Goal Met	1	1	3	0	
PMAs pending MDUFA III Decision	0	0	0	3	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions Goal Met	1	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	N/A	N/A	

Table 1.7.DMD - OIR – 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	1	1	3	0	
Average FDA days to MDUFA III decision	177	179	167.33	0	
20th Percentile FDA days to MDUFA III decision	177	179	163	0	
40th Percentile FDA days to MDUFA III decision	177	179	168	0	
60th Percentile FDA days to MDUFA III decision	177	179	171	0	
80th Percentile FDA days to MDUFA III decision	177	179	172	0	
Maximum FDA days to MDUFA III decision	177	179	173	0	
Average Industry days to MDUFA III decision	107	0	26	0	
20th Percentile Industry days to MDUFA III decision	107	0	0	0	
40th Percentile Industry days to MDUFA III decision	107	0	0	0	
60th Percentile Industry days to MDUFA III decision	107	0	16	0	
80th Percentile Industry days to MDUFA III decision	107	0	47	0	
Maximum Industry days to MDUFA III decision	107	0	78	0	
Average Total days to MDUFA III decision	284	179	193.33	0	
20th Percentile Total days to MDUFA III decision	284	179	171	0	
40th Percentile Total days to MDUFA III decision	284	179	172	0	
60th Percentile Total days to MDUFA III decision	284	179	186	0	
80th Percentile Total days to MDUFA III decision	284	179	211	0	
Maximum Total days to MDUFA III decision	284	179	237	0	

Table 1.8.DMD - OIR – 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	0	
Average FDA days to MDUFA III decision	297	0	0	0	
20th Percentile FDA days to MDUFA III decision	297	0	0	0	
40th Percentile FDA days to MDUFA III decision	297	0	0	0	
60th Percentile FDA days to MDUFA III decision	297	0	0	0	
80th Percentile FDA days to MDUFA III decision	297	0	0	0	
Maximum FDA days to MDUFA III decision	297	0	0	0	
Average Industry days to MDUFA III decision	0	0	0	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	0	0	0	0	
80th Percentile Industry days to MDUFA III decision	0	0	0	0	
Maximum Industry days to MDUFA III decision	0	0	0	0	
Average Total days to MDUFA III decision	297	0	0	0	
20th Percentile Total days to MDUFA III decision	297	0	0	0	
40th Percentile Total days to MDUFA III decision	297	0	0	0	
60th Percentile Total days to MDUFA III decision	297	0	0	0	
80th Percentile Total days to MDUFA III decision	297	0	0	0	
Maximum Total days to MDUFA III decision	297	0	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	3	3	
Number with MDUFA decision	1	1	3	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	0%	0%	N/A	
Rate of Not Approvable	0%	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	0	
Number with MDUFA decision	1	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	N/A	N/A	N/A	
Rate of Not Approvable	0%	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	6	6	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	2	1	6	6	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	0	0	
Rate of submissions not accepted for filing review	0%	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	6	6	
Number Accepted	4	1	6	6	
Completed RTF	4	1	6	6	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	0%	0%	0%	0%	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	4	1	6	6	
SI Goal Met	3	1	6	4	
SI Goal Not Met	1	0	0	1	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	75%	100%	100%	80%	

Table 1.4.DMGP - OIR – 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	4	1	6	5	
Average number of FDA days to Substantive Interaction	95.25	86	86.83	79	
20th Percentile FDA days to Substantive Interaction	90	86	90	72	
40th Percentile FDA days to Substantive Interaction	90	86	90	82	
60th Percentile FDA days to Substantive Interaction	90	86	90	86	
80th Percentile FDA days to Substantive Interaction	99	86	90	89	
Maximum FDA days to Substantive Interaction	112	86	90	94	

Table 1.5.DMGP - 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	2	1	6	6	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	2	1	6	0	
MDUFA III Decisions Goal Met	2	1	6	0	
PMAs pending MDUFA III Decision	0	0	0	6	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

Table 1.6.DMGP - 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	2	0	0	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	2	0	0	0	
MDUFA III Decisions Goal Met	2	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	N/A	N/A	

**Table 1.7.DMGP - OIR – 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	2	1	6	0	
Average FDA days to MDUFA III decision	107.50	86	128	0	
20th Percentile FDA days to MDUFA III decision	102	86	95	0	
40th Percentile FDA days to MDUFA III decision	106	86	114	0	
60th Percentile FDA days to MDUFA III decision	109	86	133	0	
80th Percentile FDA days to MDUFA III decision	113	86	164	0	
Maximum FDA days to MDUFA III decision	116	86	171	0	
Average Industry days to MDUFA III decision	94.50	0	40.67	0	
20th Percentile Industry days to MDUFA III decision	80	0	0	0	
40th Percentile Industry days to MDUFA III decision	90	0	39	0	
60th Percentile Industry days to MDUFA III decision	99	0	58	0	
80th Percentile Industry days to MDUFA III decision	109	0	63	0	
Maximum Industry days to MDUFA III decision	118	0	84	0	
Average Total days to MDUFA III decision	202	86	168.67	0	
20th Percentile Total days to MDUFA III decision	193	86	164	0	
40th Percentile Total days to MDUFA III decision	199	86	172	0	
60th Percentile Total days to MDUFA III decision	205	86	179	0	
80th Percentile Total days to MDUFA III decision	211	86	196	0	
Maximum Total days to MDUFA III decision	217	86	210	0	

**Table 1.8.DMGP - OIR – 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	2	0	0	0	
Average FDA days to MDUFA III decision	320	0	0	0	
20th Percentile FDA days to MDUFA III decision	317	0	0	0	
40th Percentile FDA days to MDUFA III decision	319	0	0	0	
60th Percentile FDA days to MDUFA III decision	321	0	0	0	
80th Percentile FDA days to MDUFA III decision	323	0	0	0	
Maximum FDA days to MDUFA III decision	325	0	0	0	
Average Industry days to MDUFA III decision	147	0	0	0	
20th Percentile Industry days to MDUFA III decision	122	0	0	0	
40th Percentile Industry days to MDUFA III decision	139	0	0	0	
60th Percentile Industry days to MDUFA III decision	155	0	0	0	
80th Percentile Industry days to MDUFA III decision	172	0	0	0	
Maximum Industry days to MDUFA III decision	189	0	0	0	
Average Total days to MDUFA III decision	467	0	0	0	
20th Percentile Total days to MDUFA III decision	445	0	0	0	
40th Percentile Total days to MDUFA III decision	460	0	0	0	
60th Percentile Total days to MDUFA III decision	474	0	0	0	
80th Percentile Total days to MDUFA III decision	489	0	0	0	
Maximum Total days to MDUFA III decision	504	0	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	6	6	
Number with MDUFA decision	2	1	6	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	0%	0%	N/A	
Rate of Not Approvable	0%	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	0	
Number with MDUFA decision	2	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	1	0	0	0	
Rate of Withdrawals	0%	N/A	N/A	N/A	
Rate of Not Approvable	50%	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	1	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	1	1	0	1	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	1	0	0	
Rate of submissions not accepted for filing review	0%	50%	N/A	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.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	1	
Number Accepted	2	1	0	1	
Completed RTF	2	2	0	1	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	0%	0%	N/A	0%	

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	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	2	0	1	
SI Goal Met	2	2	0	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	N/A	100%	

Table 1.4.DRH - OIR – 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	2	2	0	1	
Average number of FDA days to Substantive Interaction	77.50	86.50	0	87	
20th Percentile FDA days to Substantive Interaction	70	86	0	87	
40th Percentile FDA days to Substantive Interaction	75	86	0	87	
60th Percentile FDA days to Substantive Interaction	80	87	0	87	
80th Percentile FDA days to Substantive Interaction	85	87	0	87	
Maximum FDA days to Substantive Interaction	90	88	0	87	

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	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	2	0	0	
MDUFA III Decisions Goal Met	1	2	0	0	
PMAs pending MDUFA III Decision	0	0	0	1	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	N/A	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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions Goal Met	1	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	N/A	N/A	

Table 1.7.DRH - OIR – 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	1	2	0	0	
Average FDA days to MDUFA III decision	167	178	0	0	
20th Percentile FDA days to MDUFA III decision	167	177	0	0	
40th Percentile FDA days to MDUFA III decision	167	178	0	0	
60th Percentile FDA days to MDUFA III decision	167	178	0	0	
80th Percentile FDA days to MDUFA III decision	167	179	0	0	
Maximum FDA days to MDUFA III decision	167	179	0	0	
Average Industry days to MDUFA III decision	81	113	0	0	
20th Percentile Industry days to MDUFA III decision	81	109	0	0	
40th Percentile Industry days to MDUFA III decision	81	112	0	0	
60th Percentile Industry days to MDUFA III decision	81	114	0	0	
80th Percentile Industry days to MDUFA III decision	81	117	0	0	
Maximum Industry days to MDUFA III decision	81	120	0	0	
Average Total days to MDUFA III decision	248	291	0	0	
20th Percentile Total days to MDUFA III decision	248	286	0	0	
40th Percentile Total days to MDUFA III decision	248	289	0	0	
60th Percentile Total days to MDUFA III decision	248	293	0	0	
80th Percentile Total days to MDUFA III decision	248	296	0	0	
Maximum Total days to MDUFA III decision	248	299	0	0	

Table 1.8.DRH - OIR – 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	0	
Average FDA days to MDUFA III decision	206	0	0	0	
20th Percentile FDA days to MDUFA III decision	206	0	0	0	
40th Percentile FDA days to MDUFA III decision	206	0	0	0	
60th Percentile FDA days to MDUFA III decision	206	0	0	0	
80th Percentile FDA days to MDUFA III decision	206	0	0	0	
Maximum FDA days to MDUFA III decision	206	0	0	0	
Average Industry days to MDUFA III decision	0	0	0	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	0	0	0	0	
80th Percentile Industry days to MDUFA III decision	0	0	0	0	
Maximum Industry days to MDUFA III decision	0	0	0	0	
Average Total days to MDUFA III decision	206	0	0	0	
20th Percentile Total days to MDUFA III decision	206	0	0	0	
40th Percentile Total days to MDUFA III decision	206	0	0	0	
60th Percentile Total days to MDUFA III decision	206	0	0	0	
80th Percentile Total days to MDUFA III decision	206	0	0	0	
Maximum Total days to MDUFA III decision	206	0	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	1	
Number with MDUFA decision	1	2	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	1	0	0	0	
Rate of Withdrawals	0%	0%	N/A	N/A	
Rate of Not Approvable	100%	0%	N/A	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	0	
Number with MDUFA decision	1	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	N/A	N/A	N/A	
Rate of Not Approvable	0%	N/A	N/A	N/A	

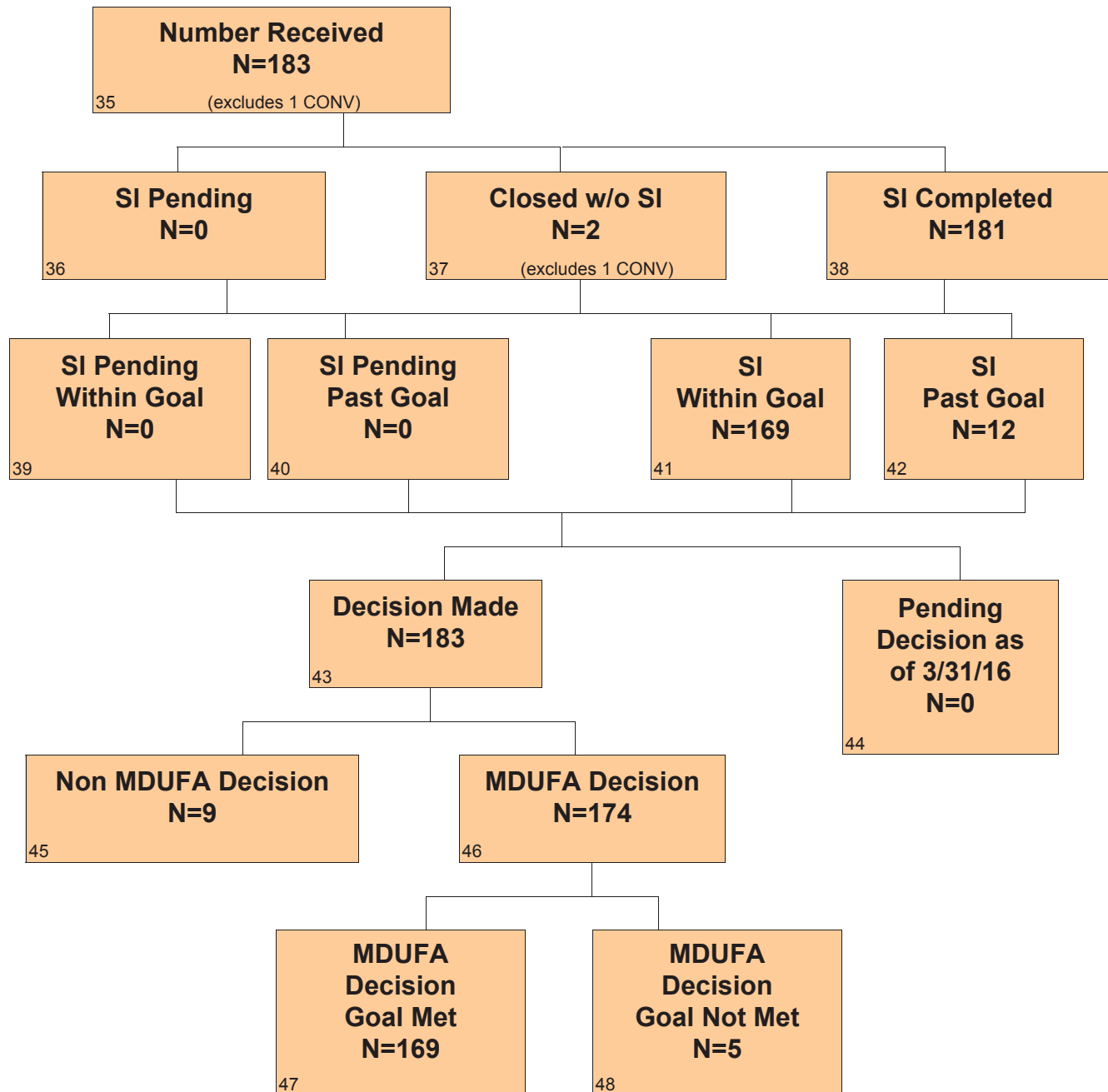
Table 1.11.DRH - OIR – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

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

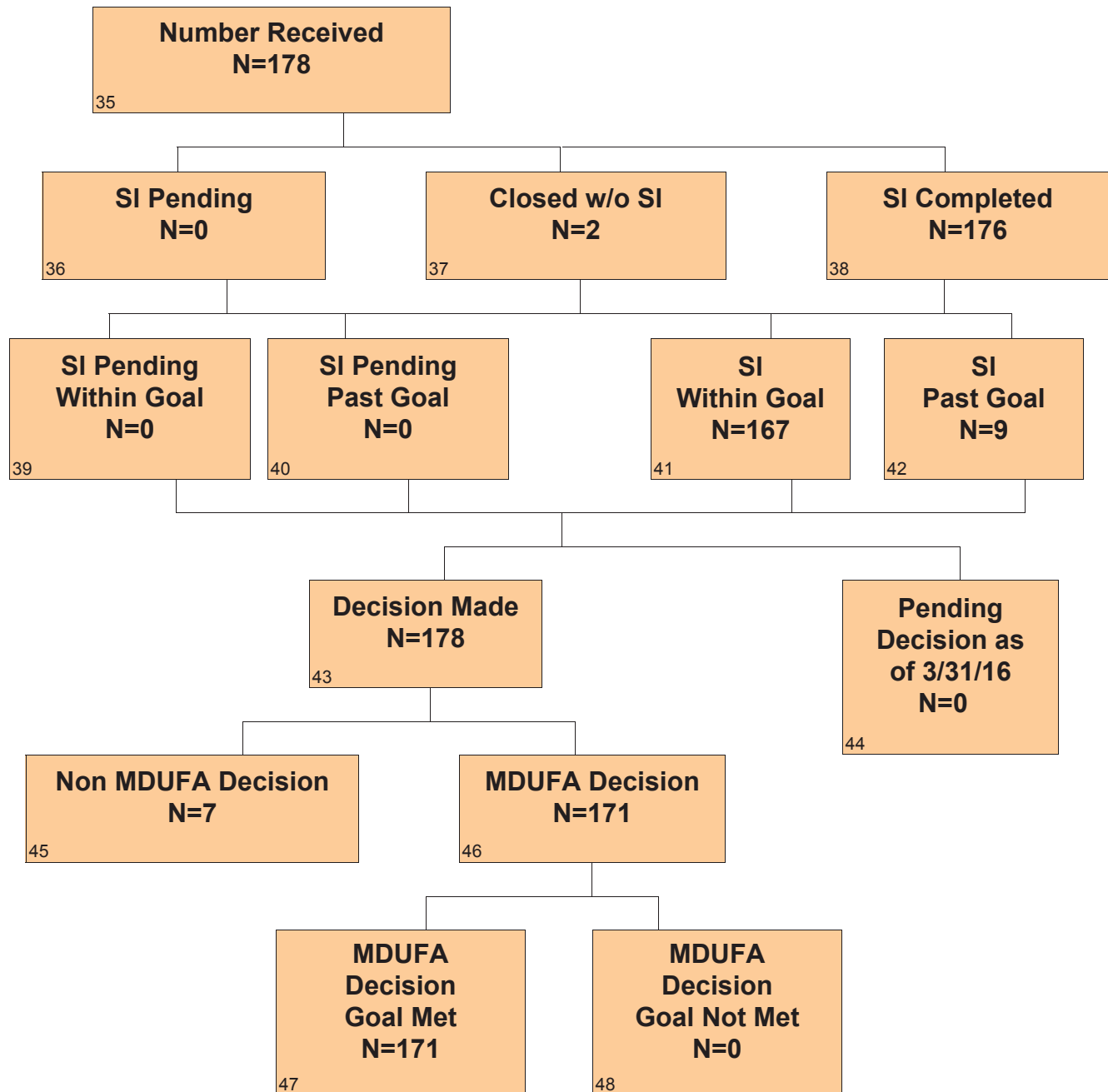
Table 1.12.DRH - OIR – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

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

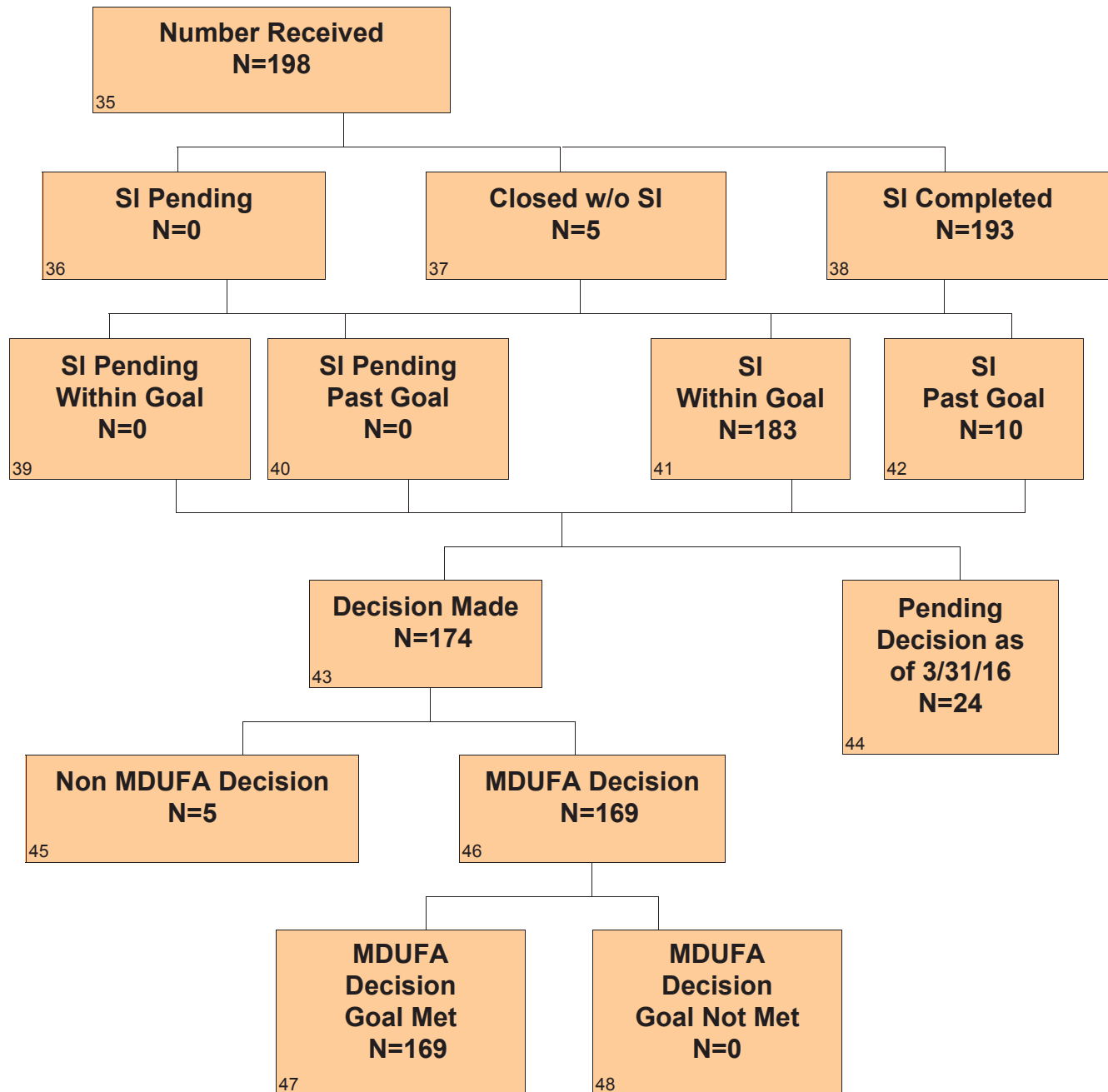
CDRH PMA 180 Day Supplements - FY 2013 As of 3/31/16



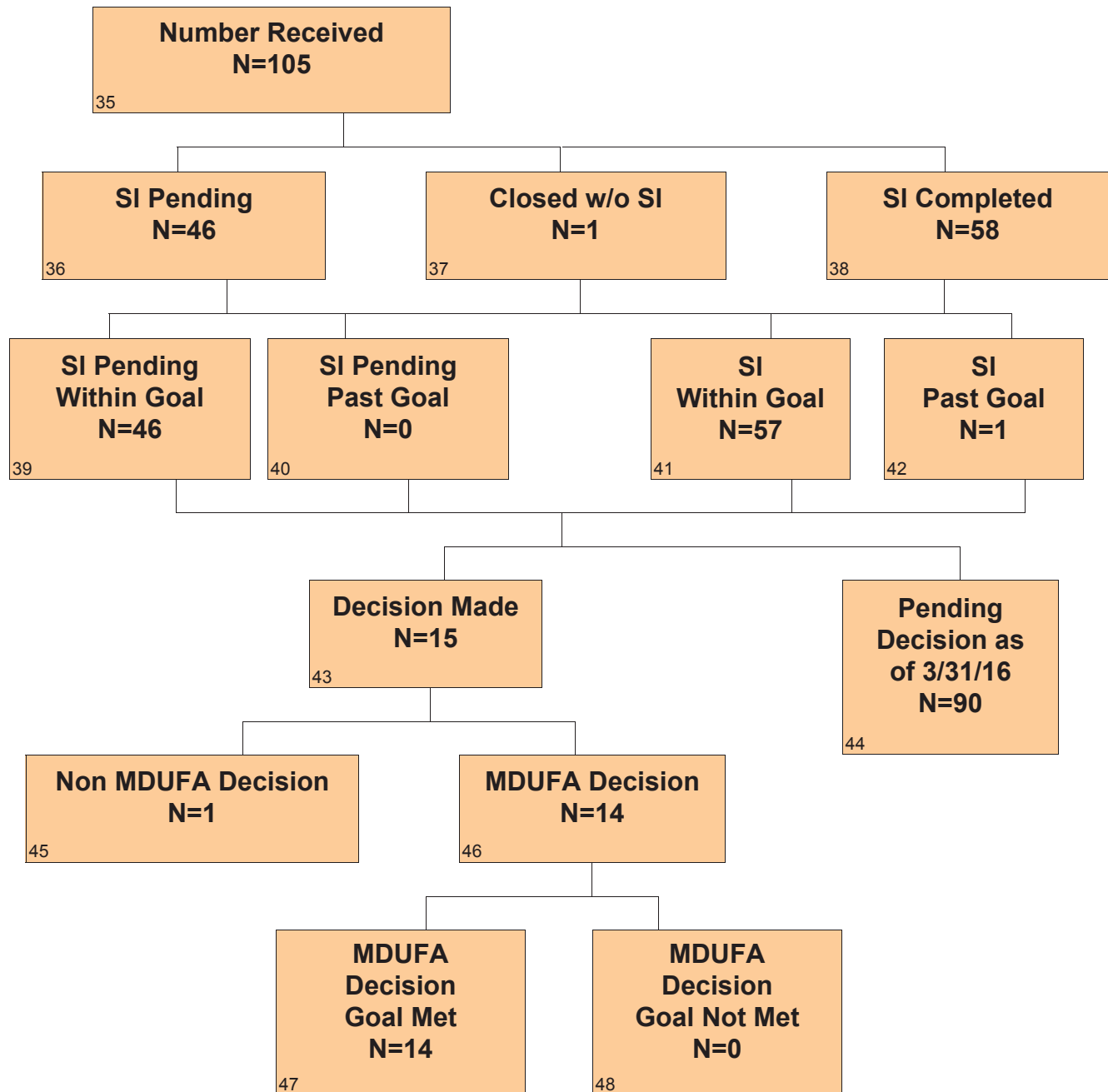
CDRH PMA 180 Day Supplements - FY 2014 As of 3/31/16



CDRH PMA 180 Day Supplements - FY 2015 As of 3/31/16



CDRH PMA 180 Day Supplements - FY 2016 As of 3/31/16



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	184	178	198	105	
SI Goal Met	169	167	183	57	
SI Goal Not Met	12	9	10	1	
SI Pending Within Goal	0	0	1	46	
SI Pending Past Goal	0	0	1	0	
Closed without SI	3	2	5	1	
Current SI Performance Percent Goal Met	93.4%	94.9%	94.3%	98.3%	

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	184	178	198	105	
Non-MDUFA III Decisions	10	7	5	1	
MDUFA III Decisions	174	171	169	14	
MDUFA III Decisions Goal Met	169	171	169	14	
Supplements pending MDUFA III Decision	0	0	24	90	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	97.1%	100%	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	184	178	199	105	
Number with MDUFA decision	174	171	169	14	
Number of Not Approvable	11	5	8	0	
Rate of Not Approvable	6.3%	2.9%	4.7%	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	5	0	0	0	
Mean FDA days for submissions that missed goal	240	0	0	0	
Mean Industry days for submissions that missed goal	231	0	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	163	165	164	93	
SI Goal Met	148	154	150	51	
SI Goal Not Met	12	9	9	1	
SI Pending Within Goal	0	0	0	40	
SI Pending Past Goal	0	0	0	0	
Closed without SI	3	2	5	1	
Current SI Performance Percent Goal Met	92.5%	94.5%	94.3%	98.1%	

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	163	165	164	93	
Non-MDUFA III Decisions	9	6	5	1	
MDUFA III Decisions	154	159	145	13	
MDUFA III Decisions Goal Met	149	159	145	13	
Supplements pending MDUFA III Decision	0	0	14	79	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	96.8%	100%	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	163	165	165	93	
Number with MDUFA decision	154	159	145	13	
Number of Not Approvable	11	5	6	0	
Rate of Not Approvable	7.1%	3.1%	4.1%	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	5	0	0	0	
Mean FDA days for submissions that missed goal	240	0	0	0	
Mean Industry days for submissions that missed goal	231	0	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	34	12	
SI Goal Met	21	13	33	6	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	6	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	97.1%	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	34	12	
Non-MDUFA III Decisions	1	1	0	0	
MDUFA III Decisions	20	12	24	1	
MDUFA III Decisions Goal Met	20	12	24	1	
Supplements pending MDUFA III Decision	0	0	10	11	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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	34	12	
Number with MDUFA decision	20	12	24	1	
Number of Not Approvable	0	0	2	0	
Rate of Not Approvable	0%	0%	8.3%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	7	3	
SI Goal Met	8	7	6	2	
SI Goal Not Met	2	2	1	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	1	
Current SI Performance Percent Goal Met	80%	77.8%	85.7%	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	7	3	
Non-MDUFA III Decisions	2	1	0	1	
MDUFA III Decisions	8	8	5	0	
MDUFA III Decisions Goal Met	6	8	5	0	
Supplements pending MDUFA III Decision	0	0	2	2	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	75%	100%	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	7	3	
Number with MDUFA decision	8	8	5	0	
Number of Not Approvable	1	2	0	0	
Rate of Not Approvable	12.5%	25%	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	2	0	0	0	
Mean FDA days for submissions that missed goal	197	0	0	0	
Mean Industry days for submissions that missed goal	313	0	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	104	53	
SI Goal Met	108	93	97	29	
SI Goal Not Met	5	1	2	1	
SI Pending Within Goal	0	0	0	23	
SI Pending Past Goal	0	0	0	0	
Closed without SI	3	0	5	0	
Current SI Performance Percent Goal Met	95.6%	98.9%	98%	96.7%	

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	104	53	
Non-MDUFA III Decisions	4	1	5	0	
MDUFA III Decisions	112	93	93	8	
MDUFA III Decisions Goal Met	111	93	93	8	
Supplements pending MDUFA III Decision	0	0	6	45	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	99.1%	100%	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	104	53	
Number with MDUFA decision	112	93	93	8	
Number of Not Approvable	6	0	5	0	
Rate of Not Approvable	5.4%	0%	5.4%	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	0	
Mean FDA days for submissions that missed goal	182	0	0	0	
Mean Industry days for submissions that missed goal	0	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	14	10	
SI Goal Met	7	13	13	8	
SI Goal Not Met	1	0	1	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	1	0	0	
Current SI Performance Percent Goal Met	87.5%	100%	92.9%	100%	

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	14	10	
Non-MDUFA III Decisions	2	1	0	0	
MDUFA III Decisions	6	13	10	1	
MDUFA III Decisions Goal Met	6	13	10	1	
Supplements pending MDUFA III Decision	0	0	4	9	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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	14	10	
Number with MDUFA decision	6	13	10	1	
Number of Not Approvable	1	0	0	0	
Rate of Not Approvable	16.7%	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	6	2	
SI Goal Met	2	2	5	2	
SI Goal Not Met	0	2	1	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	50%	83.3%	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	6	2	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	2	4	6	2	
MDUFA III Decisions Goal Met	2	4	6	2	
Supplements pending MDUFA III Decision	0	0	0	0	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	100%	

Table 2.3.DOD - ODE - 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	6	2	
Number with MDUFA decision	2	4	6	2	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	25	18	13	
SI Goal Met	11	24	17	6	
SI Goal Not Met	1	0	1	0	
SI Pending Within Goal	0	0	0	7	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	1	0	0	
Current SI Performance Percent Goal Met	91.7%	100%	94.4%	100%	

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	25	18	13	
Non-MDUFA III Decisions	0	3	0	0	
MDUFA III Decisions	12	22	17	0	
MDUFA III Decisions Goal Met	12	22	17	0	
Supplements pending MDUFA III Decision	0	0	1	13	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	25	18	13	
Number with MDUFA decision	12	22	17	0	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	8.3%	4.5%	0%	N/A	

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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	8	9	
SI Goal Met	9	7	8	2	
SI Goal Not Met	1	0	0	0	
SI Pending Within Goal	0	0	0	7	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	90%	100%	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	8	9	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	10	7	8	1	
MDUFA III Decisions Goal Met	10	7	8	1	
Supplements pending MDUFA III Decision	0	0	0	8	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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	8	9	
Number with MDUFA decision	10	7	8	1	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	10%	14.3%	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	0	0	0	

Table 2.1.DSD - 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	5	12	7	3	
SI Goal Met	3	8	4	2	
SI Goal Not Met	2	4	3	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	60%	66.7%	57.1%	100%	

Table 2.2.DSD - 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	5	12	7	3	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	4	12	6	1	
MDUFA III Decisions Goal Met	2	12	6	1	
Supplements pending MDUFA III Decision	0	0	1	2	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	50%	100%	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	5	12	7	3	
Number with MDUFA decision	4	12	6	1	
Number of Not Approvable	1	1	1	0	
Rate of Not Approvable	25%	8.3%	16.7%	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	2	0	0	0	
Mean FDA days for submissions that missed goal	312	0	0	0	
Mean Industry days for submissions that missed goal	266	0	0	0	

Table 2.1.DCTD - 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	3	3	4	1	
SI Goal Met	3	3	3	1	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	75%	100%	

Table 2.2.DCTD - 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	3	3	4	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	3	3	4	1	
MDUFA III Decisions Goal Met	3	3	4	1	
Supplements pending MDUFA III Decision	0	0	0	0	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	100%	

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	4	1	
Number with MDUFA decision	3	3	4	1	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	0%	0%	0%	

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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	3	2	
SI Goal Met	1	1	3	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	100%	100%	

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	3	2	
Non-MDUFA III Decisions	0	1	0	0	
MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions Goal Met	1	0	0	0	
Supplements pending MDUFA III Decision	0	0	3	2	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	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	3	2	
Number with MDUFA decision	1	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	N/A	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	0	0	0	

Table 2.1.DMD - 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	7	4	14	3	
SI Goal Met	7	4	14	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	100%	100%	

Table 2.2.DMD - 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	7	4	14	3	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	6	4	8	0	
MDUFA III Decisions Goal Met	6	4	8	0	
Supplements pending MDUFA III Decision	0	0	6	3	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	14	3	
Number with MDUFA decision	6	4	8	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	0%	0%	N/A	

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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	0	0	0	

Table 2.1.DMGP - 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	5	4	9	3	
SI Goal Met	5	4	9	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	3	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	100%	N/A	

Table 2.2.DMGP - 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	5	4	9	3	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	5	4	8	0	
MDUFA III Decisions Goal Met	5	4	8	0	
Supplements pending MDUFA III Decision	0	0	1	3	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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	9	3	
Number with MDUFA decision	5	4	8	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	0	0	0	

Table 2.1.DRH - 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	5	1	4	3	
SI Goal Met	5	1	4	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	100%	100%	

Table 2.2.DRH - 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	5	1	4	3	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	5	1	4	0	
MDUFA III Decisions Goal Met	5	1	4	0	
Supplements pending MDUFA III Decision	0	0	0	3	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

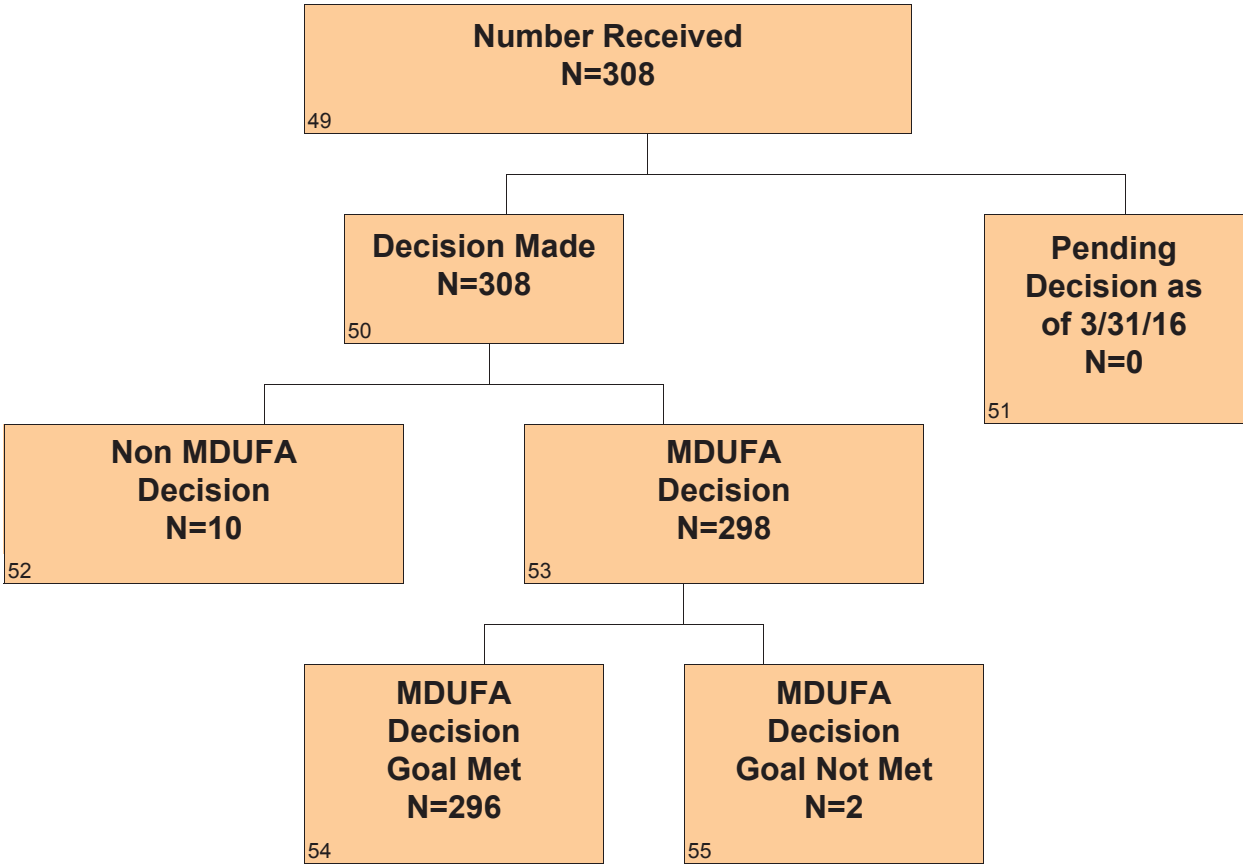
Table 2.3.DRH DRH - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1	4	3	
Number with MDUFA decision	5	1	4	0	
Number of Not Approvable	0	0	2	0	
Rate of Not Approvable	0%	0%	50%	N/A	

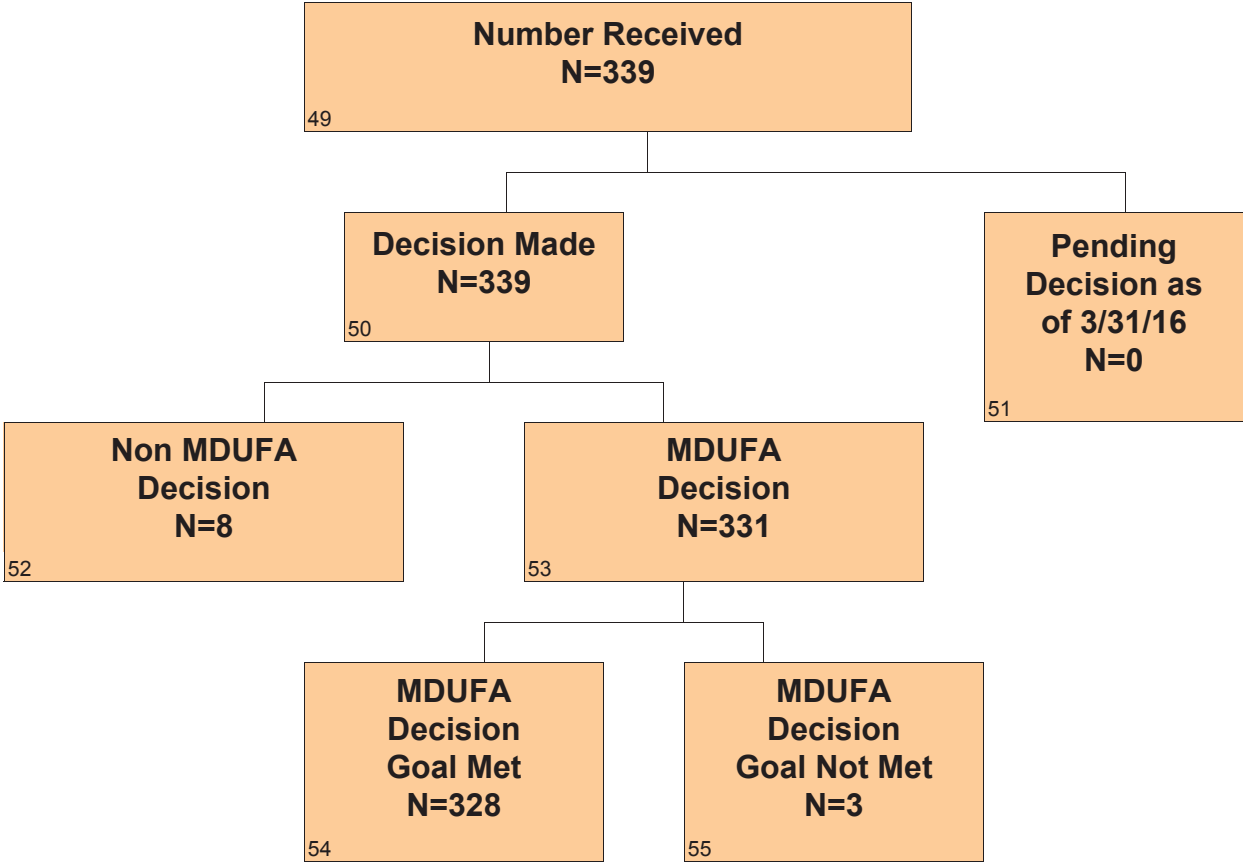
Table 2.4.DRH - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

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

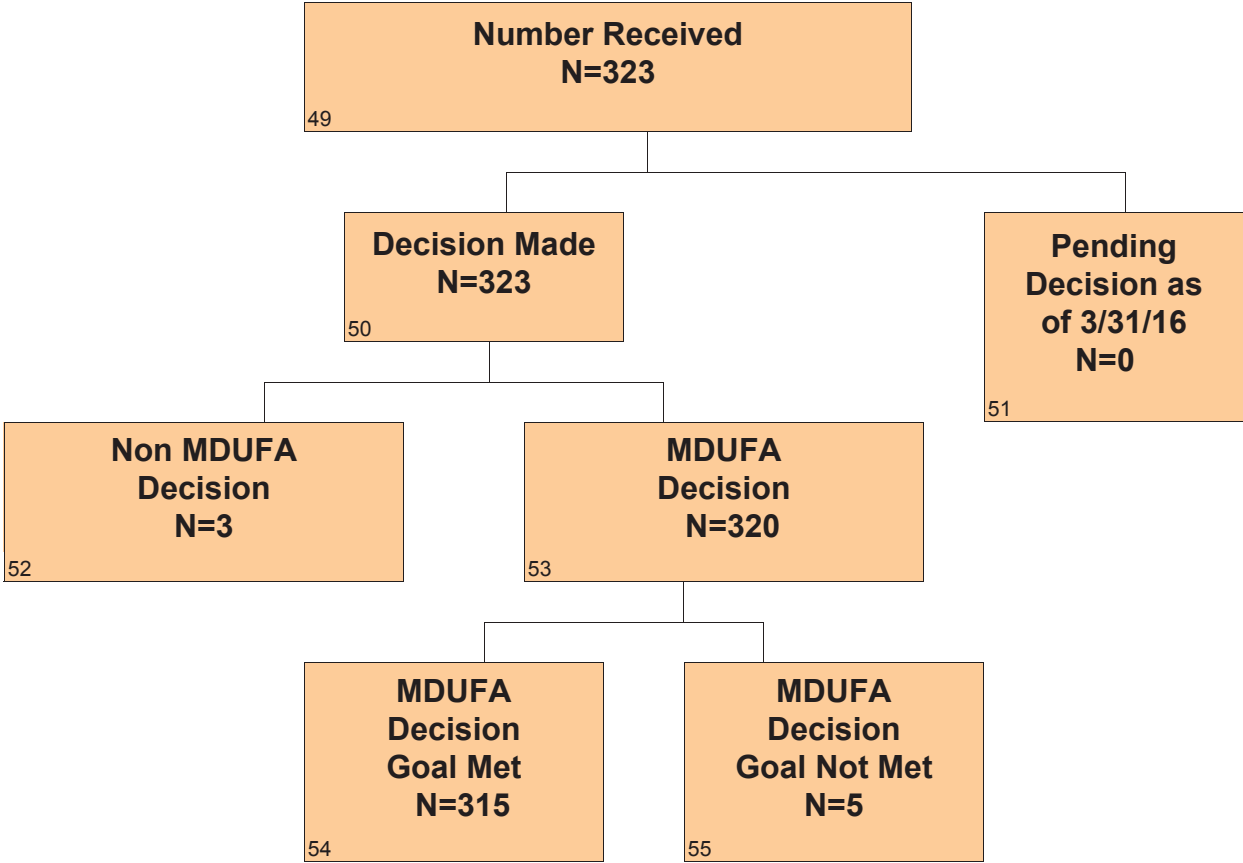
CDRH PMA Real Time Supplements - FY 2013 As of 3/31/16



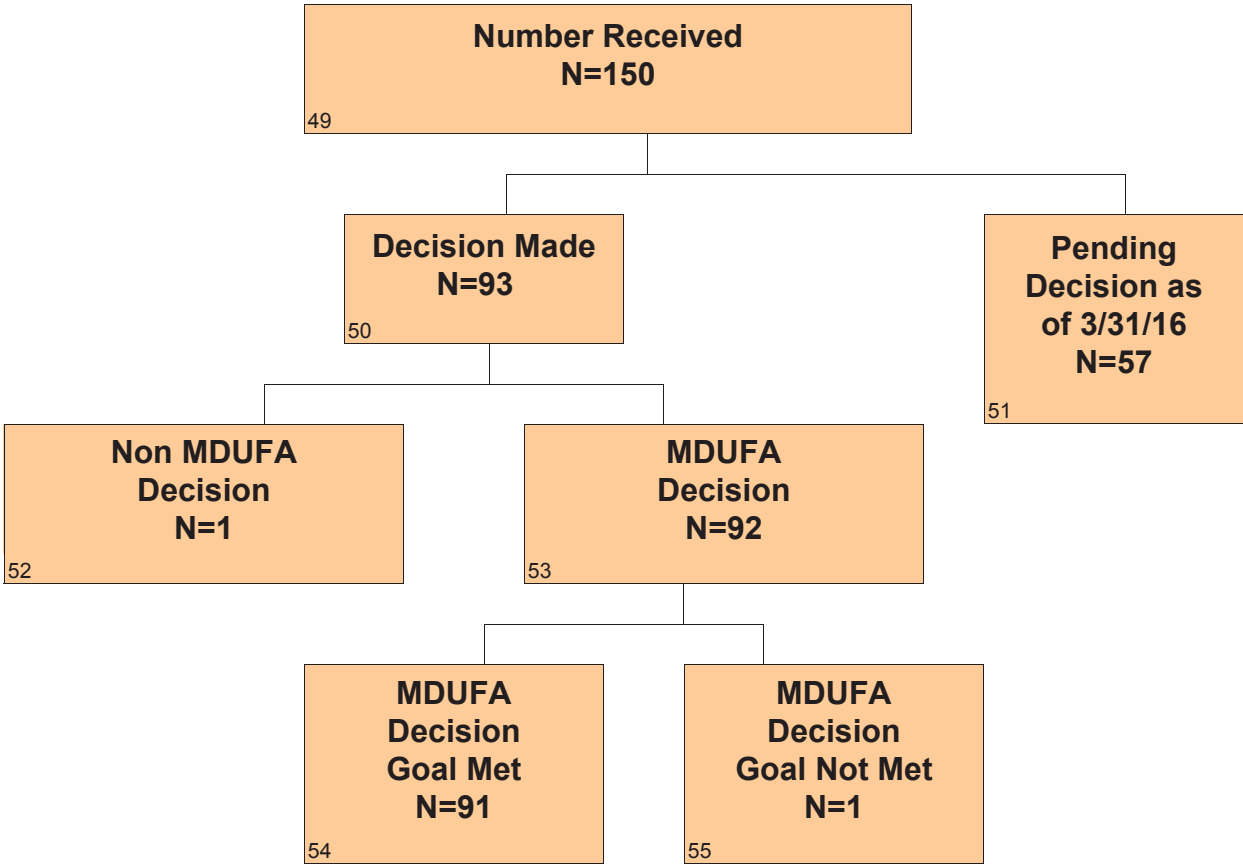
CDRH PMA Real Time Supplements - FY 2014 As of 3/31/16



CDRH PMA Real Time Supplements - FY 2015 As of 3/31/16



CDRH PMA Real Time Supplements - FY 2016 As of 3/31/16



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	323	150	
Non-MDUFA III Decisions	10	8	3	1	
MDUFA III Decisions	298	331	320	92	
MDUFA III Decisions Goal Met	296	328	315	91	
Supplements pending MDUFA III Decision	0	0	0	57	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	99.3%	99.1%	98.4%	98.9%	

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	323	150	
Number with MDUFA decision	298	331	320	92	
Number of Not Approvable	20	3	20	3	
Rate of Not Approvable	6.7%	0.9%	6.3%	3.3%	

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	5	1	
Mean FDA days for submissions that missed goal	143	100	144	91	
Mean Industry days for submissions that missed goal	0	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	271	137	
Non-MDUFA III Decisions	9	6	2	1	
MDUFA III Decisions	260	277	269	83	
MDUFA III Decisions Goal Met	258	274	264	82	
Supplements pending MDUFA III Decision	0	0	0	53	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	99.2%	98.9%	98.1%	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	271	137	
Number with MDUFA decision	260	277	269	83	
Number of Not Approvable	15	3	14	2	
Rate of Not Approvable	5.8%	1.1%	5.2%	2.4%	

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	5	1	
Mean FDA days for submissions that missed goal	143	100	144	91	
Mean Industry days for submissions that missed goal	0	0	0	0	

Table 3.1.OIR - 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	39	56	52	13	
Non-MDUFA III Decisions	1	2	1	0	
MDUFA III Decisions	38	54	51	9	
MDUFA III Decisions Goal Met	38	54	51	9	
Supplements pending MDUFA III Decision	0	0	0	4	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	100%	

Table 3.2.OIR - 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	39	56	52	13	
Number with MDUFA decision	38	54	51	9	
Number of Not Approvable	5	0	6	1	
Rate of Not Approvable	13.2%	0%	11.8%	11.1%	

Table 3.3.OIR - 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	0	0	0	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	6	6	
Non-MDUFA III Decisions	0	1	0	0	
MDUFA III Decisions	13	7	6	4	
MDUFA III Decisions Goal Met	13	5	5	3	
Supplements pending MDUFA III Decision	0	0	0	2	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	71.4%	83.3%	75%	

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	6	6	
Number with MDUFA decision	13	7	6	4	
Number of Not Approvable	1	1	2	0	
Rate of Not Approvable	7.7%	14.3%	33.3%	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	1	1	
Mean FDA days for submissions that missed goal	0	101	183	91	
Mean Industry days for submissions that missed goal	0	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	191	101	
Non-MDUFA III Decisions	6	3	2	1	
MDUFA III Decisions	170	215	189	61	
MDUFA III Decisions Goal Met	170	215	185	61	
Supplements pending MDUFA III Decision	0	0	0	39	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	97.9%	100%	

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	191	101	
Number with MDUFA decision	170	215	189	61	
Number of Not Approvable	7	1	10	0	
Rate of Not Approvable	4.1%	0.5%	5.3%	0%	

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	4	0	
Mean FDA days for submissions that missed goal	0	0	134	0	
Mean Industry days for submissions that missed goal	0	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	23	10	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	23	17	23	4	
MDUFA III Decisions Goal Met	23	16	23	4	
Supplements pending MDUFA III Decision	0	0	0	6	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	94.1%	100%	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	23	10	
Number with MDUFA decision	23	17	23	4	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	4.3%	5.9%	0%	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	0	
Mean FDA days for submissions that missed goal	0	97	0	0	
Mean Industry days for submissions that missed goal	0	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	12	2	
Non-MDUFA III Decisions	0	2	0	0	
MDUFA III Decisions	8	8	12	0	
MDUFA III Decisions Goal Met	8	8	12	0	
Supplements pending MDUFA III Decision	0	0	0	2	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	12	2	
Number with MDUFA decision	8	8	12	0	
Number of Not Approvable	2	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	21	11	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	16	17	21	8	
MDUFA III Decisions Goal Met	16	17	21	8	
Supplements pending MDUFA III Decision	0	0	0	3	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	0%	

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	21	11	
Number with MDUFA decision	16	17	21	8	
Number of Not Approvable	0	0	0	2	
Rate of Not Approvable	0%	0%	0%	25%	

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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	11	4	
Non-MDUFA III Decisions	2	0	0	0	
MDUFA III Decisions	17	2	11	3	
MDUFA III Decisions Goal Met	17	2	11	3	
Supplements pending MDUFA III Decision	0	0	0	1	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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	11	4	
Number with MDUFA decision	17	2	11	3	
Number of Not Approvable	1	0	0	0	
Rate of Not Approvable	5.9%	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	7	3	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	13	11	7	3	
MDUFA III Decisions Goal Met	11	11	7	3	
Supplements pending MDUFA III Decision	0	0	0	0	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	84.6%	100%	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	7	3	
Number with MDUFA decision	13	11	7	3	
Number of Not Approvable	3	0	2	0	
Rate of Not Approvable	23.1%	0%	28.6%	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	0	
Mean FDA days for submissions that missed goal	143	0	0	0	
Mean Industry days for submissions that missed goal	0	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	20	4	
Non-MDUFA III Decisions	0	2	0	0	
MDUFA III Decisions	6	17	20	3	
MDUFA III Decisions Goal Met	6	17	20	3	
Supplements pending MDUFA III Decision	0	0	0	1	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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	20	4	
Number with MDUFA decision	6	17	20	3	
Number of Not Approvable	0	0	4	0	
Rate of Not Approvable	0%	0%	20%	0%	

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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	4	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	12	10	4	0	
MDUFA III Decisions Goal Met	12	10	4	0	
Supplements pending MDUFA III Decision	0	0	0	0	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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	4	0	
Number with MDUFA decision	12	10	4	0	
Number of Not Approvable	2	0	0	0	
Rate of Not Approvable	16.7%	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	0	0	0	

Table 3.1.DMD - 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	13	12	13	6	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	13	12	13	5	
MDUFA III Decisions Goal Met	13	12	13	5	
Supplements pending MDUFA III Decision	0	0	0	1	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	100%	

Table 3.2.DMD - 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	13	12	13	6	
Number with MDUFA decision	13	12	13	5	
Number of Not Approvable	3	0	0	1	
Rate of Not Approvable	23.1%	0%	0%	20%	

Table 3.3.DMD - 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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	12	3	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	7	13	12	1	
MDUFA III Decisions Goal Met	7	13	12	1	
Supplements pending MDUFA III Decision	0	0	0	2	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	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	12	3	
Number with MDUFA decision	7	13	12	1	
Number of Not Approvable	0	0	2	0	
Rate of Not Approvable	0%	0%	16.7%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	3	0	
Non-MDUFA III Decisions	0	0	1	0	
MDUFA III Decisions	0	2	2	0	
MDUFA III Decisions Goal Met	0	2	2	0	
Supplements pending MDUFA III Decision	0	0	0	0	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	100%	100%	N/A	

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	3	0	
Number with MDUFA decision	0	2	2	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	N/A	0%	0%	N/A	

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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	0	0	0	

Page intentionally left blank

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2015 and March 31, 2016.

Page intentionally left blank

Section 5 PMA Annual Metrics and Goals

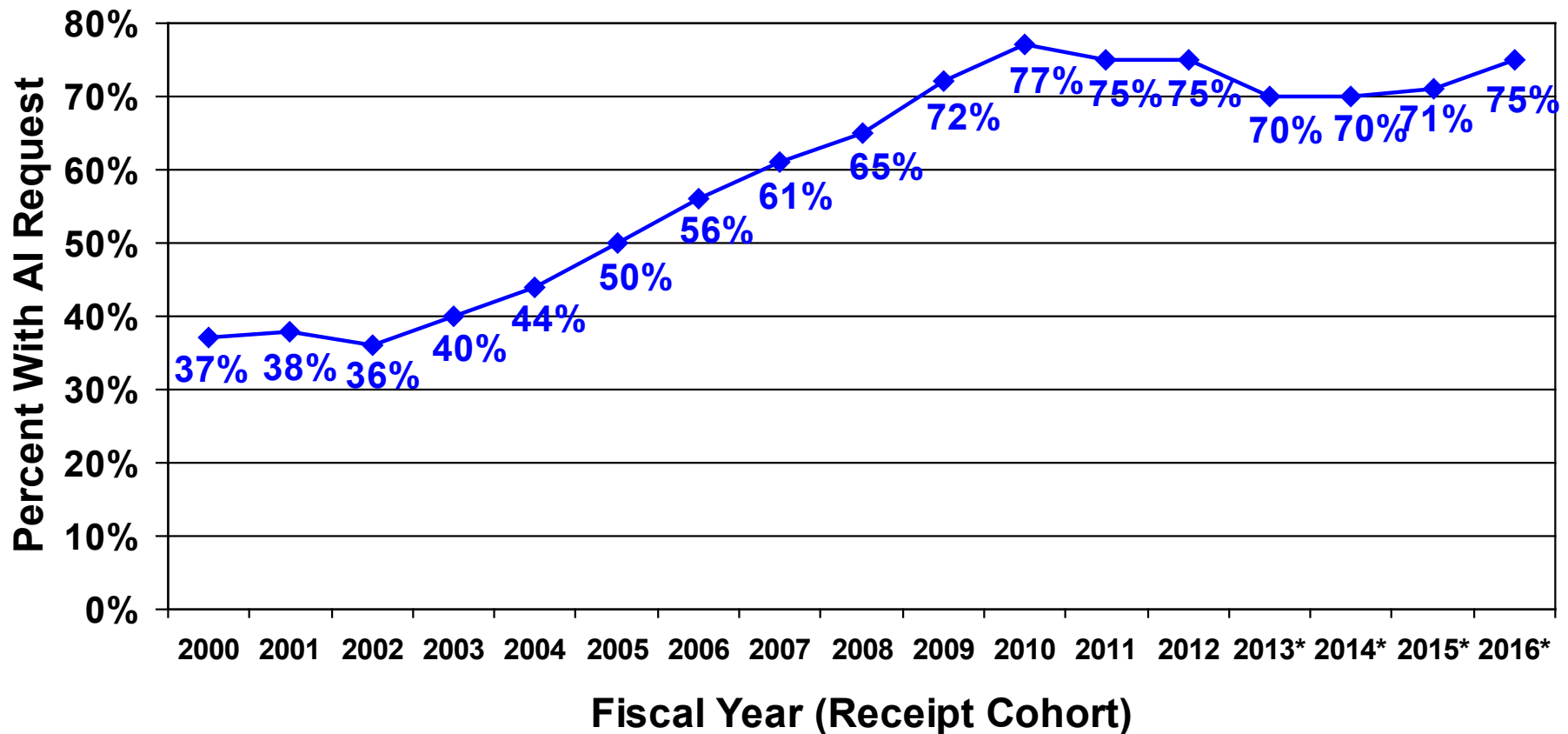
PMA Annual Metrics and Goals will be reported in the Annual Report.

Page intentionally left blank

510(k)s

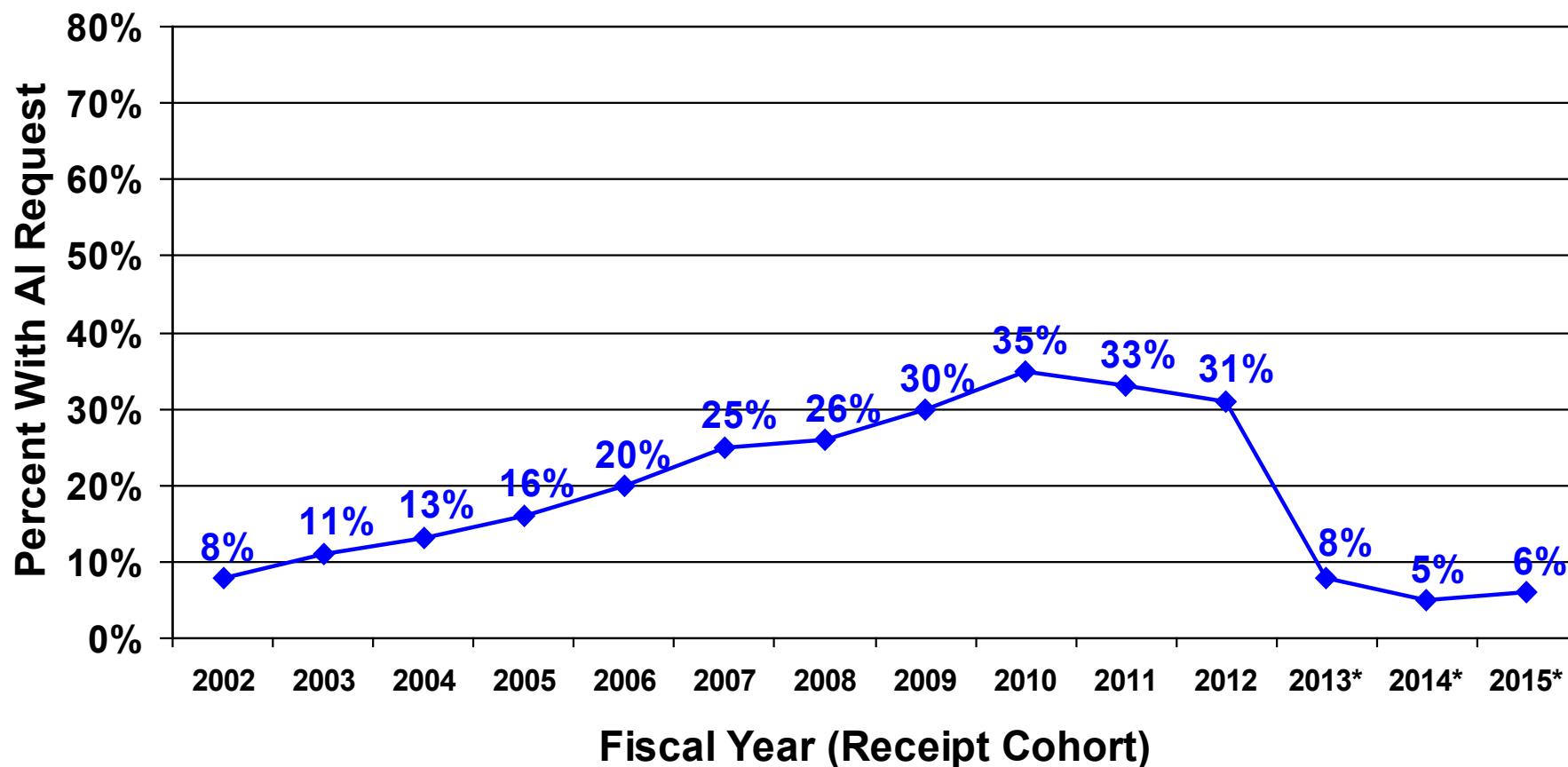
Q2FY16

Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



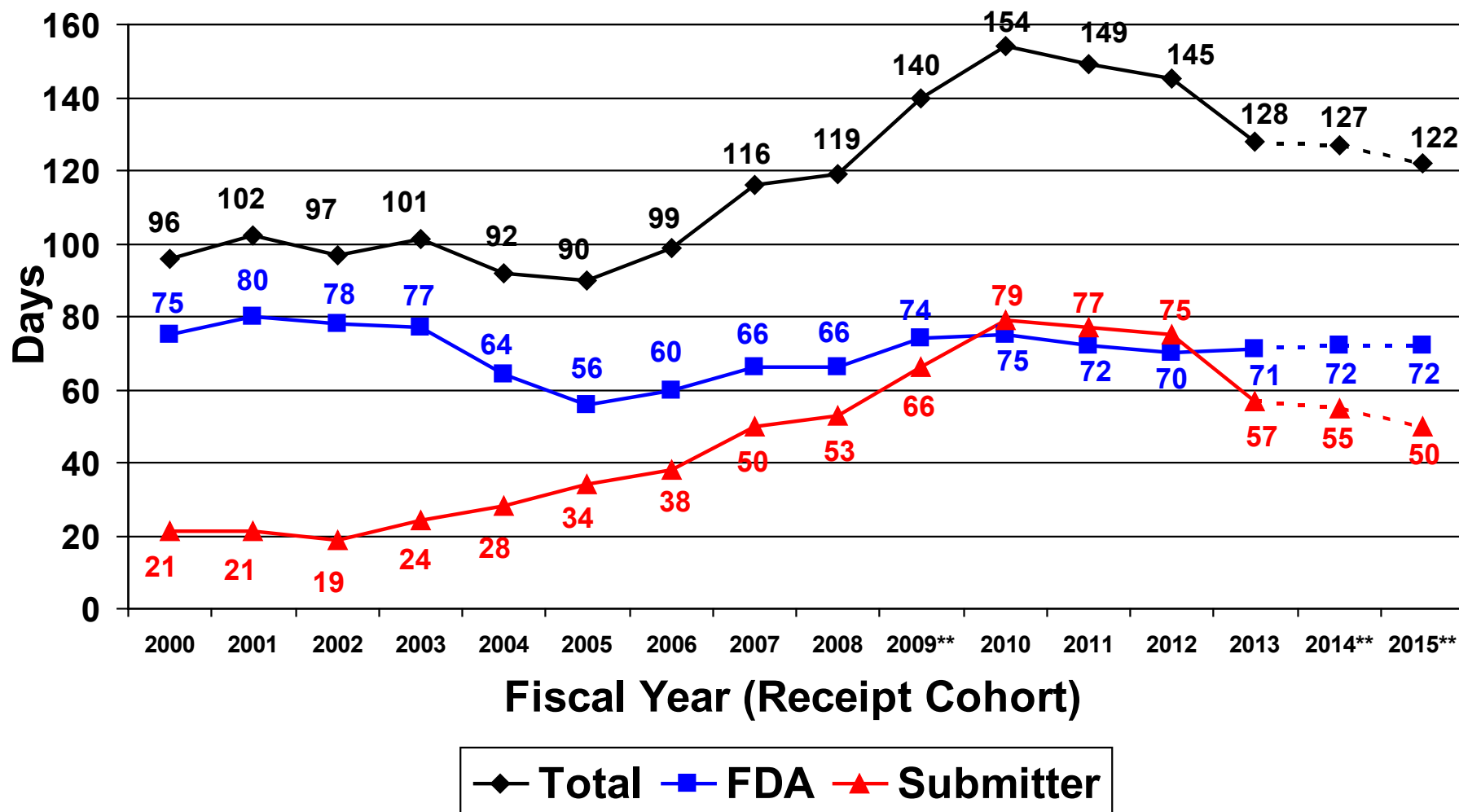
*FY 2013 - FY 2016 data are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for submissions accepted as of 12/31/2015

Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



*FY 2013 – FY 2015 data are for 510(k)s accepted as of 8/31/2015;
FY 2015 2nd cycle cohort is still open as of 3/31/2016 and data may change

Average Time to Decision: 510(k)s* (Receipt Cohorts as of March 31, 2016)

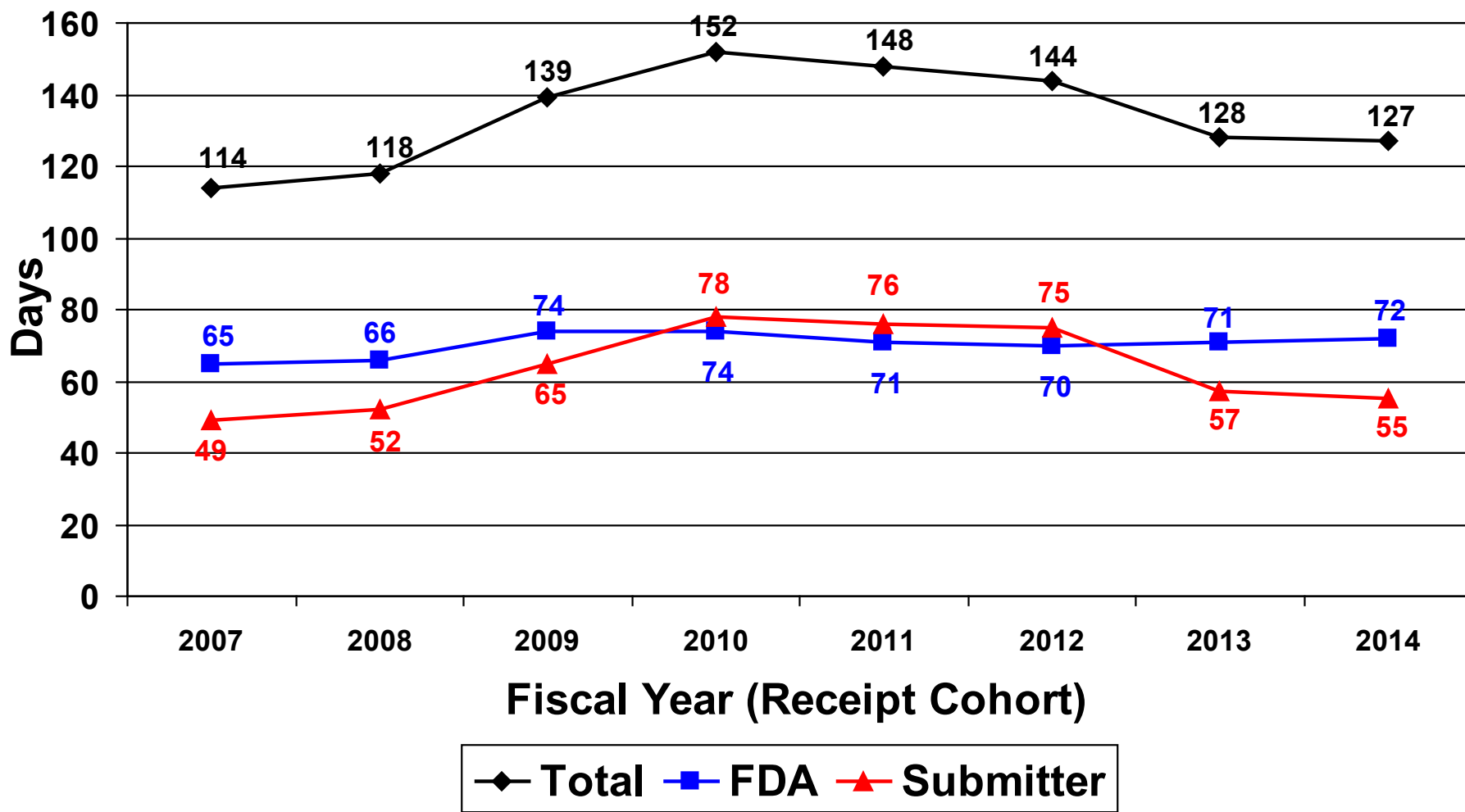


*SE and NSE decisions only; times may not add to total due to rounding

**Cohorts still open; percentage of cohort closed: FY 2009 = 99.9%, FY 2014 = 99.8%, and FY 2015 = 87.9% —average times for FY 2014 and FY 2015 will increase

Average Time to Decision: 510(k)s*

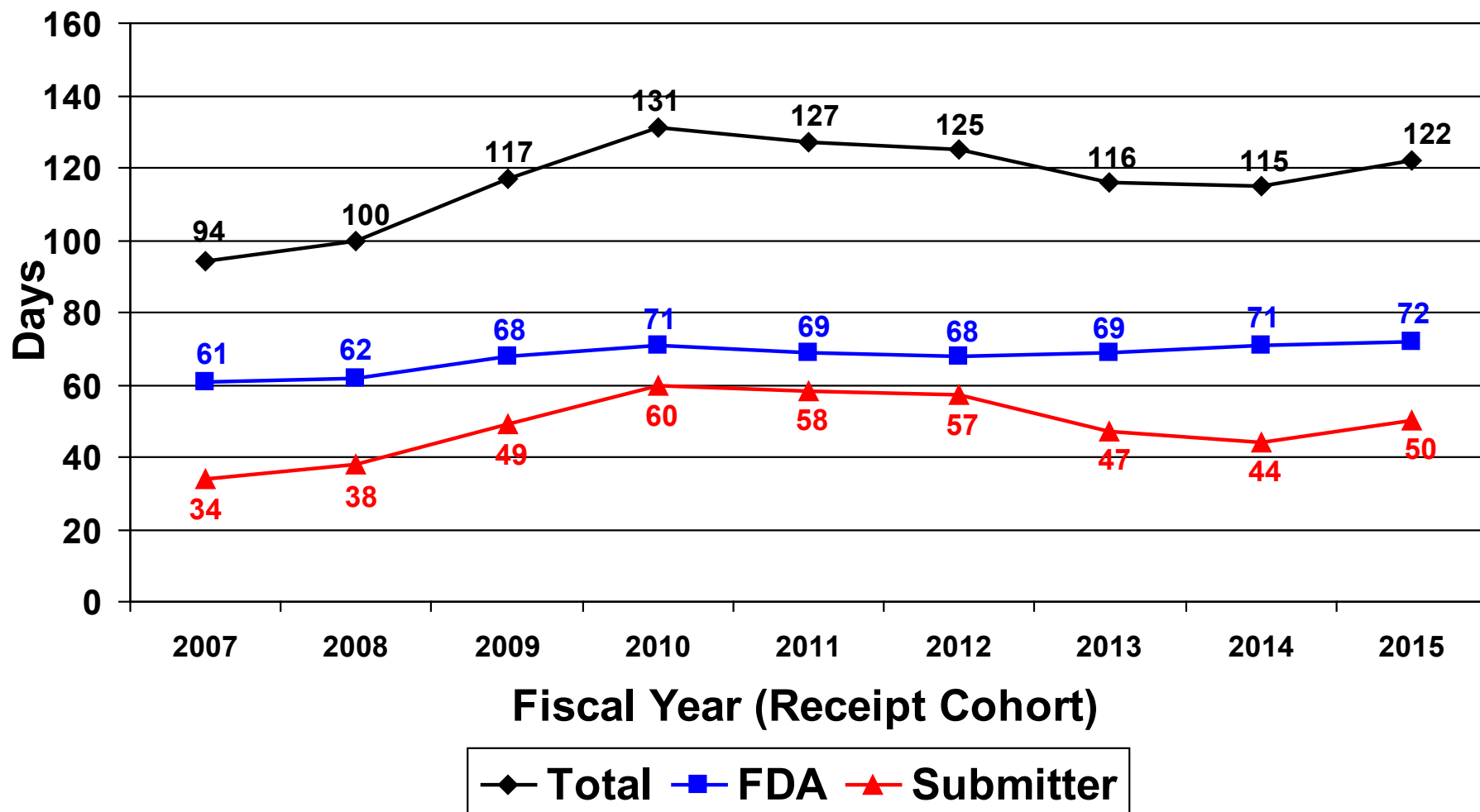
- Comparison of Receipt Cohorts When 99.8% Closed -



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

Average Time to Decision: 510(k)s*

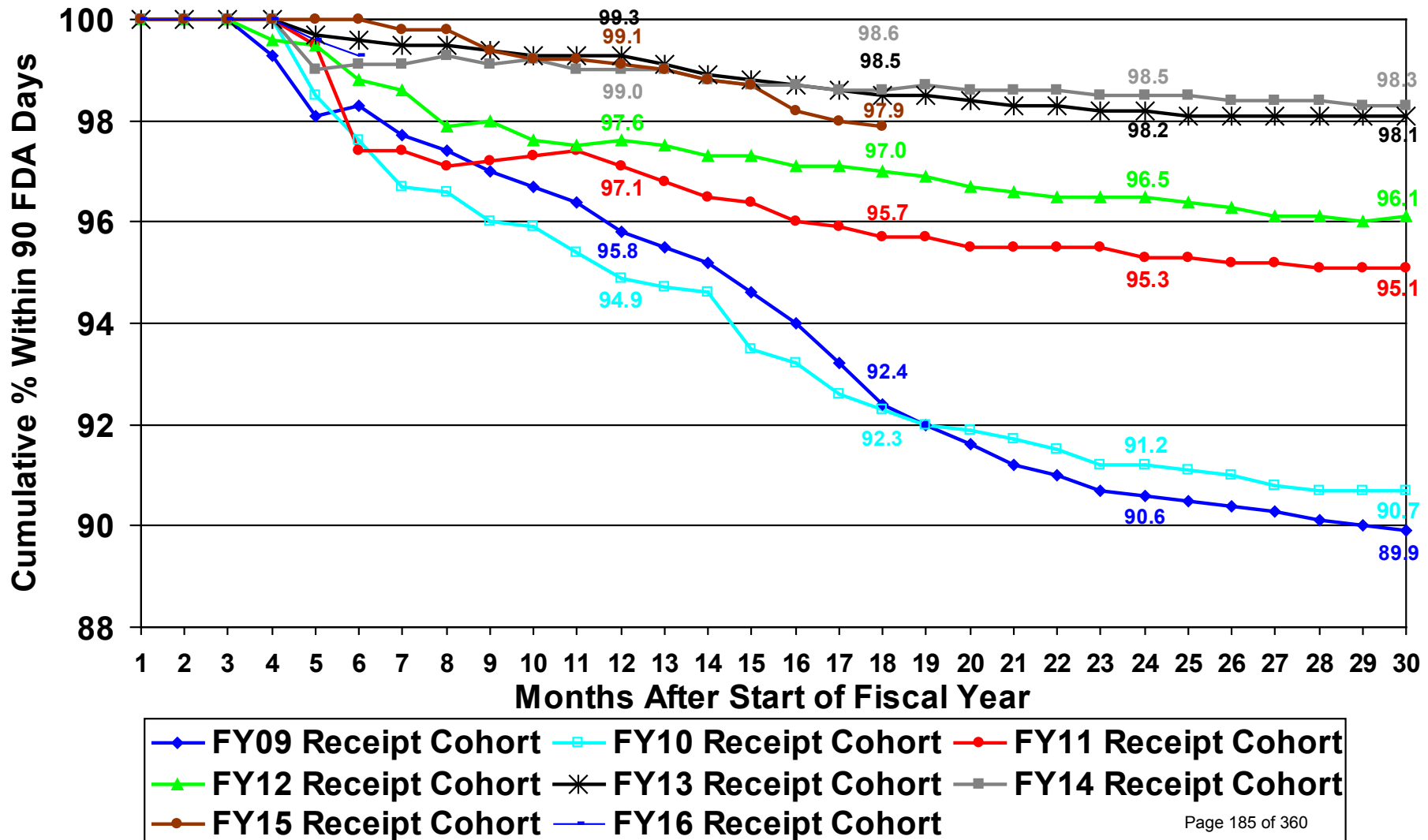
- Comparison of Receipt Cohorts When 87.9% Closed -



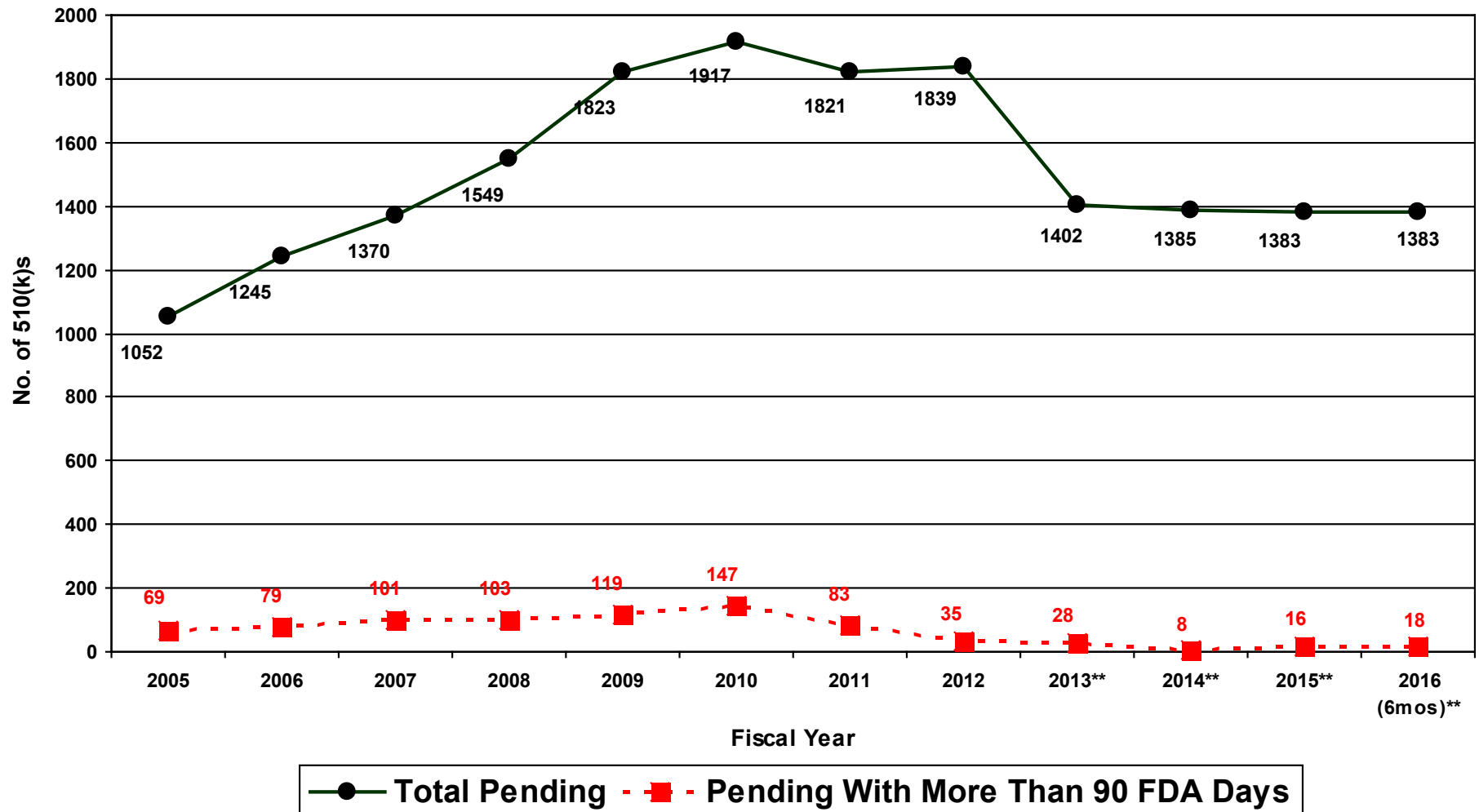
*SE and NSE decisions only; times may not add to total due to rounding

Trend in 510(k) MDUFA Decision Goal Performance

- Comparison of FY09 - FY16 Receipt Cohorts -



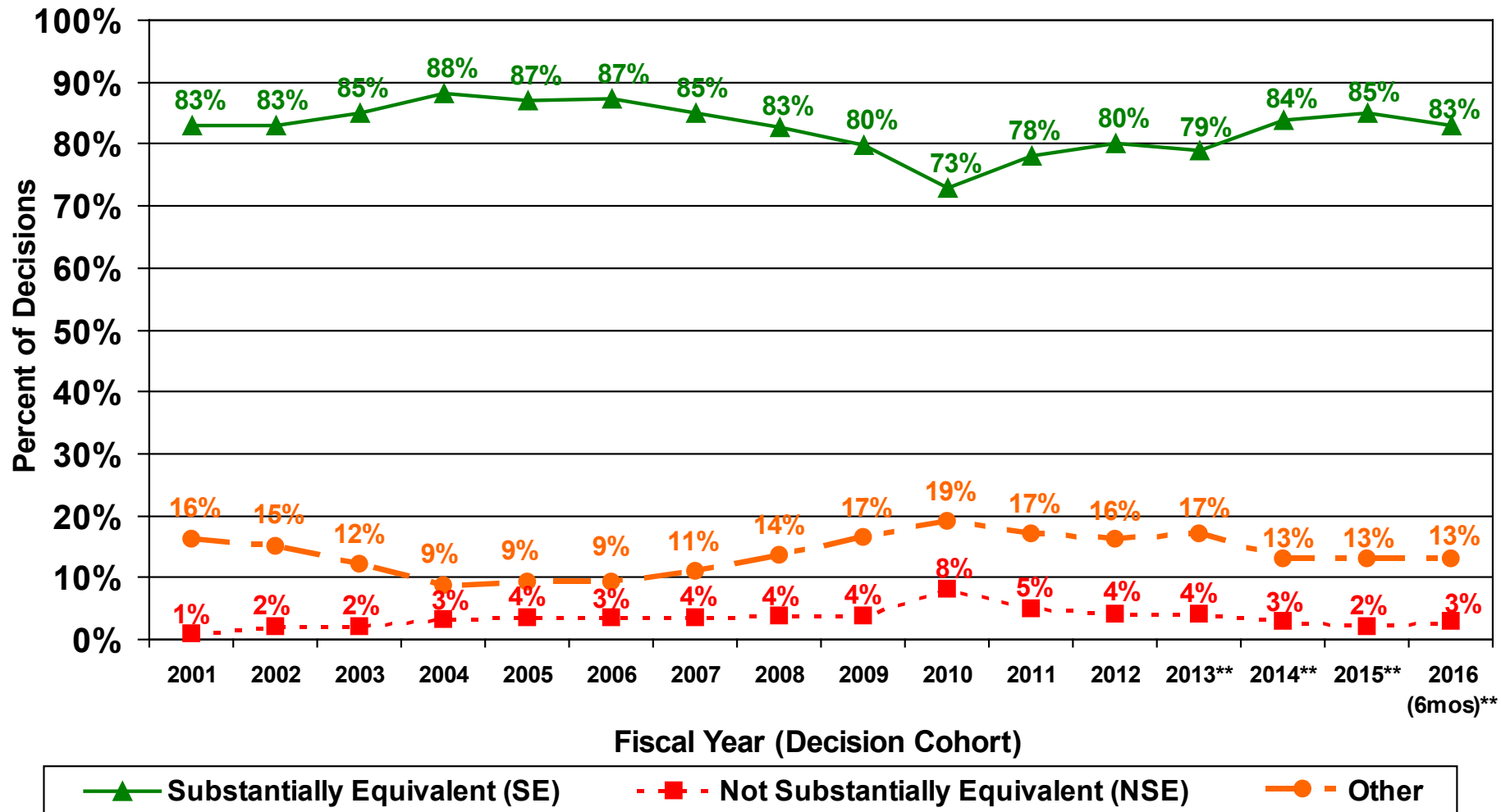
510(k)s Pending* at End of Year



*Under review or on hold

**Excludes FY 2013 - FY 2016 receipts that were not accepted for review as of end of year

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



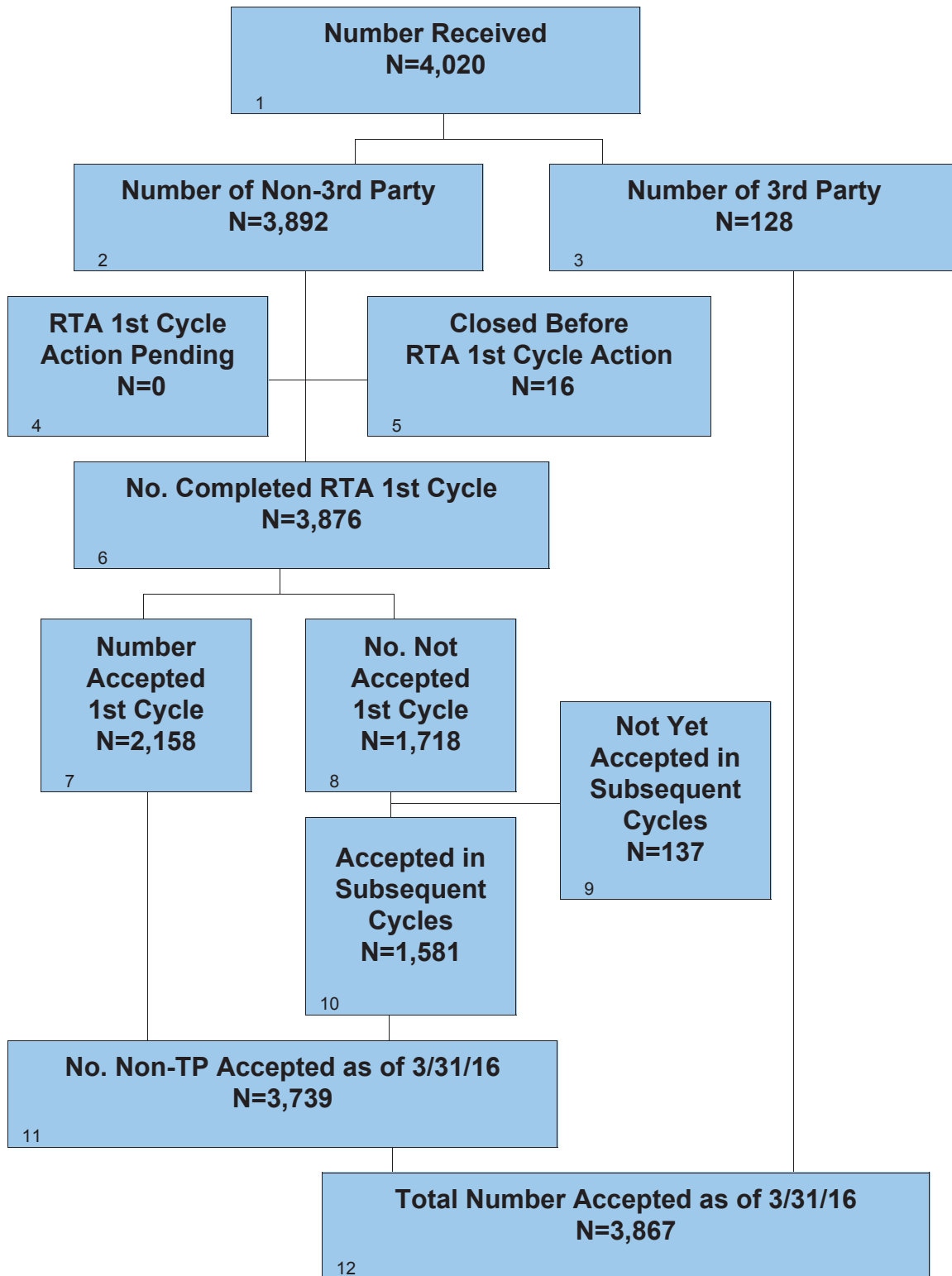
*Percentages may not add to 100% due to rounding

**Excludes final decisions made on FY 2013 - FY 2016 receipts that were not accepted for review as of 3/31/2016

Page intentionally left blank

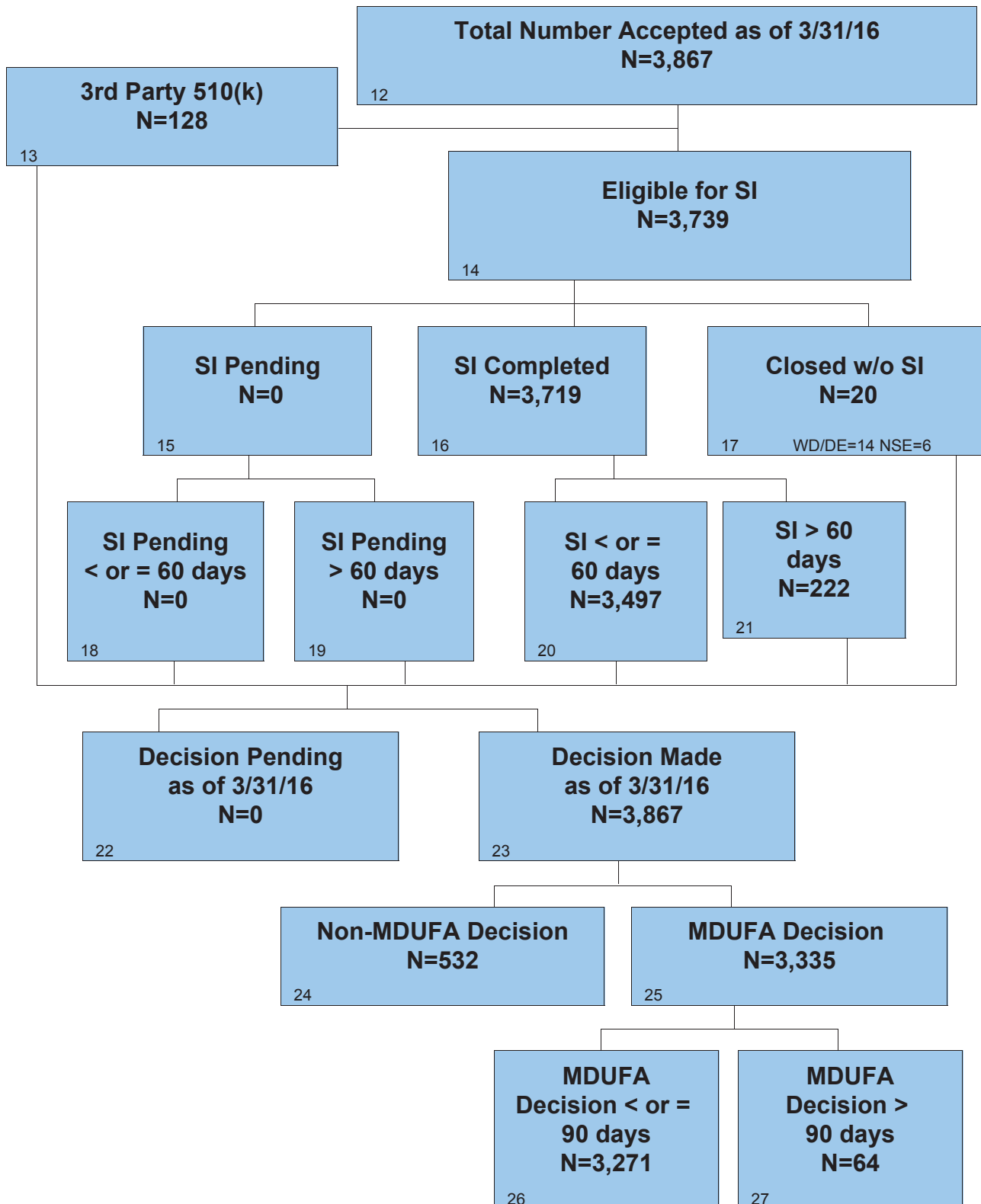
CDRH 510(k)s - FY 2013

As of 3/31/16



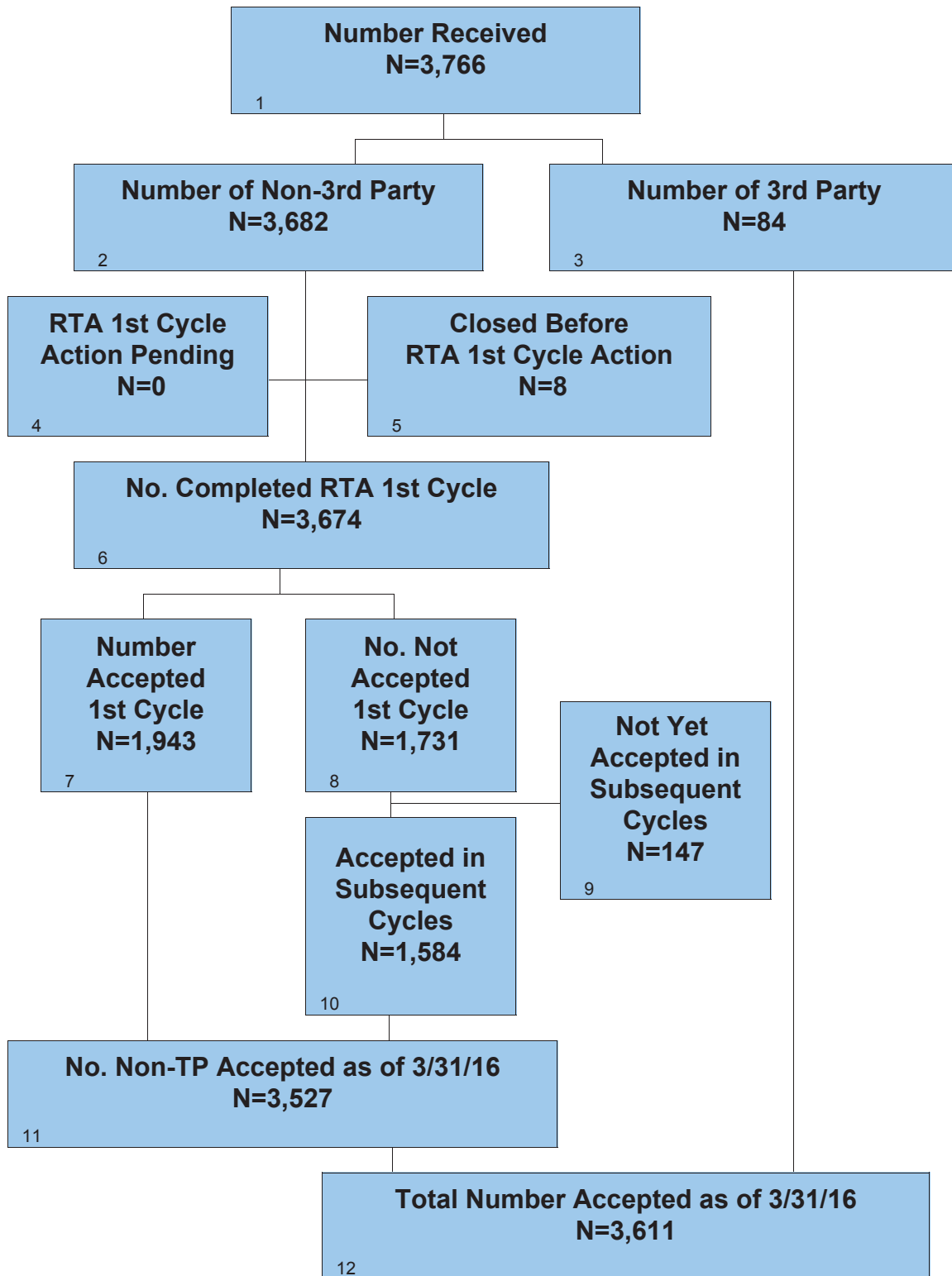
CDRH 510(k)s - FY 2013

As of 3/31/16 Conhbi YX



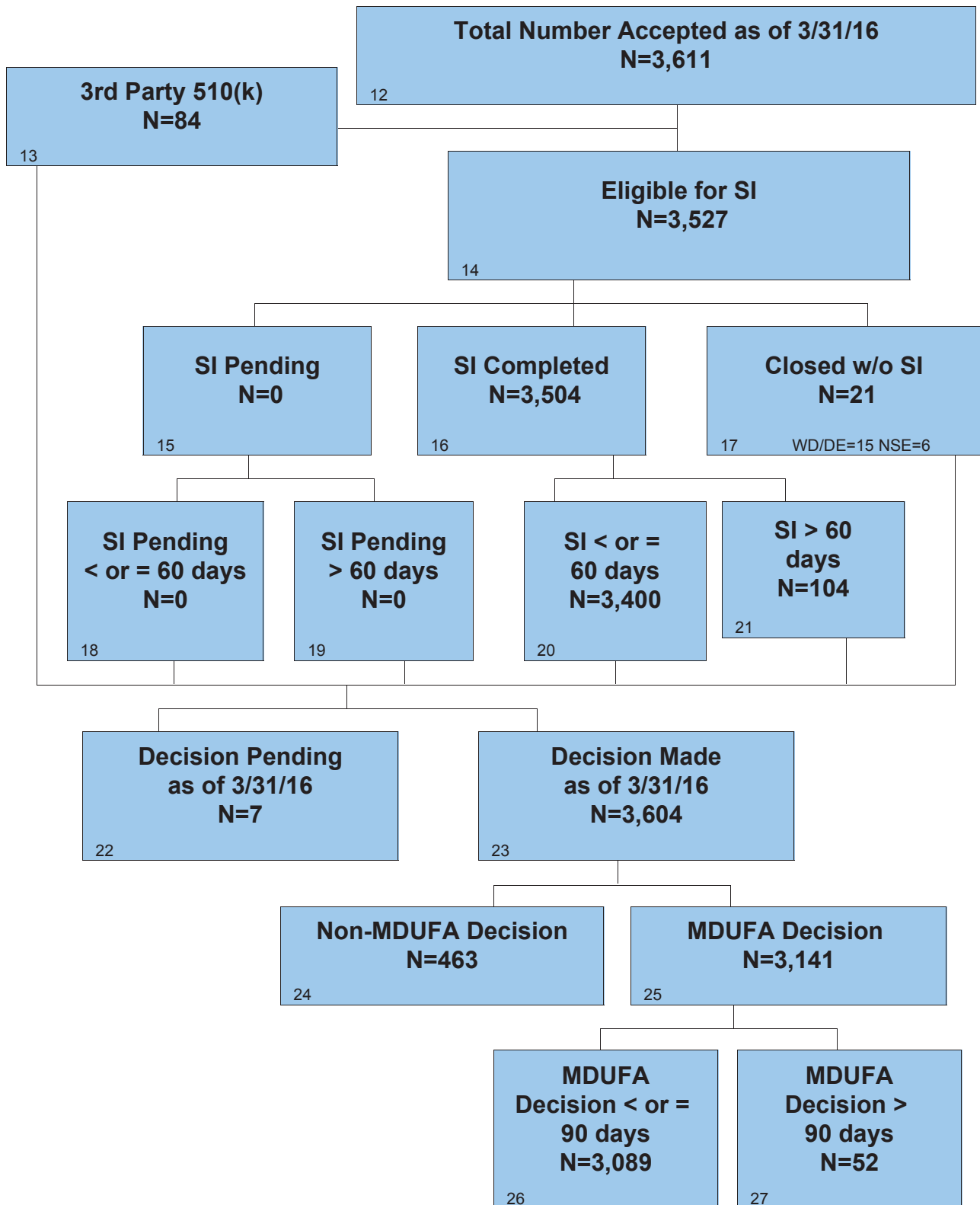
CDRH 510(k)s - FY 2014

As of 3/31/16



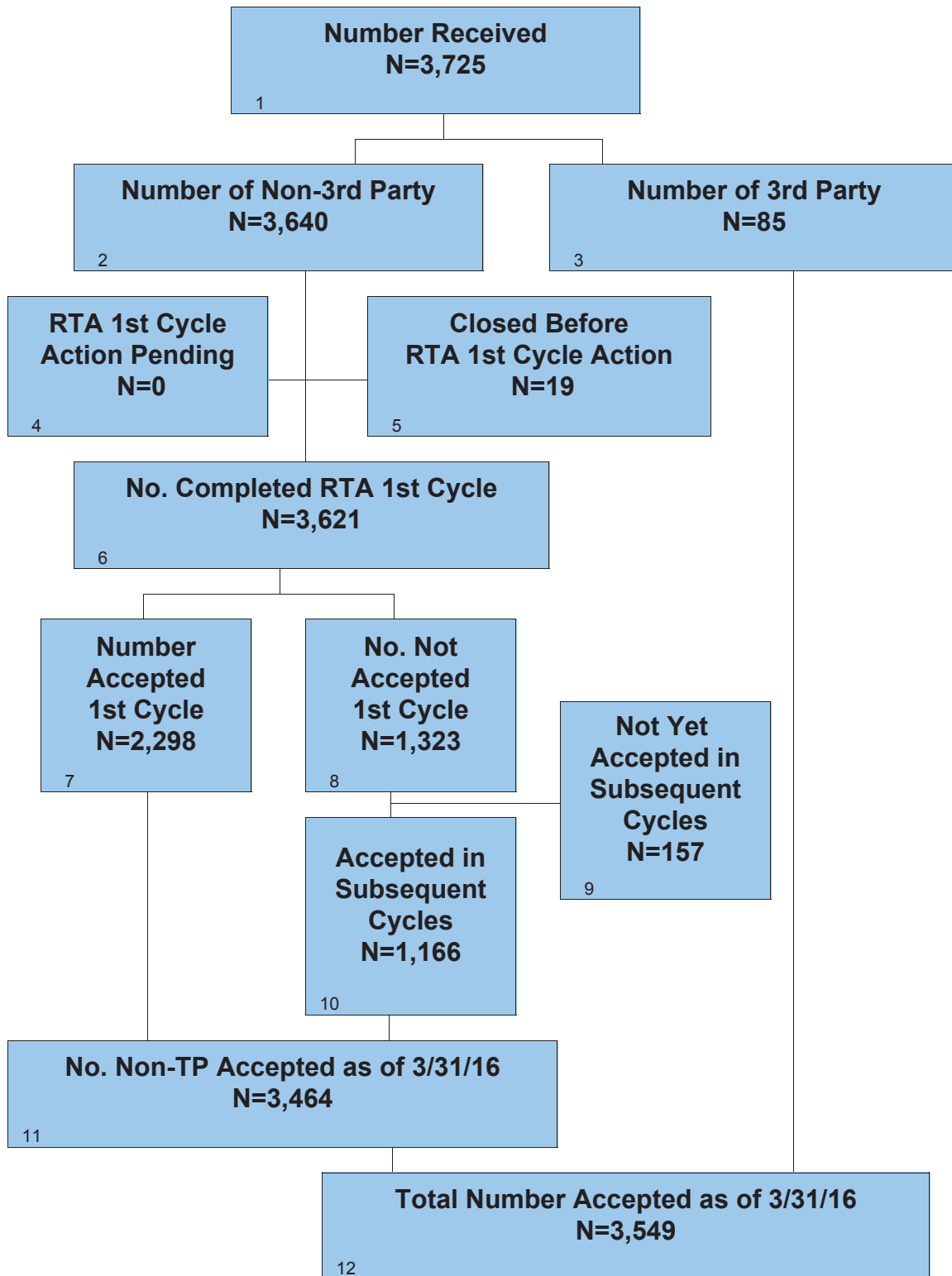
CDRH 510(k)s - FY 2014

As of 3/31/16 Continued



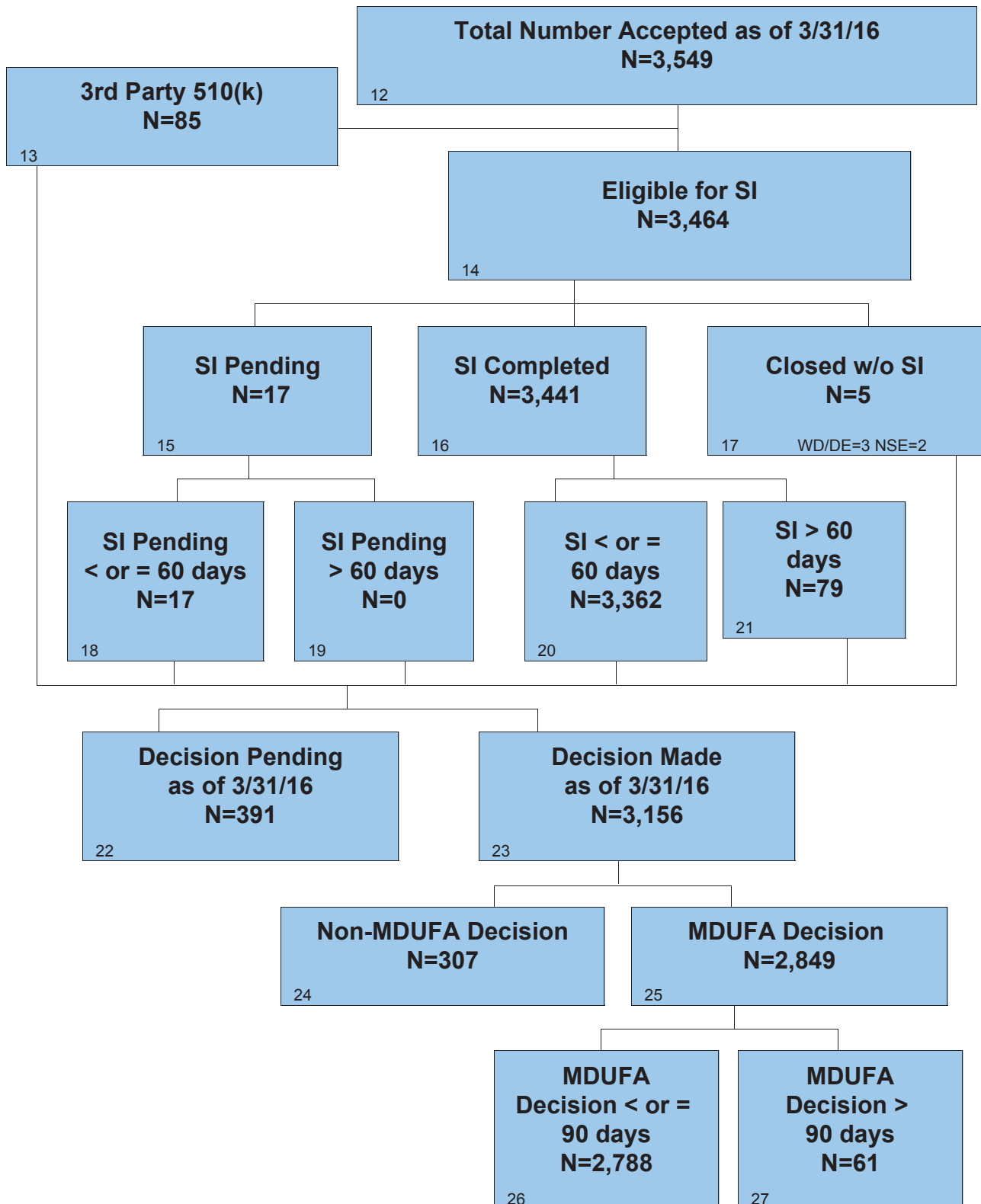
CDRH 510(k)s - FY 2015

As of 3/31/16



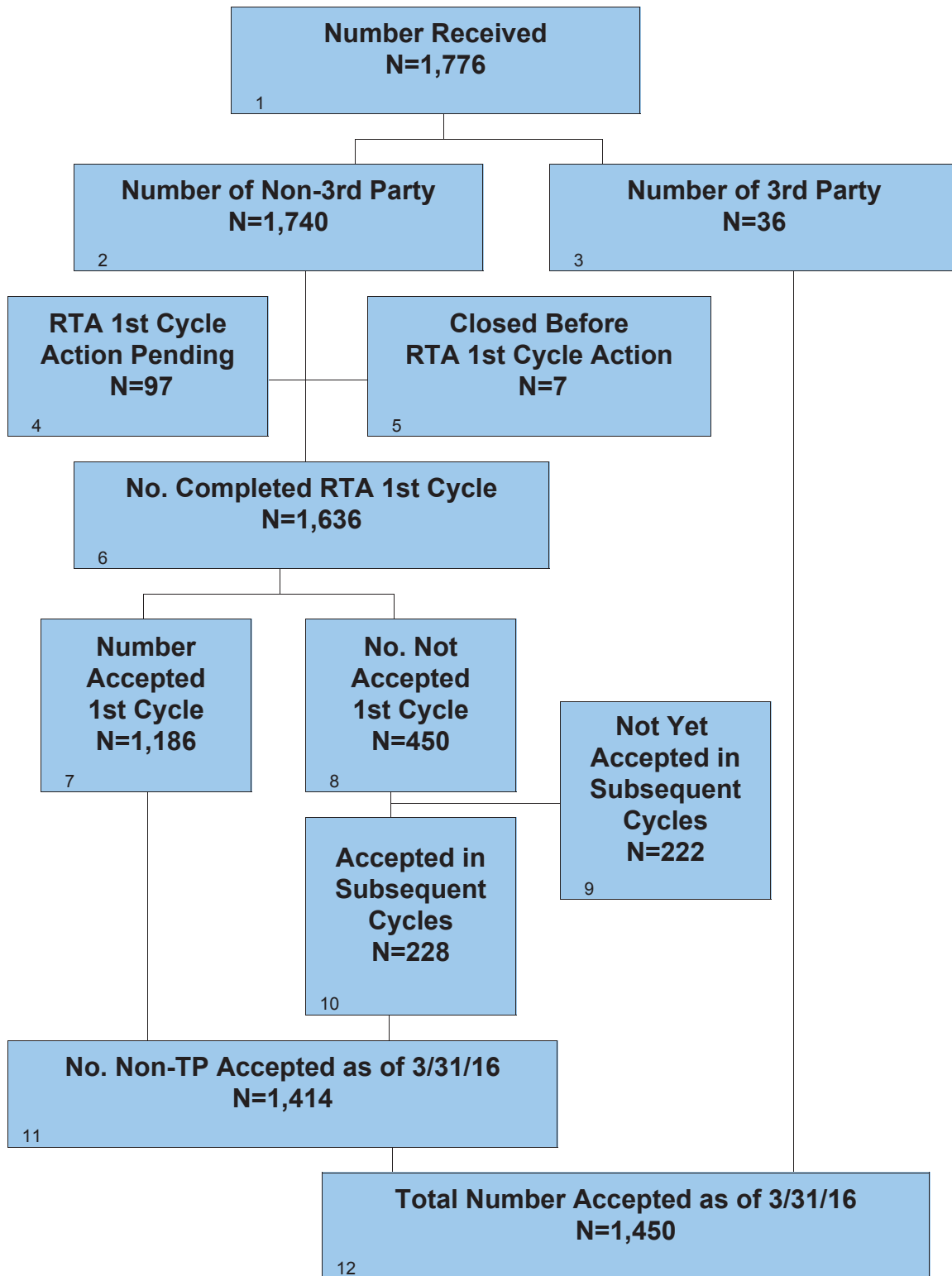
CDRH 510(k)s - FY 2015

As of 3/31/16 Conhbi YX



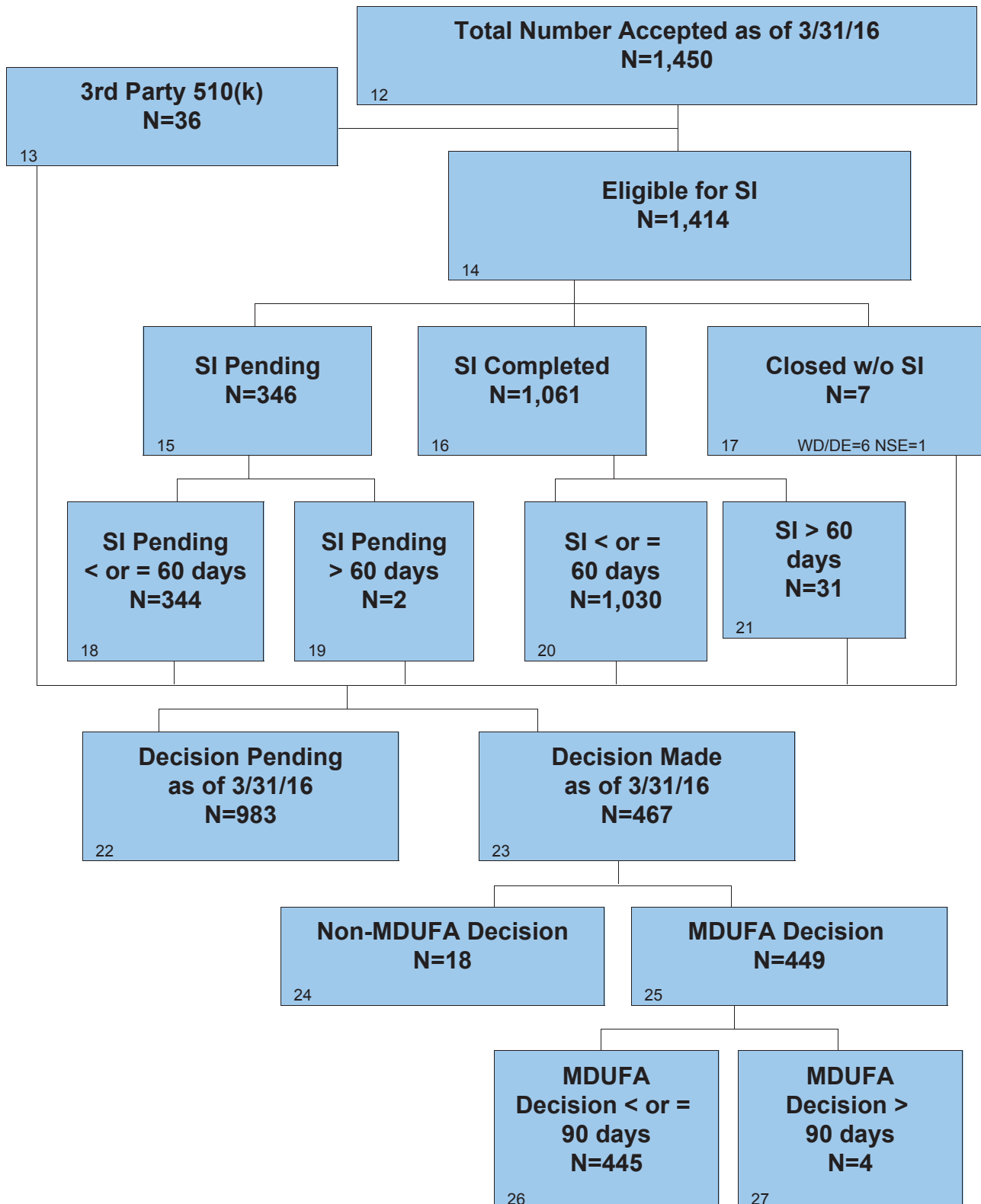
CDRH 510(k)s - FY 2016

As of 3/31/16



CDRH 510(k)s - FY 2016

As of 3/31/16 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	3,682	3,640	1,740	
Closed before RTA action	11	8	19	7	
Number Accepted	1,197	1,886	2,272	1,169	
Number without a RTA Review and > 15 Days since Date Received	42	57	26	17	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	97	
Number Not Accepted	1,715	1,731	1,323	450	
Rate of submissions not accepted for filing review	58.1%	47.1%	36.5%	27.5%	

* 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 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	3,527	3,464	1,414	
Deleted or withdrawn prior to SI	14	15	3	6	
SI within 60 FDA days	3,497	3,400	3,362	1,030	
SI over 60 FDA days	222	104	79	31	
SI pending within 60 FDA days	0	0	17	344	
SI pending over 60 FDA days	0	0	0	2	
510(k)s NSE without SI	6	6	2	1	
Current SI Performance Percent within 60 FDA days	93.9%	96.9%	97.6%	96.8%	

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	3,504	3,441	1,061	
Average number of FDA days to Substantive Interaction	47.64	49.44	49.92	48.52	
20th Percentile FDA days to Substantive Interaction	30	33	38	30	
40th Percentile FDA days to Substantive Interaction	48	52	53	51	
60th Percentile FDA days to Substantive Interaction	56	57	57	57	
80th Percentile FDA days to Substantive Interaction	59	59	59	59	
Maximum FDA days to Substantive Interaction	98	188	140	88	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	3,867	3,611	3,549	1,450	
Non-MDUFA III Decisions	532	463	307	18	
MDUFA III Decisions (SE/NSE)	3,335	3,141	2,849	449	
MDUFA III Decisions within 90 FDA Days	3,271	3,089	2,788	445	
510(k)s pending MDUFA III Decision	0	7	391	983	
510(k) pending MDUFA III Decision over 90 FDA days	0	1	14	3	
Current Performance Percent within 90 FDA Days	98.1%	98.3%	97.4%	98%	

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	1.74	1.72	1.69	1.42	
Number with MDUFA III decision	3,335	3,141	2,849	449	
Average FDA days to MDUFA III decision	70.76	72.08	71.62	54.83	
20th Percentile FDA days to MDUFA III decision	48	51	51	28	
40th Percentile FDA days to MDUFA III decision	76	80	79	46	
60th Percentile FDA days to MDUFA III decision	86	87	87	59	
80th Percentile FDA days to MDUFA III decision	89	89	89	86	
Maximum FDA days to MDUFA III decision	342	245	246	100	
Average Industry days to MDUFA III decision	57.17	55.43	50	11.47	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	14	14	11	0	
60th Percentile Industry days to MDUFA III decision	44	45	40	2	
80th Percentile Industry days to MDUFA III decision	116	115	105	21	
Maximum Industry days to MDUFA III decision	467	469	366	90	
Average Total days to MDUFA III decision	127.93	127.51	121.62	66.31	
20th Percentile Total days to MDUFA III decision	56	58	55	28	
40th Percentile Total days to MDUFA III decision	90	90	90	54	
60th Percentile Total days to MDUFA III decision	127	128	124	77	
80th Percentile Total days to MDUFA III decision	199	202	190	101	
Maximum Total days to MDUFA III decision	691	556	477	172	

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	3867	3611	3549	1450	
Number with MDUFA decision	3,335	3,141	2,849	449	
Number of SE decisions	3,202	3,055	2,778	444	
Number of NSE decisions	133	86	71	5	
Number of Withdrawals	231	213	165	16	
Number deleted	279	217	133	0	
Rate of SE decisions	96%	97.3%	97.5%	98.9%	
Rate of NSE decisions	4.0%	2.7%	2.5%	1.1%	
Rate of Withdrawals	6.0%	5.9%	4.6%	1.1%	
Rate of Deleted	7.2%	6%	3.7%	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	52	61	4	
Mean FDA days for submissions that missed goal	119	107	108	96	
Mean industry days for submissions that missed goal	138	126	107	30	

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	2,956	2,986	1,413	
Closed before RTA action	9	6	17	6	
Number Accepted	821	1,339	1,730	900	
Number without a RTA Review and > 15 Days since Date Received	24	50	23	15	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	80	
Number Not Accepted	1,535	1,561	1,216	412	
Rate of submissions not accepted for filing review	64.5%	52.9%	41%	31%	

* 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	2,830	2,832	1,123	
Deleted or withdrawn prior to SI	13	15	2	3	
SI within 60 FDA days	2,778	2,718	2,736	802	
SI over 60 FDA days	179	89	75	31	
SI pending within 60 FDA days	0	0	16	284	
SI pending over 60 FDA days	0	0	0	2	
510(k)s NSE without SI	6	6	2	1	
Current SI Performance Percent within 60 FDA days	93.8%	96.6%	97.3%	95.9%	

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	2,807	2,811	833	
Average number of FDA days to Substantive Interaction	48.32	50.38	50.95	49.89	
20th Percentile FDA days to Substantive Interaction	30	38	43	30	
40th Percentile FDA days to Substantive Interaction	49	54	54	53	
60th Percentile FDA days to Substantive Interaction	57	58	58	57	
80th Percentile FDA days to Substantive Interaction	59	60	60	60	
Maximum FDA days to Substantive Interaction	98	188	140	88	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	3,050	2,877	2,885	1,137	
Non-MDUFA III Decisions	446	390	260	14	
MDUFA III Decisions (SE/NSE)	2,604	2,481	2,287	335	
MDUFA III Decisions within 90 FDA Days	2,547	2,444	2,227	331	
510(k)s pending MDUFA III Decision	0	6	336	788	
510(k) pending MDUFA III Decision over 90 FDA days	0	1	13	3	
Current Performance Percent within 90 FDA Days	97.8%	98.5%	96.8%	97.9%	

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	1.76	1.72	1.70	1.43	
Number with MDUFA III decision	2,604	2,481	2,287	335	
Average FDA days to MDUFA III decision	72.79	73.79	74.10	57.99	
20th Percentile FDA days to MDUFA III decision	53	55	55	29	
40th Percentile FDA days to MDUFA III decision	80	83	83	52	
60th Percentile FDA days to MDUFA III decision	87	87	88	63	
80th Percentile FDA days to MDUFA III decision	89	89	89	87	
Maximum FDA days to MDUFA III decision	342	245	246	100	
Average Industry days to MDUFA III decision	57.32	55.77	51	11.40	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	17	16	14	0	
60th Percentile Industry days to MDUFA III decision	46	47	42	5	
80th Percentile Industry days to MDUFA III decision	116	117	107	21	
Maximum Industry days to MDUFA III decision	438	408	366	90	
Average Total days to MDUFA III decision	130.11	129.56	125.10	69.39	
20th Percentile Total days to MDUFA III decision	59	61	59	29	
40th Percentile Total days to MDUFA III decision	94	94	94	57	
60th Percentile Total days to MDUFA III decision	129	131	127	83	
80th Percentile Total days to MDUFA III decision	200	203	193	103	
Maximum Total days to MDUFA III decision	691	512	477	172	

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	3050	2877	2885	1137	
Number with MDUFA decision	2,604	2,481	2,287	335	
Number of SE decisions	2,493	2,414	2,234	331	
Number of NSE decisions	111	67	53	4	
Number of Withdrawals	189	177	138	12	
Number deleted	237	181	113	0	
Rate of SE decisions	95.7%	97.3%	97.7%	98.8%	
Rate of NSE decisions	4.3%	2.7%	2.3%	1.2%	
Rate of Withdrawals	6.2%	6.2%	4.8%	1.1%	
Rate of Deleted	7.8%	6.3%	3.9%	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	37	60	4	
Mean FDA days for submissions that missed goal	121	109	108	96	
Mean industry days for submissions that missed goal	137	150	108	30	

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	654	327	
Closed before RTA action	2	2	2	1	
Number Accepted	376	547	542	269	
Number without a RTA Review and > 15 Days since Date Received	18	7	3	2	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	17	
Number Not Accepted	180	170	107	38	
Rate of submissions not accepted for filing review	31.4%	23.5%	16.4%	12.3%	

* 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	697	632	291	
Deleted or withdrawn prior to SI	1	0	1	3	
SI within 60 FDA days	719	682	626	228	
SI over 60 FDA days	43	15	4	0	
SI pending within 60 FDA days	0	0	1	60	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	94.4%	97.8%	99.4%	100%	

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	697	630	228	
Average number of FDA days to Substantive Interaction	45.02	45.66	45.30	43.55	
20th Percentile FDA days to Substantive Interaction	29	30	29	28	
40th Percentile FDA days to Substantive Interaction	43	45	45	44	
60th Percentile FDA days to Substantive Interaction	51	53	53	52	
80th Percentile FDA days to Substantive Interaction	58	58	58	58	
Maximum FDA days to Substantive Interaction	91	93	70	60	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	817	734	664	313	
Non-MDUFA III Decisions	86	73	47	4	
MDUFA III Decisions (SE/NSE)	731	660	562	114	
MDUFA III Decisions within 90 FDA Days	724	645	561	114	
510(k)s pending MDUFA III Decision	0	1	55	195	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1	0	
Current Performance Percent within 90 FDA Days	99%	97.7%	99.6%	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	1.69	1.71	1.62	1.39	
Number with MDUFA III decision	731	660	562	114	
Average FDA days to MDUFA III decision	63.51	65.64	61.54	45.54	
20th Percentile FDA days to MDUFA III decision	34	33	30	25	
40th Percentile FDA days to MDUFA III decision	58	60	58	29	
60th Percentile FDA days to MDUFA III decision	81	84	76	50	
80th Percentile FDA days to MDUFA III decision	88	88	87	77	
Maximum FDA days to MDUFA III decision	121	137	91	90	
Average Industry days to MDUFA III decision	56.66	54.17	45.94	11.70	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	36	38	31	0	
80th Percentile Industry days to MDUFA III decision	112	106	97	27	
Maximum Industry days to MDUFA III decision	467	469	359	88	
Average Total days to MDUFA III decision	120.17	119.80	107.48	57.25	
20th Percentile Total days to MDUFA III decision	36	35	30	25	
40th Percentile Total days to MDUFA III decision	77	85	68	30	
60th Percentile Total days to MDUFA III decision	111	113	103	60	
80th Percentile Total days to MDUFA III decision	194	189	178	87	
Maximum Total days to MDUFA III decision	557	556	449	166	

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	734	664	313	
Number with MDUFA decision	731	660	562	114	
Number of SE decisions	709	641	544	113	
Number of NSE decisions	22	19	18	1	
Number of Withdrawals	42	36	27	4	
Number deleted	42	36	20	0	
Rate of SE decisions	97%	97.1%	96.8%	99.1%	
Rate of NSE decisions	3%	2.9%	3.2%	0.9%	
Rate of Withdrawals	5.1%	4.9%	4.1%	1.3%	
Rate of Deleted	5.1%	4.9%	3%	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	15	1	0	
Mean FDA days for submissions that missed goal	103	100	91	0	
Mean industry days for submissions that missed goal	143	67	13	0	

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	776	396	
Closed before RTA action	6	1	3	2	
Number Accepted	189	317	375	175	
Number without a RTA Review and > 15 Days since Date Received	5	14	6	4	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	24	
Number Not Accepted	437	443	392	191	
Rate of submissions not accepted for filing review	69.3%	57.2%	50.7%	51.6%	

* 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.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	724	706	261	
Deleted or withdrawn prior to SI	3	7	0	1	
SI within 60 FDA days	749	710	683	172	
SI over 60 FDA days	26	3	11	7	
SI pending within 60 FDA days	0	0	9	80	
SI pending over 60 FDA days	0	0	0	1	
510(k)s NSE without SI	4	3	2	0	
Current SI Performance Percent within 60 FDA days	96.1%	99.2%	98.1%	95.6%	

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	713	694	179	
Average number of FDA days to Substantive Interaction	50.89	53.44	54.43	53.73	
20th Percentile FDA days to Substantive Interaction	43	50	52	50	
40th Percentile FDA days to Substantive Interaction	55	57	57	57	
60th Percentile FDA days to Substantive Interaction	58	59	58	59	
80th Percentile FDA days to Substantive Interaction	60	60	60	60	
Maximum FDA days to Substantive Interaction	90	188	79	78	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	797	738	722	266	
Non-MDUFA III Decisions	165	117	68	4	
MDUFA III Decisions (SE/NSE)	632	618	522	42	
MDUFA III Decisions within 90 FDA Days	613	602	481	39	
510(k)s pending MDUFA III Decision	0	3	132	220	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	8	2	
Current Performance Percent within 90 FDA Days	97%	97.4%	90.8%	88.6%	

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	1.79	1.83	1.82	1.81	
Number with MDUFA III decision	632	618	522	42	
Average FDA days to MDUFA III decision	78.01	80.04	83.68	70.19	
20th Percentile FDA days to MDUFA III decision	63	78	85	43	
40th Percentile FDA days to MDUFA III decision	84	86	87	81	
60th Percentile FDA days to MDUFA III decision	88	88	89	88	
80th Percentile FDA days to MDUFA III decision	90	90	90	90	
Maximum FDA days to MDUFA III decision	280	107	246	100	
Average Industry days to MDUFA III decision	64.17	68.40	62.68	19.98	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	21	28	25	9	
60th Percentile Industry days to MDUFA III decision	54	69	64	19	
80th Percentile Industry days to MDUFA III decision	141	143	123	35	
Maximum Industry days to MDUFA III decision	420	357	366	90	
Average Total days to MDUFA III decision	142.18	148.44	146.35	90.17	
20th Percentile Total days to MDUFA III decision	78	87	90	57	
40th Percentile Total days to MDUFA III decision	102	114	111	88	
60th Percentile Total days to MDUFA III decision	140	156	151	99	
80th Percentile Total days to MDUFA III decision	220	231	212	118	
Maximum Total days to MDUFA III decision	610	446	477	172	

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	738	722	266	
Number with MDUFA decision	632	618	522	42	
Number of SE decisions	603	593	510	40	
Number of NSE decisions	29	25	12	2	
Number of Withdrawals	56	53	37	4	
Number deleted	104	53	26	0	
Rate of SE decisions	95.4%	96%	97.7%	95.2%	
Rate of NSE decisions	4.6%	4%	2.3%	4.8%	
Rate of Withdrawals	7%	7.2%	5.1%	1.5%	
Rate of Deleted	13%	7.2%	3.6%	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	16	41	3	
Mean FDA days for submissions that missed goal	125	98	105	94	
Mean industry days for submissions that missed goal	157	159	96	28	

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	408	406	219	
Closed before RTA action	0	1	2	3	
Number Accepted	151	196	278	147	
Number without a RTA Review and > 15 Days since Date Received	10	9	5	8	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	11	
Number Not Accepted	175	202	121	50	
Rate of submissions not accepted for filing review	52.1%	49.6%	30%	24.4%	

* 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.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	401	396	182	
Deleted or withdrawn prior to SI	2	2	1	0	
SI within 60 FDA days	392	380	379	129	
SI over 60 FDA days	38	19	15	9	
SI pending within 60 FDA days	0	0	1	44	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	91.2%	95.2%	96.2%	93.5%	

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	399	394	138	
Average number of FDA days to Substantive Interaction	45.52	46.49	47.31	49.22	
20th Percentile FDA days to Substantive Interaction	29	29	29	30	
40th Percentile FDA days to Substantive Interaction	43	46	49	51	
60th Percentile FDA days to Substantive Interaction	50	55	56	57	
80th Percentile FDA days to Substantive Interaction	58	59	59	60	
Maximum FDA days to Substantive Interaction	98	90	140	80	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	456	415	408	185	
Non-MDUFA III Decisions	29	42	27	3	
MDUFA III Decisions (SE/NSE)	427	373	353	60	
MDUFA III Decisions within 90 FDA Days	412	367	344	59	
510(k)s pending MDUFA III Decision	0	0	27	122	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1	1	
Current Performance Percent within 90 FDA Days	96.5%	98.4%	97.2%	96.7%	

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	1.72	1.66	1.67	1.50	
Number with MDUFA III decision	427	373	353	60	
Average FDA days to MDUFA III decision	67.24	68.49	67.56	56.82	
20th Percentile FDA days to MDUFA III decision	36	40	30	29	
40th Percentile FDA days to MDUFA III decision	59	60	60	50	
60th Percentile FDA days to MDUFA III decision	86	87	87	59	
80th Percentile FDA days to MDUFA III decision	89	89	89	87	
Maximum FDA days to MDUFA III decision	237	210	160	100	
Average Industry days to MDUFA III decision	47.54	48.56	41.25	14.57	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	11	10	11	0	
60th Percentile Industry days to MDUFA III decision	38	34	34	7	
80th Percentile Industry days to MDUFA III decision	84	113	75	24	
Maximum Industry days to MDUFA III decision	358	295	290	90	
Average Total days to MDUFA III decision	114.78	117.05	108.81	71.38	
20th Percentile Total days to MDUFA III decision	41	46	30	29	
40th Percentile Total days to MDUFA III decision	85	87	76	55	
60th Percentile Total days to MDUFA III decision	119	119	117	79	
80th Percentile Total days to MDUFA III decision	171	195	163	106	
Maximum Total days to MDUFA III decision	451	505	420	157	

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	415	408	185	
Number with MDUFA decision	427	373	353	60	
Number of SE decisions	418	369	345	60	
Number of NSE decisions	9	4	8	0	
Number of Withdrawals	14	21	14	2	
Number deleted	14	21	14	0	
Rate of SE decisions	97.9%	98.9%	97.7%	100%	
Rate of NSE decisions	2.1%	1.1%	2.3%	0%	
Rate of Withdrawals	3.1%	5.1%	3.4%	1.1%	
Rate of Deleted	3.1%	5.1%	3.4%	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	6	9	1	
Mean FDA days for submissions that missed goal	123	127	113	100	
Mean industry days for submissions that missed goal	114	136	99	36	

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	230	108	
Closed before RTA action	0	1	0	0	
Number Accepted	39	81	110	71	
Number without a RTA Review and > 15 Days since Date Received	1	4	3	1	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	7	
Number Not Accepted	150	120	117	29	
Rate of submissions not accepted for filing review	78.9%	58.5%	50.9%	28.7%	

* 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.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	189	218	82	
Deleted or withdrawn prior to SI	1	1	0	2	
SI within 60 FDA days	203	181	215	59	
SI over 60 FDA days	26	7	1	0	
SI pending within 60 FDA days	0	0	2	21	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	88.6%	96.3%	99.5%	100%	

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	188	216	59	
Average number of FDA days to Substantive Interaction	51.90	53.87	54.32	52	
20th Percentile FDA days to Substantive Interaction	43	53	53	30	
40th Percentile FDA days to Substantive Interaction	55	58	57	57	
60th Percentile FDA days to Substantive Interaction	58	59	59	59	
80th Percentile FDA days to Substantive Interaction	60	60	60	60	
Maximum FDA days to Substantive Interaction	80	64	61	60	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	236	192	226	84	
Non-MDUFA III Decisions	31	37	23	3	
MDUFA III Decisions (SE/NSE)	205	154	168	23	
MDUFA III Decisions within 90 FDA Days	199	148	168	23	
510(k)s pending MDUFA III Decision	0	1	34	58	
510(k) pending MDUFA III Decision over 90 FDA days	0	1	1	0	
Current Performance Percent within 90 FDA Days	97.1%	95.5%	99.4%	100%	

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	1.90	1.88	1.87	1.65	
Number with MDUFA III decision	205	154	168	23	
Average FDA days to MDUFA III decision	83.72	83.95	79.07	69.83	
20th Percentile FDA days to MDUFA III decision	86	86	61	35	
40th Percentile FDA days to MDUFA III decision	88	88	88	80	
60th Percentile FDA days to MDUFA III decision	89	89	89	89	
80th Percentile FDA days to MDUFA III decision	90	90	90	90	
Maximum FDA days to MDUFA III decision	148	245	90	90	
Average Industry days to MDUFA III decision	77.48	76.59	63.08	16	
20th Percentile Industry days to MDUFA III decision	8	7	4	0	
40th Percentile Industry days to MDUFA III decision	41	44	27	6	
60th Percentile Industry days to MDUFA III decision	84	82	58	16	
80th Percentile Industry days to MDUFA III decision	152	156	125	25	
Maximum Industry days to MDUFA III decision	345	291	359	68	
Average Total days to MDUFA III decision	161.20	160.55	142.14	85.83	
20th Percentile Total days to MDUFA III decision	90	90	84	43	
40th Percentile Total days to MDUFA III decision	128	131	113	85	
60th Percentile Total days to MDUFA III decision	174	170	144	101	
80th Percentile Total days to MDUFA III decision	240	249	214	115	
Maximum Total days to MDUFA III decision	435	385	449	158	

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	192	226	84	
Number with MDUFA decision	205	154	168	23	
Number of SE decisions	187	145	165	23	
Number of NSE decisions	18	9	3	0	
Number of Withdrawals	13	18	8	2	
Number deleted	13	16	15	0	
Rate of SE decisions	91.2%	94.2%	98.2%	100%	
Rate of NSE decisions	8.8%	5.8%	1.8%	0%	
Rate of Withdrawals	5.5%	9.4%	3.5%	2.4%	
Rate of Deleted	5.5%	8.3%	6.6%	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	6	0	0	
Mean FDA days for submissions that missed goal	105	133	0	0	
Mean industry days for submissions that missed goal	122	152	0	0	

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	669	282	
Closed before RTA action	0	1	3	1	
Number Accepted	181	313	395	203	
Number without a RTA Review and > 15 Days since Date Received	0	3	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	12	
Number Not Accepted	342	348	271	66	
Rate of submissions not accepted for filing review	65.4%	52.4%	40.7%	24.5%	

* 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.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	654	656	251	
Deleted or withdrawn prior to SI	3	1	0	0	
SI within 60 FDA days	623	636	636	200	
SI over 60 FDA days	29	15	18	3	
SI pending within 60 FDA days	0	0	2	48	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	2	0	0	
Current SI Performance Percent within 60 FDA days	95.6%	97.4%	97.2%	98.5%	

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	651	654	203	
Average number of FDA days to Substantive Interaction	47.88	48.77	48.87	47.88	
20th Percentile FDA days to Substantive Interaction	30	29	34	29	
40th Percentile FDA days to Substantive Interaction	48	52	51	52	
60th Percentile FDA days to Substantive Interaction	56	57	56	56	
80th Percentile FDA days to Substantive Interaction	59	59	59	58	
Maximum FDA days to Substantive Interaction	88	90	92	63	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	656	654	656	251	
Non-MDUFA III Decisions	73	50	47	2	
MDUFA III Decisions (SE/NSE)	583	604	567	102	
MDUFA III Decisions within 90 FDA Days	579	602	567	102	
510(k)s pending MDUFA III Decision	0	0	42	147	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1	0	
Current Performance Percent within 90 FDA Days	99.3%	99.7%	99.8%	100%	

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	1.61	1.56	1.58	1.24	
Number with MDUFA III decision	583	604	567	102	
Average FDA days to MDUFA III decision	69.88	68.99	69.21	56.17	
20th Percentile FDA days to MDUFA III decision	49	47	49	29	
40th Percentile FDA days to MDUFA III decision	74	73	70	52	
60th Percentile FDA days to MDUFA III decision	85	85	85	58	
80th Percentile FDA days to MDUFA III decision	88	88	88	84	
Maximum FDA days to MDUFA III decision	100	94	90	90	
Average Industry days to MDUFA III decision	40.52	38.43	35.05	5.22	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	2	0	0	0	
60th Percentile Industry days to MDUFA III decision	30	23	20	0	
80th Percentile Industry days to MDUFA III decision	75	78	63	6	
Maximum Industry days to MDUFA III decision	430	264	187	63	
Average Total days to MDUFA III decision	110.40	107.42	104.26	61.38	
20th Percentile Total days to MDUFA III decision	52	50	52	29	
40th Percentile Total days to MDUFA III decision	85	84	84	56	
60th Percentile Total days to MDUFA III decision	110	105	102	62	
80th Percentile Total days to MDUFA III decision	163	161	148	87	
Maximum Total days to MDUFA III decision	520	352	275	143	

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	654	656	251	
Number with MDUFA decision	583	604	567	102	
Number of SE decisions	564	596	557	102	
Number of NSE decisions	19	8	10	0	
Number of Withdrawals	37	26	30	2	
Number deleted	35	24	17	0	
Rate of SE decisions	96.7%	98.7%	98.2%	100%	
Rate of NSE decisions	3.3%	1.3%	1.8%	0%	
Rate of Withdrawals	5.6%	4%	4.6%	0.8%	
Rate of Deleted	5.3%	3.7%	2.6%	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	0	
Mean FDA days for submissions that missed goal	97	93	0	0	
Mean industry days for submissions that missed goal	104	53	0	0	

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	142	142	56	
Closed before RTA action	0	0	1	0	
Number Accepted	59	75	79	45	
Number without a RTA Review and > 15 Days since Date Received	5	2	2	1	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted	54	65	60	10	
Rate of submissions not accepted for filing review	45.8%	45.8%	42.6%	17.9%	

* 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.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	137	137	52	
Deleted or withdrawn prior to SI	0	1	0	0	
SI within 60 FDA days	134	135	135	41	
SI over 60 FDA days	5	1	2	2	
SI pending within 60 FDA days	0	0	0	9	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	96.4%	99.3%	98.5%	95.3%	

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	136	137	43	
Average number of FDA days to Substantive Interaction	48.74	51.29	52.51	49.21	
20th Percentile FDA days to Substantive Interaction	43	46	49	32	
40th Percentile FDA days to Substantive Interaction	49	53	56	50	
60th Percentile FDA days to Substantive Interaction	54	57	58	57	
80th Percentile FDA days to Substantive Interaction	57	59	60	59	
Maximum FDA days to Substantive Interaction	88	62	64	64	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	146	139	140	52	
Non-MDUFA III Decisions	20	27	16	0	
MDUFA III Decisions (SE/NSE)	126	111	108	18	
MDUFA III Decisions within 90 FDA Days	123	111	108	18	
510(k)s pending MDUFA III Decision	0	1	16	34	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	97.6%	100%	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	1.85	1.80	1.69	1.44	
Number with MDUFA III decision	126	111	108	18	
Average FDA days to MDUFA III decision	75.45	78.31	74.58	62.17	
20th Percentile FDA days to MDUFA III decision	56	60	56	30	
40th Percentile FDA days to MDUFA III decision	84	87	85	58	
60th Percentile FDA days to MDUFA III decision	88	89	88	85	
80th Percentile FDA days to MDUFA III decision	90	90	90	90	
Maximum FDA days to MDUFA III decision	91	90	90	90	
Average Industry days to MDUFA III decision	62.85	56.66	45.52	8.78	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	21	21	11	0	
60th Percentile Industry days to MDUFA III decision	60	42	35	12	
80th Percentile Industry days to MDUFA III decision	160	115	100	21	
Maximum Industry days to MDUFA III decision	250	333	180	27	
Average Total days to MDUFA III decision	138.30	134.96	120.10	70.94	
20th Percentile Total days to MDUFA III decision	70	79	60	30	
40th Percentile Total days to MDUFA III decision	105	105	89	59	
60th Percentile Total days to MDUFA III decision	135	132	123	88	
80th Percentile Total days to MDUFA III decision	230	203	189	111	
Maximum Total days to MDUFA III decision	332	423	270	115	

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	139	140	52	
Number with MDUFA decision	126	111	108	18	
Number of SE decisions	121	104	98	17	
Number of NSE decisions	5	7	10	1	
Number of Withdrawals	8	7	7	0	
Number deleted	11	17	8	0	
Rate of SE decisions	96%	93.7%	90.7%	94.4%	
Rate of NSE decisions	4%	6.3%	9.3%	5.6%	
Rate of Withdrawals	5.5%	5%	5%	0%	
Rate of Deleted	7.5%	12.2%	5.7%	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	0	
Mean FDA days for submissions that missed goal	91	0	0	0	
Mean industry days for submissions that missed goal	123	0	0	0	

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	270	128	
Closed before RTA action	0	2	7	0	
Number Accepted	66	145	185	97	
Number without a RTA Review and > 15 Days since Date Received	0	7	2	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	12	
Number Not Accepted	144	123	76	19	
Rate of submissions not accepted for filing review	68.6%	44.7%	28.9%	16.4%	

* 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.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	248	102	
Deleted or withdrawn prior to SI	1	3	1	0	
SI within 60 FDA days	253	255	245	74	
SI over 60 FDA days	9	7	2	0	
SI pending within 60 FDA days	0	0	0	28	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	2	1	0	0	
Current SI Performance Percent within 60 FDA days	95.8%	97%	99.2%	100%	

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	247	74	
Average number of FDA days to Substantive Interaction	48.19	48.90	48.35	45.53	
20th Percentile FDA days to Substantive Interaction	36	38	37	28	
40th Percentile FDA days to Substantive Interaction	50	50	47	47	
60th Percentile FDA days to Substantive Interaction	56	56	56	56	
80th Percentile FDA days to Substantive Interaction	58	59	59	58	
Maximum FDA days to Substantive Interaction	73	100	87	60	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	278	274	252	104	
Non-MDUFA III Decisions	42	37	18	0	
MDUFA III Decisions (SE/NSE)	236	237	203	34	
MDUFA III Decisions within 90 FDA Days	236	237	201	34	
510(k)s pending MDUFA III Decision	0	0	31	70	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	100%	100%	99%	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	1.87	1.78	1.70	1.24	
Number with MDUFA III decision	236	237	203	34	
Average FDA days to MDUFA III decision	71.43	71.07	72.52	43.88	
20th Percentile FDA days to MDUFA III decision	54	52	52	25	
40th Percentile FDA days to MDUFA III decision	80	77	81	28	
60th Percentile FDA days to MDUFA III decision	86	86	86	46	
80th Percentile FDA days to MDUFA III decision	88	88	89	69	
Maximum FDA days to MDUFA III decision	90	90	112	90	
Average Industry days to MDUFA III decision	73.14	58.05	67.67	7.79	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	32	22	18	0	
60th Percentile Industry days to MDUFA III decision	74	55	73	0	
80th Percentile Industry days to MDUFA III decision	152	112	159	8	
Maximum Industry days to MDUFA III decision	416	236	359	77	
Average Total days to MDUFA III decision	144.56	129.12	140.18	51.68	
20th Percentile Total days to MDUFA III decision	59	60	58	25	
40th Percentile Total days to MDUFA III decision	112	103	98	28	
60th Percentile Total days to MDUFA III decision	154	135	154	48	
80th Percentile Total days to MDUFA III decision	239	199	239	80	
Maximum Total days to MDUFA III decision	506	316	449	165	

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	252	104	
Number with MDUFA decision	236	237	203	34	
Number of SE decisions	221	232	199	34	
Number of NSE decisions	15	5	4	0	
Number of Withdrawals	18	11	10	0	
Number deleted	22	22	7	0	
Rate of SE decisions	93.6%	97.9%	98%	100%	
Rate of NSE decisions	6.4%	2.1%	2%	0%	
Rate of Withdrawals	6.5%	4%	4%	0%	
Rate of Deleted	7.9%	8%	2.8%	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	2	0	
Mean FDA days for submissions that missed goal	0	0	110	0	
Mean industry days for submissions that missed goal	0	0	247	0	

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	483	493	224	
Closed before RTA action	3	0	1	0	
Number Accepted	136	212	308	162	
Number without a RTA Review and > 15 Days since Date Received	3	11	5	1	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	14	
Number Not Accepted	233	260	179	47	
Rate of submissions not accepted for filing review	62.6%	53.8%	36.4%	22.4%	

* 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.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	458	471	193	
Deleted or withdrawn prior to SI	3	0	0	0	
SI within 60 FDA days	424	421	443	127	
SI over 60 FDA days	46	37	26	10	
SI pending within 60 FDA days	0	0	2	54	
SI pending over 60 FDA days	0	0	0	1	
510(k)s NSE without SI	0	0	0	1	
Current SI Performance Percent within 60 FDA days	90.2%	91.9%	94.5%	91.4%	

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	458	469	137	
Average number of FDA days to Substantive Interaction	45.44	50.42	51.13	50.16	
20th Percentile FDA days to Substantive Interaction	28	36	42	30	
40th Percentile FDA days to Substantive Interaction	44	53	55	52	
60th Percentile FDA days to Substantive Interaction	56	57	58	57	
80th Percentile FDA days to Substantive Interaction	59	60	60	59	
Maximum FDA days to Substantive Interaction	90	90	93	88	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	481	465	481	195	
Non-MDUFA III Decisions	86	80	61	2	
MDUFA III Decisions (SE/NSE)	395	384	366	56	
MDUFA III Decisions within 90 FDA Days	385	377	358	56	
510(k)s pending MDUFA III Decision	0	1	54	137	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	2	0	
Current Performance Percent within 90 FDA Days	97.5%	98.2%	97.3%	100%	

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	1.77	1.74	1.69	1.43	
Number with MDUFA III decision	395	384	366	56	
Average FDA days to MDUFA III decision	69.04	72.71	72.78	55.80	
20th Percentile FDA days to MDUFA III decision	43	55	51	29	
40th Percentile FDA days to MDUFA III decision	70	79	81	51	
60th Percentile FDA days to MDUFA III decision	85	87	87	60	
80th Percentile FDA days to MDUFA III decision	89	89	89	85	
Maximum FDA days to MDUFA III decision	342	147	150	90	
Average Industry days to MDUFA III decision	60.03	59.70	55.27	13.96	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	20	17	15	0	
60th Percentile Industry days to MDUFA III decision	44	51	43	7	
80th Percentile Industry days to MDUFA III decision	125	122	111	31	
Maximum Industry days to MDUFA III decision	438	408	342	86	
Average Total days to MDUFA III decision	129.07	132.41	128.04	69.77	
20th Percentile Total days to MDUFA III decision	51	61	57	29	
40th Percentile Total days to MDUFA III decision	93	90	91	58	
60th Percentile Total days to MDUFA III decision	128	134	129	77	
80th Percentile Total days to MDUFA III decision	204	211	199	111	
Maximum Total days to MDUFA III decision	691	512	432	141	

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	465	481	195	
Number with MDUFA decision	395	384	366	56	
Number of SE decisions	379	375	360	55	
Number of NSE decisions	16	9	6	1	
Number of Withdrawals	43	41	32	2	
Number deleted	38	28	26	0	
Rate of SE decisions	95.9%	97.7%	98.4%	98.2%	
Rate of NSE decisions	4.1%	2.3%	1.6%	1.8%	
Rate of Withdrawals	8.9%	8.8%	6.7%	1.0%	
Rate of Deleted	7.9%	6%	5.4%	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	7	8	0	
Mean FDA days for submissions that missed goal	137	106	114	0	
Mean industry days for submissions that missed goal	160	171	148	0	

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	191	94	
Closed before RTA action	1	1	1	1	
Number Accepted	118	127	154	73	
Number without a RTA Review and > 15 Days since Date Received	0	1	1	2	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	6	
Number Not Accepted	69	66	35	12	
Rate of submissions not accepted for filing review	36.9%	34%	18.4%	13.8%	

* 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.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	184	179	80	
Deleted or withdrawn prior to SI	0	0	0	2	
SI within 60 FDA days	247	184	176	63	
SI over 60 FDA days	0	0	2	0	
SI pending within 60 FDA days	0	0	1	15	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	100%	100%	98.9%	100%	

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	184	178	63	
Average number of FDA days to Substantive Interaction	41.03	42.67	43.59	46.79	
20th Percentile FDA days to Substantive Interaction	29	30	29	36	
40th Percentile FDA days to Substantive Interaction	38	43	42	46	
60th Percentile FDA days to Substantive Interaction	45	47	49	50	
80th Percentile FDA days to Substantive Interaction	52	54	58	59	
Maximum FDA days to Substantive Interaction	60	60	65	60	

Table 6.4.DCTD - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	247	184	179	80	
Non-MDUFA III Decisions	34	35	22	2	
MDUFA III Decisions (SE/NSE)	213	149	130	12	
MDUFA III Decisions within 90 FDA Days	212	147	130	12	
510(k)s pending MDUFA III Decision	0	0	27	66	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1	0	
Current Performance Percent within 90 FDA Days	99.5%	98.7%	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	1.86	1.94	1.68	1.17	
Number with MDUFA III decision	213	149	130	12	
Average FDA days to MDUFA III decision	64.94	67.23	64.72	60.50	
20th Percentile FDA days to MDUFA III decision	34	35	31	30	
40th Percentile FDA days to MDUFA III decision	58	59	59	49	
60th Percentile FDA days to MDUFA III decision	84	85	83	81	
80th Percentile FDA days to MDUFA III decision	88	88	89	87	
Maximum FDA days to MDUFA III decision	99	131	90	88	
Average Industry days to MDUFA III decision	83.44	85.41	55.18	6.58	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	12	11	0	0	
60th Percentile Industry days to MDUFA III decision	69	75	58	0	
80th Percentile Industry days to MDUFA III decision	166	175	112	0	
Maximum Industry days to MDUFA III decision	467	469	359	45	
Average Total days to MDUFA III decision	148.38	152.64	119.89	67.08	
20th Percentile Total days to MDUFA III decision	35	35	31	30	
40th Percentile Total days to MDUFA III decision	87	84	77	58	
60th Percentile Total days to MDUFA III decision	148	161	132	84	
80th Percentile Total days to MDUFA III decision	245	262	196	88	
Maximum Total days to MDUFA III decision	557	556	449	121	

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	184	179	80	
Number with MDUFA decision	213	149	130	12	
Number of SE decisions	207	148	125	12	
Number of NSE decisions	6	1	5	0	
Number of Withdrawals	17	20	11	2	
Number deleted	17	15	11	0	
Rate of SE decisions	97.2%	99.3%	96.2%	100%	
Rate of NSE decisions	2.8%	0.7%	3.8%	0%	
Rate of Withdrawals	6.9%	10.9%	6.1%	2.5%	
Rate of Deleted	6.9%	8.2%	6.1%	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	2	0	0	
Mean FDA days for submissions that missed goal	99	121	0	0	
Mean industry days for submissions that missed goal	193	254	0	0	

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	60	34	
Closed before RTA action	1	1	0	0	
Number Accepted	38	57	50	29	
Number without a RTA Review and > 15 Days since Date Received	3	0	1	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	2	
Number Not Accepted	14	15	9	3	
Rate of submissions not accepted for filing review	25.5%	20.8%	15%	9.4%	

* 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.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	65	57	31	
Deleted or withdrawn prior to SI	0	0	1	0	
SI within 60 FDA days	68	65	56	20	
SI over 60 FDA days	1	0	0	0	
SI pending within 60 FDA days	0	0	0	11	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	98.6%	100%	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	65	56	20	
Average number of FDA days to Substantive Interaction	47.62	50.98	52.45	52.90	
20th Percentile FDA days to Substantive Interaction	41	46	49	51	
40th Percentile FDA days to Substantive Interaction	50	52	57	58	
60th Percentile FDA days to Substantive Interaction	54	57	59	59	
80th Percentile FDA days to Substantive Interaction	58	59	60	60	
Maximum FDA days to Substantive Interaction	63	60	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% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	69	65	57	31	
Non-MDUFA III Decisions	22	20	8	0	
MDUFA III Decisions (SE/NSE)	47	44	40	4	
MDUFA III Decisions within 90 FDA Days	47	43	40	4	
510(k)s pending MDUFA III Decision	0	1	9	27	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	100%	97.7%	100%	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	1.96	1.86	1.90	1.00	
Number with MDUFA III decision	47	44	40	4	
Average FDA days to MDUFA III decision	71.62	79.45	74.08	39.00	
20th Percentile FDA days to MDUFA III decision	50	70	32	25	
40th Percentile FDA days to MDUFA III decision	77	88	88	28	
60th Percentile FDA days to MDUFA III decision	86	89	89	29	
80th Percentile FDA days to MDUFA III decision	88	90	90	49	
Maximum FDA days to MDUFA III decision	90	91	90	77	
Average Industry days to MDUFA III decision	115.40	106.39	116.53	0	
20th Percentile Industry days to MDUFA III decision	29	45	0	0	
40th Percentile Industry days to MDUFA III decision	89	63	98	0	
60th Percentile Industry days to MDUFA III decision	157	154	155	0	
80th Percentile Industry days to MDUFA III decision	177	176	177	0	
Maximum Industry days to MDUFA III decision	329	325	355	0	
Average Total days to MDUFA III decision	187.02	185.84	190.60	39	
20th Percentile Total days to MDUFA III decision	91	118	32	25	
40th Percentile Total days to MDUFA III decision	151	140	187	28	
60th Percentile Total days to MDUFA III decision	236	237	245	29	
80th Percentile Total days to MDUFA III decision	264	265	265	49	
Maximum Total days to MDUFA III decision	417	414	442	77	

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	65	57	31	
Number with MDUFA decision	47	44	40	4	
Number of SE decisions	43	37	40	4	
Number of NSE decisions	4	7	0	0	
Number of Withdrawals	6	7	5	0	
Number deleted	14	13	3	0	
Rate of SE decisions	91.5%	84.1%	100%	100%	
Rate of NSE decisions	8.5%	15.9%	0%	0%	
Rate of Withdrawals	8.7%	10.8%	8.8%	0%	
Rate of Deleted	20.3%	20%	5.3%	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	0	
Mean FDA days for submissions that missed goal	0	91	0	0	
Mean industry days for submissions that missed goal	0	47	0	0	

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	69	30	
Closed before RTA action	0	0	1	0	
Number Accepted	55	80	66	28	
Number without a RTA Review and > 15 Days since Date Received	0	1	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	1	
Number Not Accepted	4	3	2	1	
Rate of submissions not accepted for filing review	6.8%	3.6%	2.9%	3.4%	

* 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.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	83	67	28	
Deleted or withdrawn prior to SI	0	0	0	0	
SI within 60 FDA days	79	82	67	24	
SI over 60 FDA days	1	1	0	0	
SI pending within 60 FDA days	0	0	0	4	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	98.8%	98.8%	100%	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	83	67	24	
Average number of FDA days to Substantive Interaction	43.11	47.63	48.34	41.54	
20th Percentile FDA days to Substantive Interaction	28	29	31	26	
40th Percentile FDA days to Substantive Interaction	39	51	55	29	
60th Percentile FDA days to Substantive Interaction	53	56	57	54	
80th Percentile FDA days to Substantive Interaction	57	59	59	57	
Maximum FDA days to Substantive Interaction	61	61	60	60	

Table 6.4.DMD - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	80	83	67	28	
Non-MDUFA III Decisions	9	7	6	1	
MDUFA III Decisions (SE/NSE)	71	76	56	12	
MDUFA III Decisions within 90 FDA Days	71	76	56	12	
510(k)s pending MDUFA III Decision	0	0	5	15	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	100%	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	1.31	1.46	1.45	1.17	
Number with MDUFA III decision	71	76	56	12	
Average FDA days to MDUFA III decision	58.48	65.83	65.59	45.58	
20th Percentile FDA days to MDUFA III decision	29	36	33	26	
40th Percentile FDA days to MDUFA III decision	55	72	60	28	
60th Percentile FDA days to MDUFA III decision	78	81	84	29	
80th Percentile FDA days to MDUFA III decision	81	86	87	83	
Maximum FDA days to MDUFA III decision	89	90	90	90	
Average Industry days to MDUFA III decision	31.55	51.88	48.95	6.42	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	0	24	31	0	
80th Percentile Industry days to MDUFA III decision	65	126	118	0	
Maximum Industry days to MDUFA III decision	180	349	180	77	
Average Total days to MDUFA III decision	90.03	117.71	114.54	52.00	
20th Percentile Total days to MDUFA III decision	29	36	33	26	
40th Percentile Total days to MDUFA III decision	58	85	85	28	
60th Percentile Total days to MDUFA III decision	81	97	117	29	
80th Percentile Total days to MDUFA III decision	133	213	205	83	
Maximum Total days to MDUFA III decision	267	434	266	166	

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	83	67	28	
Number with MDUFA decision	71	76	56	12	
Number of SE decisions	71	73	54	12	
Number of NSE decisions	0	3	2	0	
Number of Withdrawals	6	5	5	1	
Number deleted	3	2	1	0	
Rate of SE decisions	100%	96.1%	96.4%	100%	
Rate of NSE decisions	0%	3.9%	3.6%	0%	
Rate of Withdrawals	7.5%	6%	7.5%	3.6%	
Rate of Deleted	3.8%	2.4%	1.5%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	0	0	0	

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	5	3	
Closed before RTA action	0	0	0	0	
Number Accepted	14	9	4	3	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted	3	0	1	0	
Rate of submissions not accepted for filing review	17.6%	0%	20%	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	5	3	
Deleted or withdrawn prior to SI	0	0	0	0	
SI within 60 FDA days	18	9	5	3	
SI over 60 FDA days	0	0	0	0	
SI pending within 60 FDA days	0	0	0	0	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	100%	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	5	3	
Average number of FDA days to Substantive Interaction	51.72	45.78	44.60	47.67	
20th Percentile FDA days to Substantive Interaction	44	29	30	41	
40th Percentile FDA days to Substantive Interaction	55	47	41	46	
60th Percentile FDA days to Substantive Interaction	58	56	52	51	
80th Percentile FDA days to Substantive Interaction	59	58	57	54	
Maximum FDA days to Substantive Interaction	60	60	58	58	

Table 6.4.DMGP - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	18	9	5	3	
Non-MDUFA III Decisions	4	2	4	0	
MDUFA III Decisions (SE/NSE)	14	7	1	0	
MDUFA III Decisions within 90 FDA Days	14	7	1	0	
510(k)s pending MDUFA III Decision	0	0	0	3	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	100%	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	2.36	1.57	3	0	
Number with MDUFA III decision	14	7	1		
Average FDA days to MDUFA III decision	83.71	78.14	90	0	
20th Percentile FDA days to MDUFA III decision	81	79	90	0	
40th Percentile FDA days to MDUFA III decision	88	88	90	0	
60th Percentile FDA days to MDUFA III decision	88	89	90	0	
80th Percentile FDA days to MDUFA III decision	89	90	90	0	
Maximum FDA days to MDUFA III decision	90	90	90	0	
Average Industry days to MDUFA III decision	151.93	81.71	164	0	
20th Percentile Industry days to MDUFA III decision	26	0	164	0	
40th Percentile Industry days to MDUFA III decision	166	16	164	0	
60th Percentile Industry days to MDUFA III decision	175	122	164	0	
80th Percentile Industry days to MDUFA III decision	233	177	164	0	
Maximum Industry days to MDUFA III decision	320	179	164	0	
Average Total days to MDUFA III decision	235.64	159.86	254	0	
20th Percentile Total days to MDUFA III decision	103	80	254	0	
40th Percentile Total days to MDUFA III decision	255	106	254	0	
60th Percentile Total days to MDUFA III decision	263	211	254	0	
80th Percentile Total days to MDUFA III decision	317	266	254	0	
Maximum Total days to MDUFA III decision	408	267	254	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	5	3	
Number with MDUFA decision	14	7	1	0	
Number of SE decisions	11	6	1	0	
Number of NSE decisions	3	1	0	0	
Number of Withdrawals	3	2	4	0	
Number deleted	1	0	0	0	
Rate of SE decisions	78.6%	85.7%	100%	0%	
Rate of NSE decisions	21.4%	14.3%	0%	0%	
Rate of Withdrawals	16.7%	22.2%	80%	0%	
Rate of Deleted	5.6%	0%	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	0	0	0	

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	329	166	
Closed before RTA action	0	0	0	0	
Number Accepted	151	274	268	136	
Number without a RTA Review and > 15 Days since Date Received	15	5	1	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	8	
Number Not Accepted	90	86	60	22	
Rate of submissions not accepted for filing review	35.2%	23.6%	18.2%	13.9%	

* 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.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	324	149	
Deleted or withdrawn prior to SI	1	0	0	1	
SI within 60 FDA days	307	342	322	118	
SI over 60 FDA days	41	14	2	0	
SI pending within 60 FDA days	0	0	0	30	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	88.2%	96.1%	99.4%	100%	

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	324	118	
Average number of FDA days to Substantive Interaction	47.42	45.76	44.38	40.54	
20th Percentile FDA days to Substantive Interaction	31	30	29	24	
40th Percentile FDA days to Substantive Interaction	44	44	44	40	
60th Percentile FDA days to Substantive Interaction	56	54	51	47	
80th Percentile FDA days to Substantive Interaction	59	59	57	55	
Maximum FDA days to Substantive Interaction	91	93	70	60	

Table 6.4.DRH - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% SI within 90 FDA days	93% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
510(k)s accepted	403	393	356	171	
Non-MDUFA III Decisions	17	9	7	1	
MDUFA III Decisions (SE/NSE)	386	384	335	86	
MDUFA III Decisions within 90 FDA Days	380	372	334	86	
510(k)s pending MDUFA III Decision	0	0	14	84	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	98.4%	96.9%	99.7%	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	1.61	1.65	1.58	1.47	
Number with MDUFA III decision	386	384	335	86	
Average FDA days to MDUFA III decision	61.93	63.17	58.04	43.76	
20th Percentile FDA days to MDUFA III decision	35	31	29	24	
40th Percentile FDA days to MDUFA III decision	56	58	55	29	
60th Percentile FDA days to MDUFA III decision	77	79	71	46	
80th Percentile FDA days to MDUFA III decision	87	88	81	70	
Maximum FDA days to MDUFA III decision	121	137	91	90	
Average Industry days to MDUFA III decision	35.89	36.01	33.07	13.70	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	0	0	0	0	
60th Percentile Industry days to MDUFA III decision	20	27	21	7	
80th Percentile Industry days to MDUFA III decision	60	64	57	28	
Maximum Industry days to MDUFA III decision	358	346	319	88	
Average Total days to MDUFA III decision	97.82	99.18	91.12	57.45	
20th Percentile Total days to MDUFA III decision	37	32	30	24	
40th Percentile Total days to MDUFA III decision	71	77	59	30	
60th Percentile Total days to MDUFA III decision	90	102	90	58	
80th Percentile Total days to MDUFA III decision	137	141	140	93	
Maximum Total days to MDUFA III decision	466	428	406	144	

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	356	171	
Number with MDUFA decision	386	384	335	86	
Number of SE decisions	377	377	324	85	
Number of NSE decisions	9	7	11	1	
Number of Withdrawals	10	2	2	1	
Number deleted	7	6	5	0	
Rate of SE decisions	97.7%	98.2%	96.7%	98.8%	
Rate of NSE decisions	2.3%	1.8%	3.3%	1.2%	
Rate of Withdrawals	2.5%	0.5%	0.6%	0.6%	
Rate of Deleted	1.7%	1.5%	1.4%	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	1	0	
Mean FDA days for submissions that missed goal	104	98	91	0	
Mean industry days for submissions that missed goal	135	37	13	0	

Section 7 510(k) Annual General Metrics - Annual Metrics and Goals will be reported in the Annual Report.

Page intentionally left blank

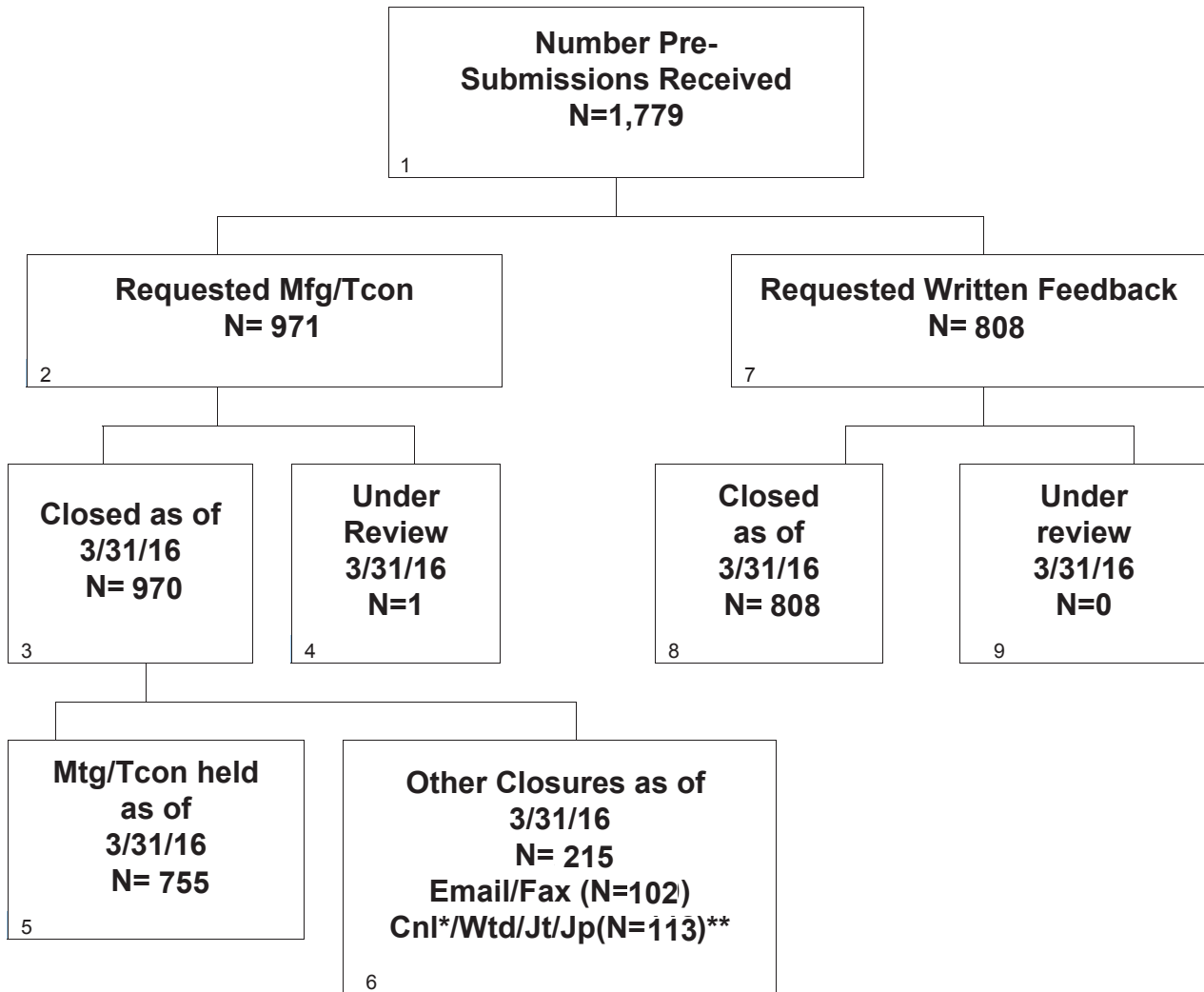
Section 8 Annual Metrics for De Novo Requests

De Novo Annual Metrics and Goals will be reported in the Annual Report.

Page intentionally left blank

CDRH Pre-Submissions - FY 2013

As of 3/31/16

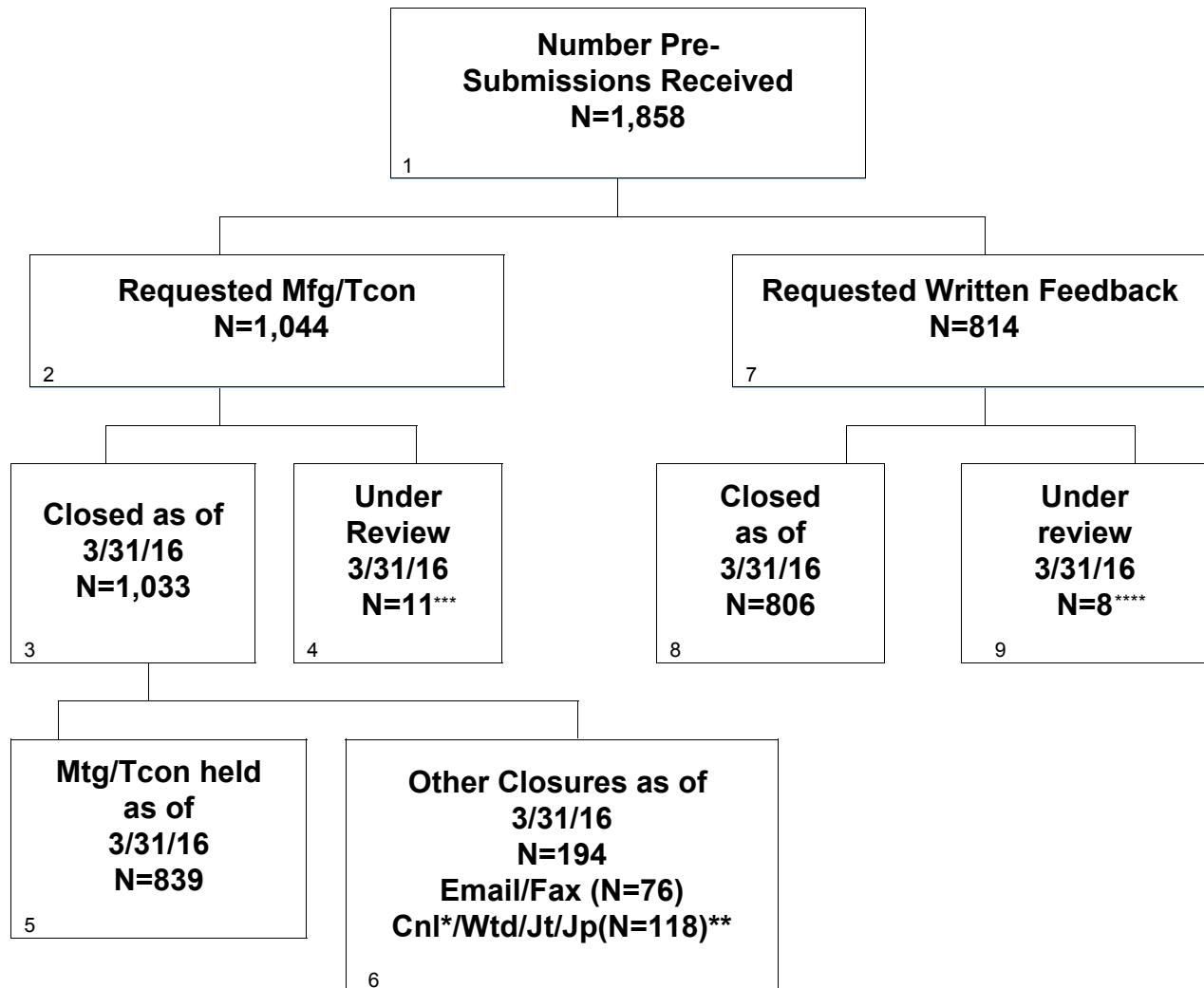


*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

**Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

CDRH Pre-Submissions - FY 2014

As of 3/31/16



*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

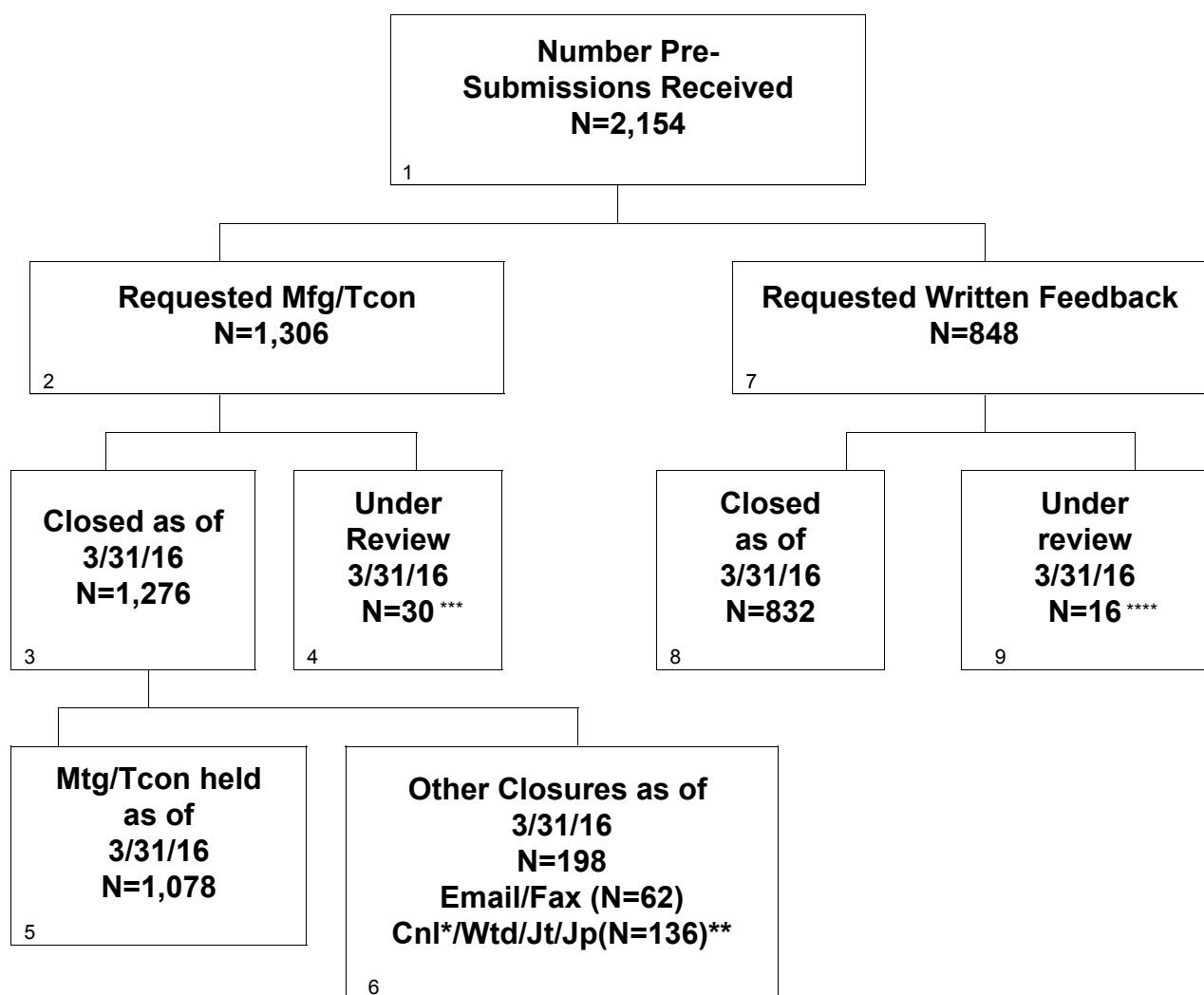
**Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

*** Includes 10 Pre-Submissions on RTA Hold as of 3/31/2016

**** Includes 7 Pre-Submissions on RTA Hold as of 3/31/2016

CDRH Pre-Submissions - FY 2015

As of 3/31/16



*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

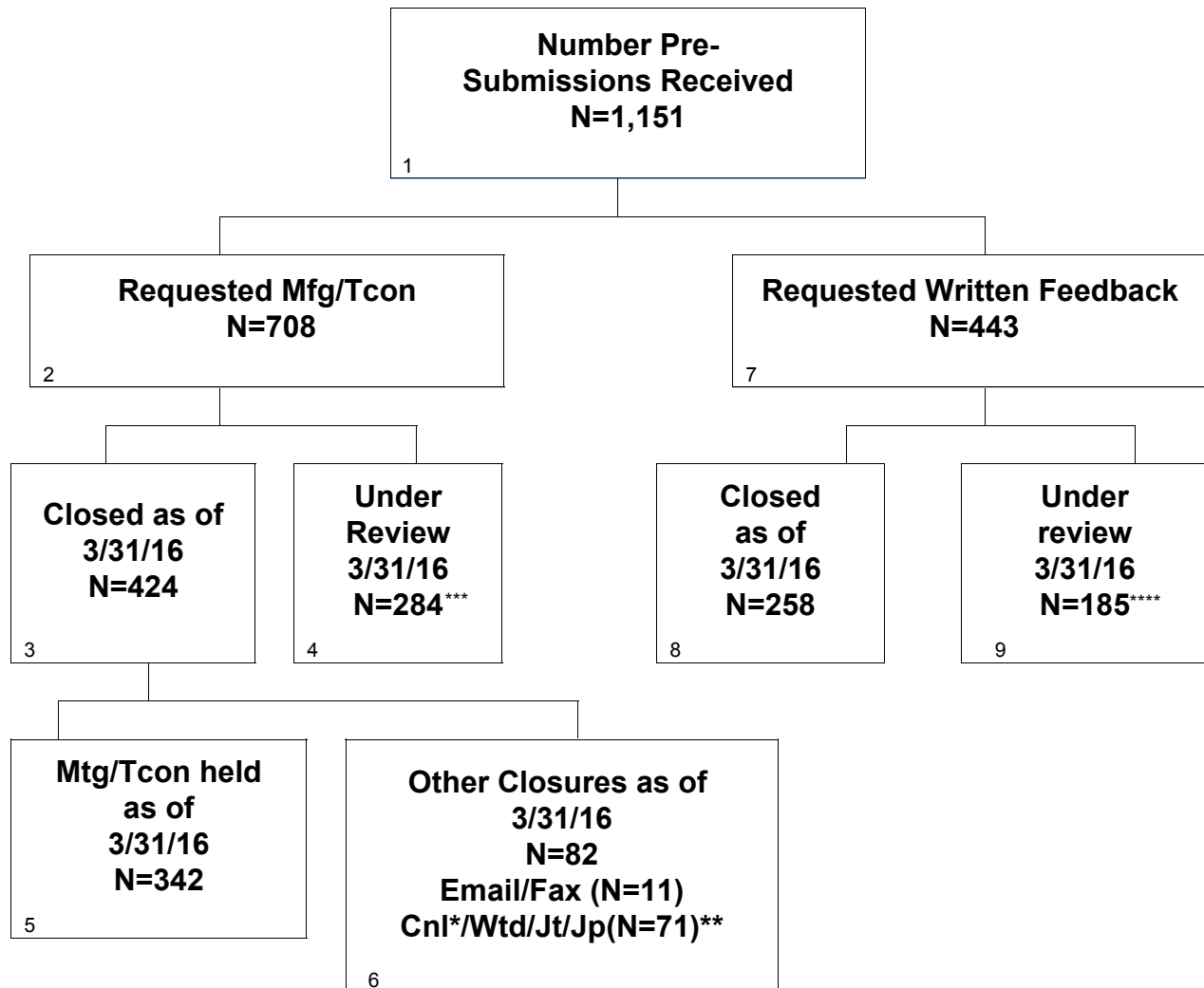
**Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

*** Includes 21 Pre-Submissions on RTA Hold as of 3/31/2016

**** Includes 11 Pre-Submissions on RTA Hold as of 3/31/2016

CDRH Pre-Submissions - FY 2016

As of 3/31/16



*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

**Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

*** Includes 8 Pre-Submissions on RTA Hold as of 3/31/2016

**** Includes 10 Pre-Submissions on RTA Hold as of 3/31/2016

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	1,858	2,154	1,151	
Number requesting a meeting or teleconference	971	1,044	1,306	708	
Number with meetings or teleconferences held	755	839	1,078	342	
Average days to meeting	59.2	65.0	65.4	53.2	
20th Percentile days to meeting	38	48	51	40	
40th Percentile days to meeting	55	62	64	52	
60th Percentile days to meeting	66	70	70	60	
80th Percentile days to meeting	77	78	77	68	
Maximum days to meeting	183	243	249	80	

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	1,141	1,351	710	
Number requesting a meeting or teleconference	611	698	860	471	
Number with meetings or teleconferences held	455	555	693	218	
Average days to meeting	61.8	67.8	68.3	53.7	
20th Percentile days to meeting	40	49	52	38	
40th Percentile days to meeting	57	63	65	51	
60th Percentile days to meeting	67	72	72	63	
80th Percentile days to meeting	79	83	82	69	
Maximum days to meeting	183	243	249	80	

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	803	441	
Number requesting a meeting or teleconference	360	346	446	237	
Number with meetings or teleconferences held	300	284	385	124	
Average days to meeting	55.4	59.5	60.3	52.5	
20th Percentile days to meeting	37	46	51	42	
40th Percentile days to meeting	53	60	62	54	
60th Percentile days to meeting	63	68	68	59	
80th Percentile days to meeting	71	72	71	65	
Maximum days to meeting	138	115	112	69	

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	232	152	
Number requesting a meeting or teleconference	82	110	137	96	
Number with meetings or teleconferences held	58	82	106	50	
Average days to meeting	68.3	70.7	74.0	66.1	
20th Percentile days to meeting	52	55	64	64	
40th Percentile days to meeting	65	65	70	67	
60th Percentile days to meeting	75	75	77	69	
80th Percentile days to meeting	83	85	86	71	
Maximum days to meeting	121	149	142	74	

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	391	216	
Number requesting a meeting or teleconference	214	236	264	139	
Number with meetings or teleconferences held	173	200	223	68	
Average days to meeting	56.0	59.3	57.1	47.8	
20th Percentile days to meeting	35	44	43	25	
40th Percentile days to meeting	49	54	52	49	
60th Percentile days to meeting	62	65	63	57	
80th Percentile days to meeting	74	74	71	66	
Maximum days to meeting	134	140	218	71	

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	154	61	
Number requesting a meeting or teleconference	50	72	108	52	
Number with meetings or teleconferences held	32	49	92	28	
Average days to meeting	70.3	88.8	81.8	61.9	
20th Percentile days to meeting	48	67	66	41	
40th Percentile days to meeting	63	78	75	66	
60th Percentile days to meeting	77	90	83	73	
80th Percentile days to meeting	91	112	95	75	
Maximum days to meeting	163	243	249	80	

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	125	58	
Number requesting a meeting or teleconference	61	71	83	46	
Number with meetings or teleconferences held	39	62	66	13	
Average days to meeting	60.6	75.3	70.5	51.3	
20th Percentile days to meeting	45	62	59	41	
40th Percentile days to meeting	57	71	69	42	
60th Percentile days to meeting	69	77	76	60	
80th Percentile days to meeting	77	89	82	63	
Maximum days to meeting	129	158	126	69	

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	107	54	
Number requesting a meeting or teleconference	49	46	75	34	
Number with meetings or teleconferences held	35	34	55	14	
Average days to meeting	66.4	75.4	74.1	0.0	
20th Percentile days to meeting	53	66	65	0	
40th Percentile days to meeting	64	69	73	0	
60th Percentile days to meeting	70	73	77	0	
80th Percentile days to meeting	83	86	83	0	
Maximum days to meeting	118	146	99	0	

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	136	160	83	
Number requesting a meeting or teleconference	76	83	90	48	
Number with meetings or teleconferences held	60	66	71	21	
Average days to meeting	60	59.8	69.9	52	
20th Percentile days to meeting	47	44	56	45	
40th Percentile days to meeting	60	57	68	48	
60th Percentile days to meeting	67	67	73	49	
80th Percentile days to meeting	71	75	79	57	
Maximum days to meeting	132	119	129	68	

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	182	86	
Number requesting a meeting or teleconference	79	80	103	56	
Number with meetings or teleconferences held	58	62	80	24	
Average days to meeting	67.5	71.8	69.8	46.5	
20th Percentile days to meeting	41	63	59	41	
40th Percentile days to meeting	64	69	67	50	
60th Percentile days to meeting	73	77	70	52	
80th Percentile days to meeting	85	89	79	54	
Maximum days to meeting	183	111	189	57	

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	232	123	
Number requesting a meeting or teleconference	107	99	151	68	
Number with meetings or teleconferences held	91	88	137	37	
Average days to meeting	51.3	57	55.4	51.6	
20th Percentile days to meeting	36	42	38	47	
40th Percentile days to meeting	49	55	57	54	
60th Percentile days to meeting	59	65	65	57	
80th Percentile days to meeting	68	70	70	59	
Maximum days to meeting	90	112	97	65	

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	119	70	
Number requesting a meeting or teleconference	66	72	65	42	
Number with meetings or teleconferences held	54	67	65	20	
Average days to meeting	61.1	65.0	67.6	59.6	
20th Percentile days to meeting	41	56	61	57	
40th Percentile days to meeting	64	67	66	60	
60th Percentile days to meeting	70	71	70	60	
80th Percentile days to meeting	81	73	73	63	
Maximum days to meeting	99	113	111	69	

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	212	114	
Number requesting a meeting or teleconference	59	48	63	44	
Number with meetings or teleconferences held	49	28	44	21	
Average days to meeting	52.6	60.4	61.1	54.7	
20th Percentile days to meeting	42	43	53	51	
40th Percentile days to meeting	51	56	63	60	
60th Percentile days to meeting	61	68	67	68	
80th Percentile days to meeting	67	77	72	68	
Maximum days to meeting	81	91	112	68	

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	171	97	
Number requesting a meeting or teleconference	83	90	118	56	
Number with meetings or teleconferences held	70	69	102	28	
Average days to meeting	63	57.8	61.6	46.5	
20th Percentile days to meeting	44	40	50	35	
40th Percentile days to meeting	56	60	63	42	
60th Percentile days to meeting	66	68	69	51	
80th Percentile days to meeting	83	71	72	63	
Maximum days to meeting	138	115	94	69	

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	69	37	
Number requesting a meeting or teleconference	45	37	49	27	
Number with meetings or teleconferences held	36	32	37	18	
Average days to meeting	46.7	57.5	61	52.9	
20th Percentile days to meeting	31	47	54	41	
40th Percentile days to meeting	43	59	62	51	
60th Percentile days to meeting	57	68	65	59	
80th Percentile days to meeting	63	72	70	64	
Maximum days to meeting	98	107	91	68	

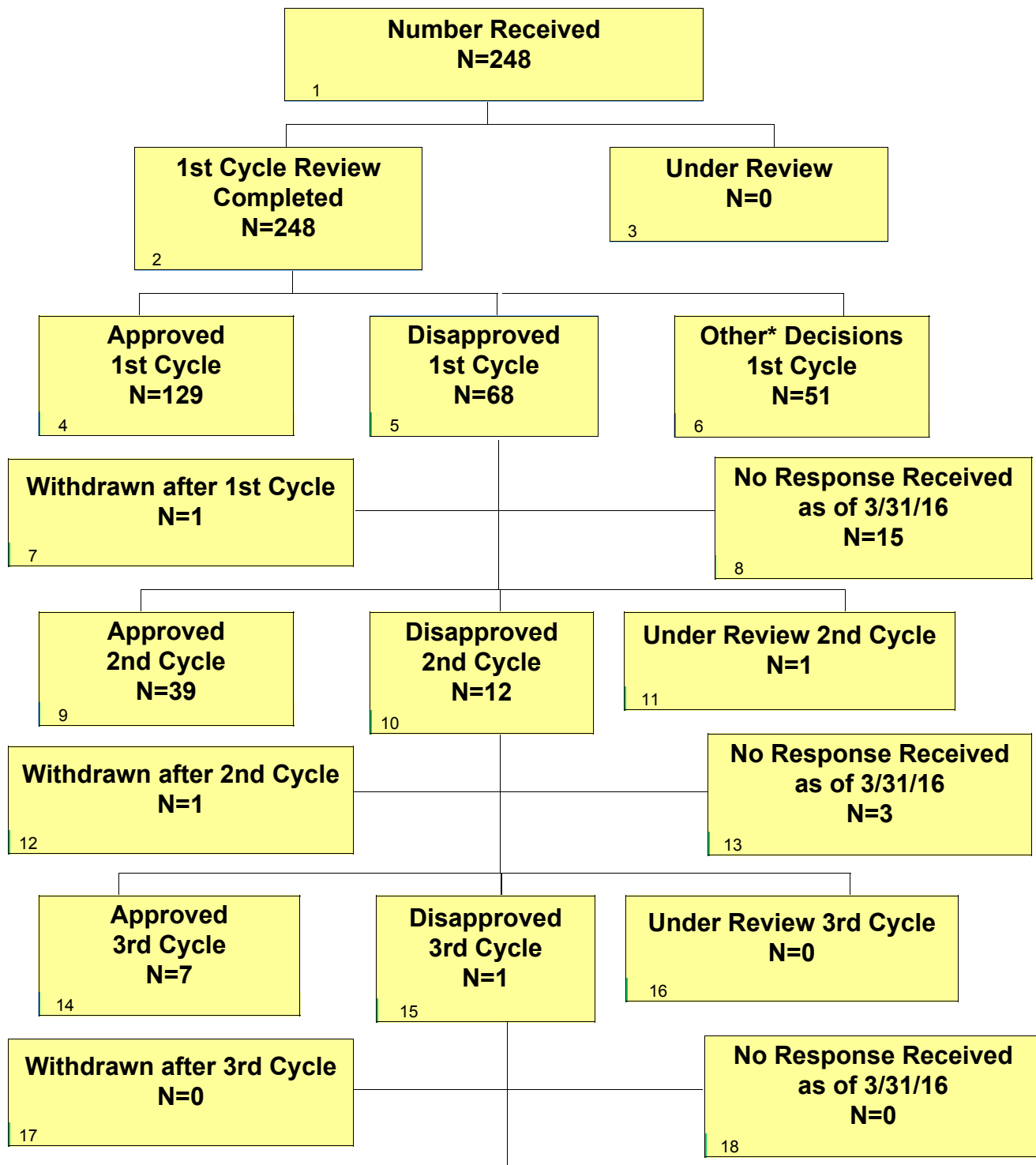
Section 10 CLIA Waiver Annual Metrics

CLIA Waiver Annual Metrics and Goals will be reported in the Annual Report.

Page intentionally left blank

CDRH IDEs - FY 2014

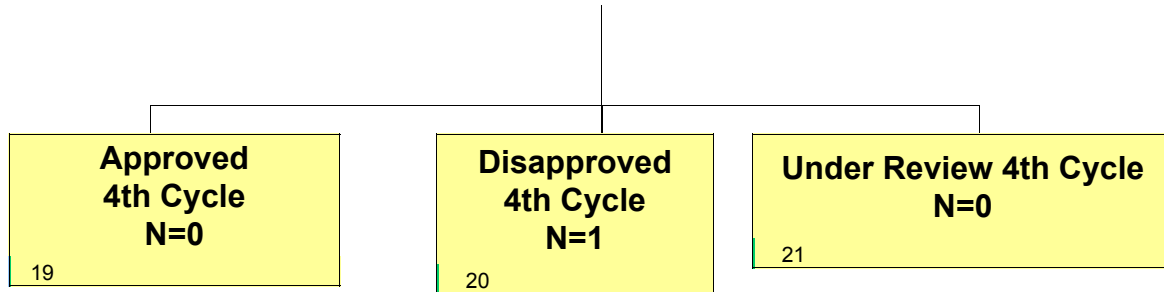
As of 3/31/16



* Other decisions include withdrawn (N=34), RTA (N=2), nonsignificant risk device (N=9), exempt (N=3), product jurisdiction pending (N=0), or product jurisdiction transferred (N=3).

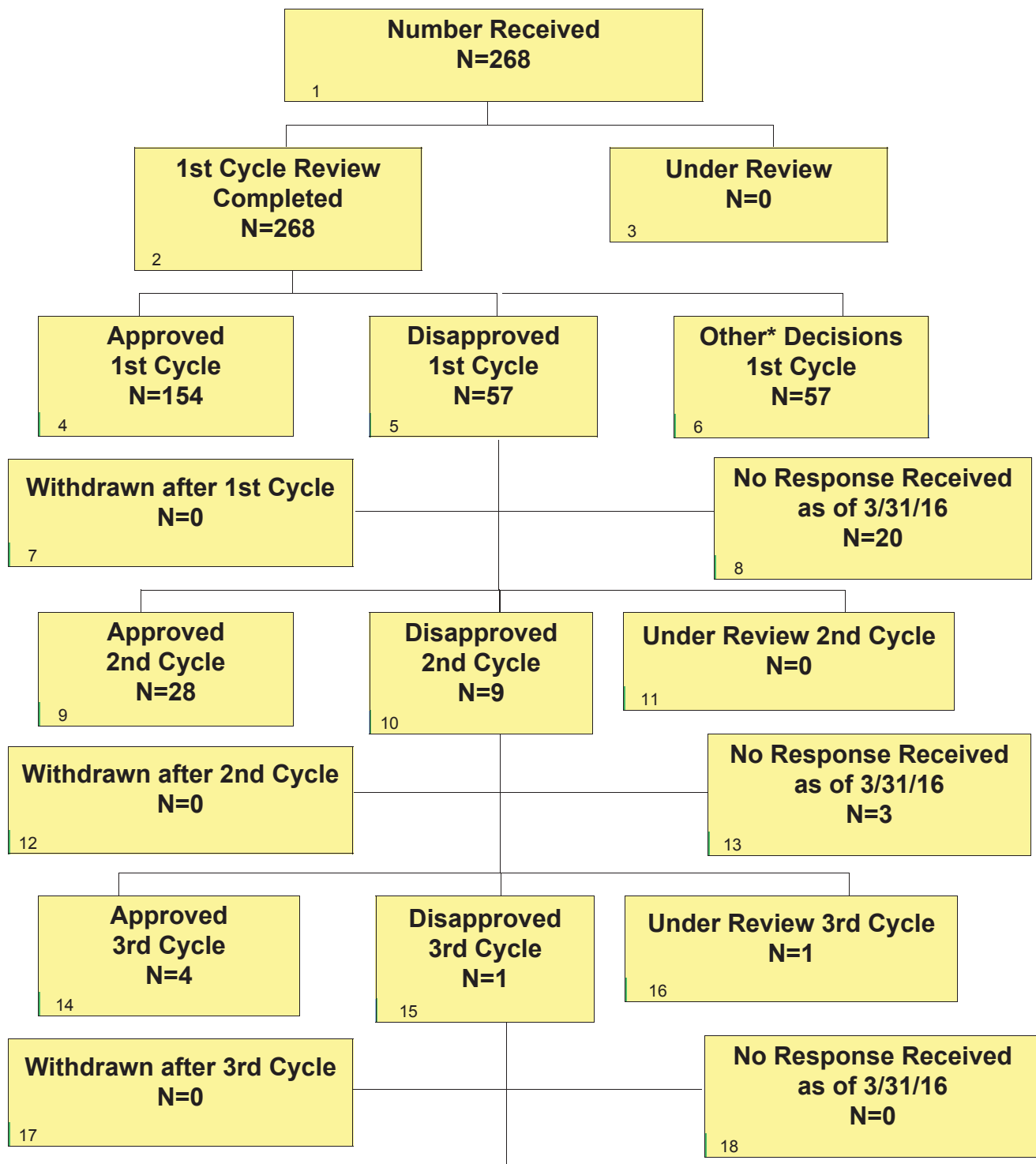
CDRH IDEs - FY 2014

As of 3/31/16 Continued



CDRH IDEs - FY 2015

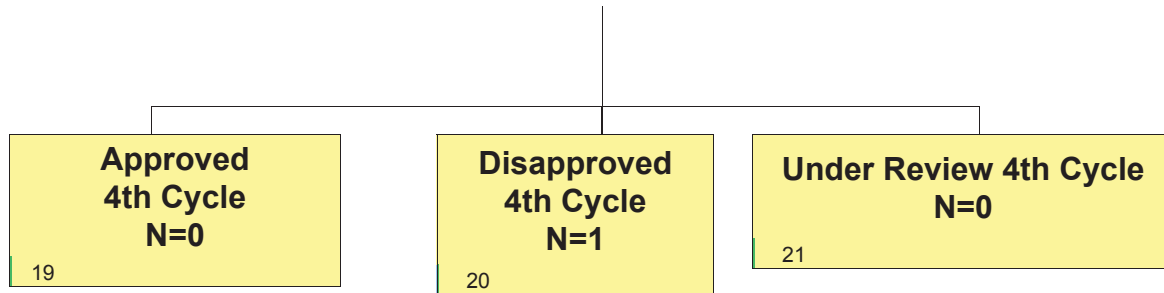
As of 3/31/16



* Other decisions include withdrawn (N=38), RTA (N=0), nonsignificant risk device (N=13), exempt (N=5), product jurisdiction pending (N=0), or product jurisdiction transferred (N=1).

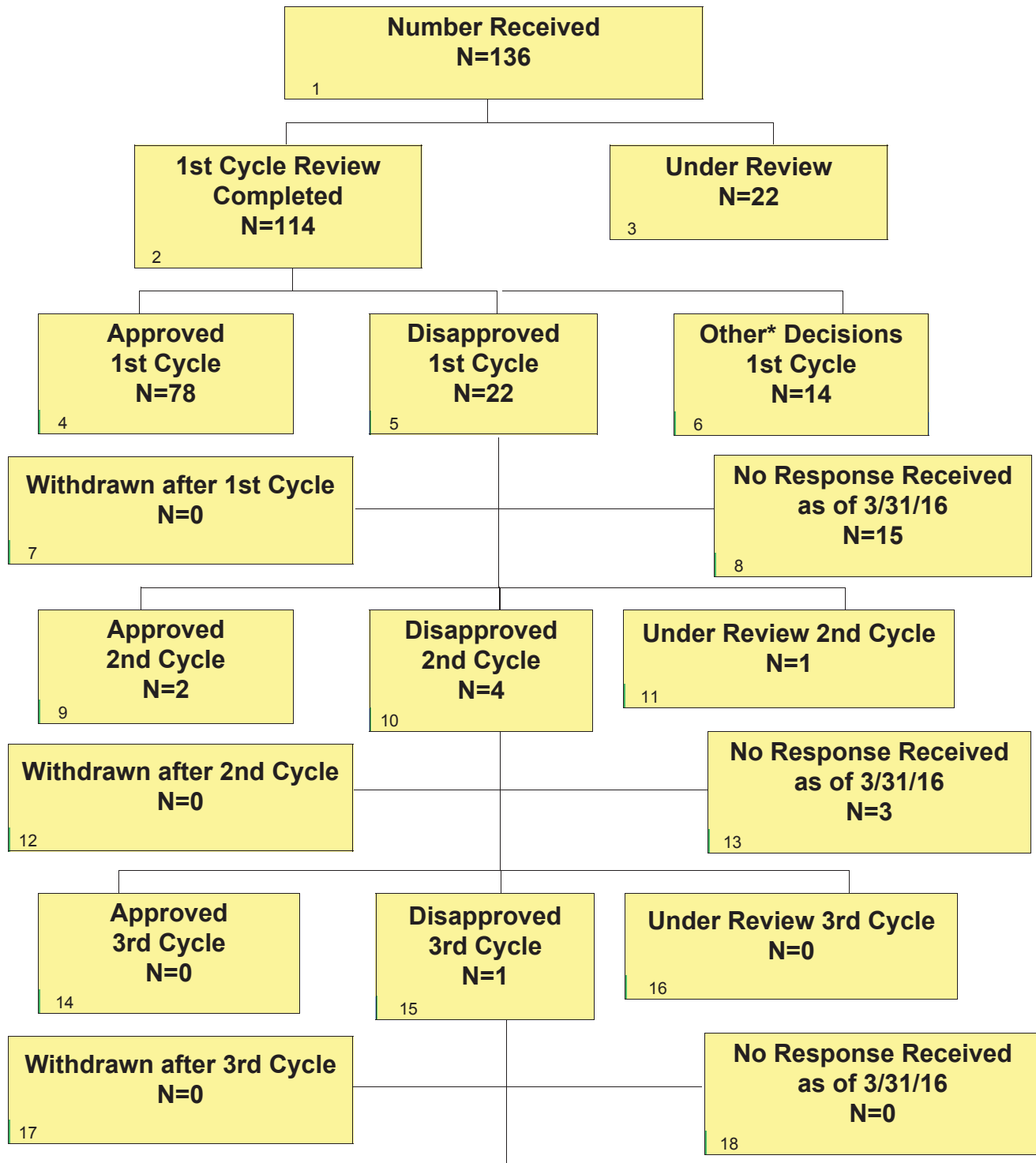
CDRH IDEs - FY 2015

As of 3/31/16 Continued



CDRH IDEs - FY 2016

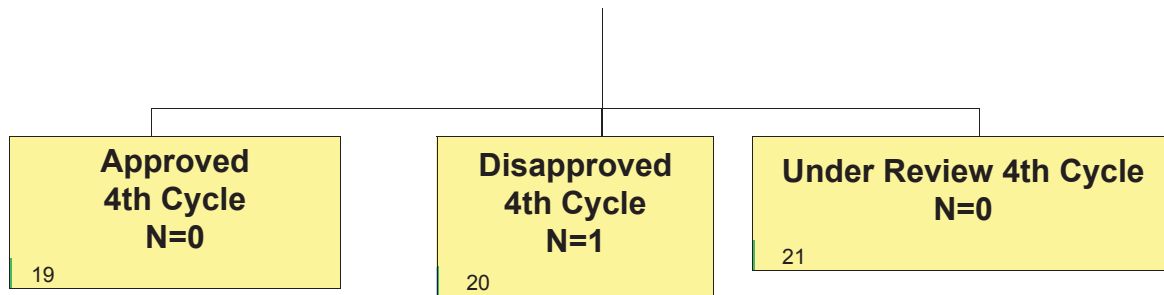
As of 3/31/16



* Other decisions include withdrawn (N=9), RTA (N=0), nonsignificant risk device (N=2), exempt (N=1), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1).

CDRH IDEs - FY 2016

As of 3/31/16 Continued



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	268	136	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.2	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0.2	0	

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	231	112	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.4	1.2	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.4	0.2	0	

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	37	24	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.1	1	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.1	0.0	0.0	

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	19	10	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.7	1.2	1.0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.7	0.2	0.0	

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	58	36	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.5	1.4	1.0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.5	0.4	0.0	

Table 11.1.DNPMD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	35	39	37	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.1	1.1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0.1	0.1	

Table 11.1.DOD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	13	13	2	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.2	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.2	0	

Table 11.1.DOED - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	18	26	5	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.1	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.1	0	

Table 11.1.DRGUD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	31	43	17	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.5	1.3	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.5	0.3	0	

Table 11.1.DSD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	25	33	5	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.1	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.1	0	

Table 11.1.DCTD - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	29	14	14	
Average number of cycles to approval or conditional approval of the IDE	N/A	1	1.1	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0.1	0	

Table 11.1.DIHD - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	2	2	0	
Average number of cycles to approval or conditional approval of the IDE	N/A	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	N/A	

Table 11.1.DMD - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	1	1	0	
Average number of cycles to approval or conditional approval of the IDE	N/A	1	1	N/A	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0	N/A	

Table 11.1.DMGP - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	19	17	6	
Average number of cycles to approval or conditional approval of the IDE	N/A	1	1	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0	0	

Table 11.1.DRH - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	9	3	4	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.6	1	1	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.6	0	0	

Page intentionally left blank

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.

Page intentionally left blank

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 [#]	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).

[#] 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 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 2016**

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	3	0	
Closed before RTA action	0	0	0	0	
Number Accepted	1	6	3	0	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	0	0	
Rate of submissions not accepted for filing review	0%	0%	0%	0%	
Completed RTF	0	0	0	0	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	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	3	0	
SI within 90 FDA days	0	6	3	0	
SI over 90 FDA days	1	0	0	0	
SI pending within 90 FDA days	0	0	0	0	
SI pending over 90 FDA days	0	0	0	0	
Closed without SI	0	0	0	0	
Current SI Performance Percent within 90 FDA days	0%	100%	100%	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	3	0	
Average number of FDA days to Substantive Interaction	101	88	87	0	
20th Percentile FDA days to Substantive Interaction	101	87	85	0	
40th Percentile FDA days to Substantive Interaction	101	88	86	0	
60th Percentile FDA days to Substantive Interaction	101	88	86	0	
80th Percentile FDA days to Substantive Interaction	101	90	90	0	
Maximum FDA days to Substantive Interaction	101	90	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	3	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	0	6	2	0	
MDUFA III Decisions within 180 FDA Days	0	6	2	0	
PMAs pending MDUFA III Decision	0	0	1	0	
PMAs pending MDUFA III Decision over 180 FDA days	0	0	0	0	
Current Performance Percent within 180 FDA Days	0%	100%	100%	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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions within 320 FDA Days	1	0	0	0	
PMAs pending MDUFA III Decision	0	0	0	0	
PMAs pending MDUFA III Decision over 320 FDA days	0	0	0	0	
Current Performance Percent within 320 FDA Days	100%	0%	0%	0%	

**Table 1.6 CBER – 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	0	6	2	0	
Average FDA days to MDUFA III decision	0	173	168	0	
20th Percentile FDA days to MDUFA III decision	0	170	165	0	
40th Percentile FDA days to MDUFA III decision	0	172	165	0	
60th Percentile FDA days to MDUFA III decision	0	176	171	0	
80th Percentile FDA days to MDUFA III decision	0	177	171	0	
Maximum FDA days to MDUFA III decision	0	180	171	0	
Average Industry days to MDUFA III decision	0	137	56	0	
20th Percentile Industry days to MDUFA III decision	0	0	56	0	
40th Percentile Industry days to MDUFA III decision	0	41	56	0	
60th Percentile Industry days to MDUFA III decision	0	178	56	0	
80th Percentile Industry days to MDUFA III decision	0	284	56	0	
Maximum Industry days to MDUFA III decision	0	317	56	0	
Average Total days to MDUFA III decision	0	310	196	0	
20th Percentile Total days to MDUFA III decision	0	172	171	0	
40th Percentile Total days to MDUFA III decision	0	218	171	0	
60th Percentile Total days to MDUFA III decision	0	358	221	0	
80th Percentile Total days to MDUFA III decision	0	460	221	0	
Maximum Total days to MDUFA III decision	0	479	221	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	0	
Average FDA days to MDUFA III decision	303	0	0	0	
20th Percentile FDA days to MDUFA III decision	303	0	0	0	
40th Percentile FDA days to MDUFA III decision	303	0	0	0	
60th Percentile FDA days to MDUFA III decision	303	0	0	0	
80th Percentile FDA days to MDUFA III decision	303	0	0	0	
Maximum FDA days to MDUFA III decision	303	0	0	0	
Average Industry days to MDUFA III decision	41	0	0	0	
20th Percentile Industry days to MDUFA III decision	41	0	0	0	
40th Percentile Industry days to MDUFA III decision	41	0	0	0	
60th Percentile Industry days to MDUFA III decision	41	0	0	0	
80th Percentile Industry days to MDUFA III decision	41	0	0	0	
Maximum Industry days to MDUFA III decision	41	0	0	0	
Average Total days to MDUFA III decision	344	0	0	0	
20th Percentile Total days to MDUFA III decision	344	0	0	0	
40th Percentile Total days to MDUFA III decision	344	0	0	0	
60th Percentile Total days to MDUFA III decision	344	0	0	0	
80th Percentile Total days to MDUFA III decision	344	0	0	0	
Maximum Total days to MDUFA III decision	344	0	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	3	0	
Number with MDUFA decision	0	6	2	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	0%	0%	0%	
Rate of Not Approvable	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	0	
Number with MDUFA decision	1	0	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Withdrawals	0%	0%	0%	0%	
Rate of Not Approvable	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	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	5	2	
SI within 90 FDA days	2	1	3	0	
SI over 90 FDA days	0	0	0	1	
SI pending within 90 FDA days	0	0	1	0	
SI pending over 90 FDA days	0	0	0	1	
Closed without SI	1	0	1	0	
Current SI Performance Percent within 90 FDA days	100%	100%	75%	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	5	2	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	2	1	2	1	
MDUFA III Decisions within 180 FDA Days	2	1	2	1	
Supplements pending MDUFA III Decision	0	0	3	1	
Supplements pending MDUFA III Decision over 180 FDA days	0	0	0	0	
Current Performance Percent within 180 FDA Days	100%	100%	100%	100%	

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	5	2	
Number with MDUFA decision	2	1	2	1	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	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	5	3	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	3	2	5	3	
MDUFA III Decisions within 90 FDA Days	3	2	5	3	
Supplements pending MDUFA III Decision	0	0	0	0	
Supplements pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	100%	100%	100%	100%	

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	5	3	
Number with MDUFA decision	3	2	5	3	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	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	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean Industry days for submissions that missed goal	0	0	0	0	

Section 5 PMA Annual Metrics and Goals - PMA Annual Metrics and Goals will be reported in the Annual Report.

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	56	21	
Closed before RTA action	1	5	4	0	
Number Accepted	40	51	51	19	
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	
Number Not Accepted	19	6	5	2	
Rate of submissions not accepted for review	32.2%	10.5%	8.9%	9.5%	

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	51	51	19	
SI within 60 FDA days	41	49	48	13	
SI over 60 FDA days	6	2	1	0	
SI pending within 60 FDA days	0	0	0	6	
SI pending over 60 FDA days	0	0	0	0	
510(k)s NSE without SI	0	0	0	0	
Current SI Performance Percent within 60 FDA days	87.2%	96.1%	98%	100%	

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	51	49	13	
Average number of FDA days to Substantive Interaction	49	50	48	43	
20th Percentile FDA days to Substantive Interaction	30	34	30	24	
40th Percentile FDA days to Substantive Interaction	46	54	52	41	
60th Percentile FDA days to Substantive Interaction	58	57	58	52	
80th Percentile FDA days to Substantive Interaction	59	60	59	57	
Maximum FDA days to Substantive Interaction	90	90	62	60	

Table 6.4 CBER – 510(k) MDUFA Decision Performance Goals

Performance Goals:	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	47	51	51	19	
Non-MDUFA III Decisions	8	5	6	0	
MDUFA III Decisions (SE/NSE)	39	41	36	8	
MDUFA III Decisions within 90 FDA Days	37	41	36	8	
510(k)s pending MDUFA III Decision	0	5	9	11	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	94.9%	100%	100%	100%	

Table 6.5 CBER – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.69	1.46	1.44	1.25	
Number with MDUFA III decision	39	41	36	8	
Average FDA days to MDUFA III decision	71	68	66	55	
20th Percentile FDA days to MDUFA III decision	30	31	30	24	
40th Percentile FDA days to MDUFA III decision	81	63	75	61	
60th Percentile FDA days to MDUFA III decision	87	85	81	72	
80th Percentile FDA days to MDUFA III decision	89	88	87	80	
Maximum FDA days to MDUFA III decision	94	162	90	80	
Average Industry days to MDUFA III decision	76	57	37	13	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	19	0	0	0	
60th Percentile Industry days to MDUFA III decision	83	28	14	0	
80th Percentile Industry days to MDUFA III decision	150	112	74	40	
Maximum Industry days to MDUFA III decision	370	317	309	65	
Average Total days to MDUFA III decision	147	125	103	68	
20th Percentile Total days to MDUFA III decision	30	37	37	30	
40th Percentile Total days to MDUFA III decision	108	79	76	72	
60th Percentile Total days to MDUFA III decision	171	107	87	77	
80th Percentile Total days to MDUFA III decision	244	191	136	80	
Maximum Total days to MDUFA III decision	460	479	398	126	

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	51	51	19	
Number with MDUFA decision	39	41	36	8	
Number of SE decisions	36	38	32	8	
Number of NSE decisions	3	3	4	0	
Number of Withdrawals	8	5	6	0	
Number deleted	0	0	0	0	
Rate of SE decisions	92.3%	92.7%	88.9%	100%	
Rate of NSE decisions	7.7%	7.3%	11.1%	0%	
Rate of Withdrawals	17%	9.8%	11.8%	0%	
Rate of Deleted	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	0	
Mean FDA days for submissions that missed goal	94	0	0	0	
Mean industry days for submissions that missed goal	150	0	0	0	

Section 7 510(k) Annual General Metrics - 510(k) Annual Metrics and Goals will be reported in the Annual Report.

Section 8 De Novo Petitions **De Novo Annual Metrics and Goals will be reported in the Annual Report**

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	60	37	
Number requesting a meeting or teleconference	34	46	48	28	
Number with meetings or teleconferences granted	29	41	45	25	
Number with meeting granted and industry cancelled	13	7	12	4	
Number with meeting granted and FDA cancelled	0	1	1	0	
Number with meeting granted and pending within timeframe	0	0	0	5	
Number with meeting granted and pending outside timeframe	0	0	0	1	
Number with meetings or teleconferences held	15	33	32	15	
Average days to meeting	65	68	68	52	
20th Percentile days to meeting	55	44	58	20	
40th Percentile days to meeting	58	62	68	28	
60th Percentile days to meeting	61	78	76	62	
80th Percentile days to meeting	70	92	83	79	
Maximum days to meeting	122	132	101	105	

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	3	
Number of Standard BLA First Actions less than or equal to 10 months	9	10	2	0	
Number of Standard BLA First Actions greater than 10 months	0	0	0	0	
Number of Standard BLAs Pending	0	0	0	3	
Number of Priority BLA Filed	0	0	2	0	
Number of Priority BLA First Actions less than or equal to 10 months	0	0	2	0	
Number of Priority BLA First Actions greater than 10 months	0	0	0	0	
Number of Priority BLAs Pending	0	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	1	0	
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0	17	1	0	
Number of Standard Efficacy Supplements First Actions greater than 10 months	0	0	0	0	
Number of Standard Efficacy Supplements Pending	0	0	0	0	
Number of Priority Efficacy Supplements Filed	0	0	0	0	
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0	0	0	0	

Number of Priority Efficacy Supplements Frist Actions greater than 10 months	0	0	0	0	
Number of Priority Efficacy Supplements Pending	0	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	19	16	
Number of Standard PAS Supplements First Actions less than or equal to 4months	20	6	19	2	
Number of Standard PAS Supplements First Actions greater than 4 months	0	0	0	0	
Number of Standard PAS Supplements Pending	0	0	0	14	

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	0	
Number of Class 1 Resubmission Actions less than or equal to 2 months	10	6	1	0	
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0	0	
Number of Class 1 Resbumssions Pending	0	0	0	0	
Number of Class 2 Resubmissions Received	0	2	16	8	
Number of Class 2 Resubmission Actions less than or equal to 6 months	0	2	16	0	
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0	0	
Number of Class 2 Resubmissions Pending	0	0	0	8	

IDEs

CBER – Annual General Metric Report for IDEs - IDE Annual Metrics and Goals will be reported in the Annual Report.

**FY 2016 Medical Device User Fee Collections
as of March 31, 2016
Excludes Unearned Fees**

	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$92,150,351	\$248,791	\$91,901,560		
Application Fees	\$18,958,420	\$266,150	\$18,692,270		
Total	\$111,108,771	\$514,941	\$110,593,830	\$137,677,000	80%

**Medical Device User Fee Collection History
Excludes Unearned Fees, Includes Refunds**

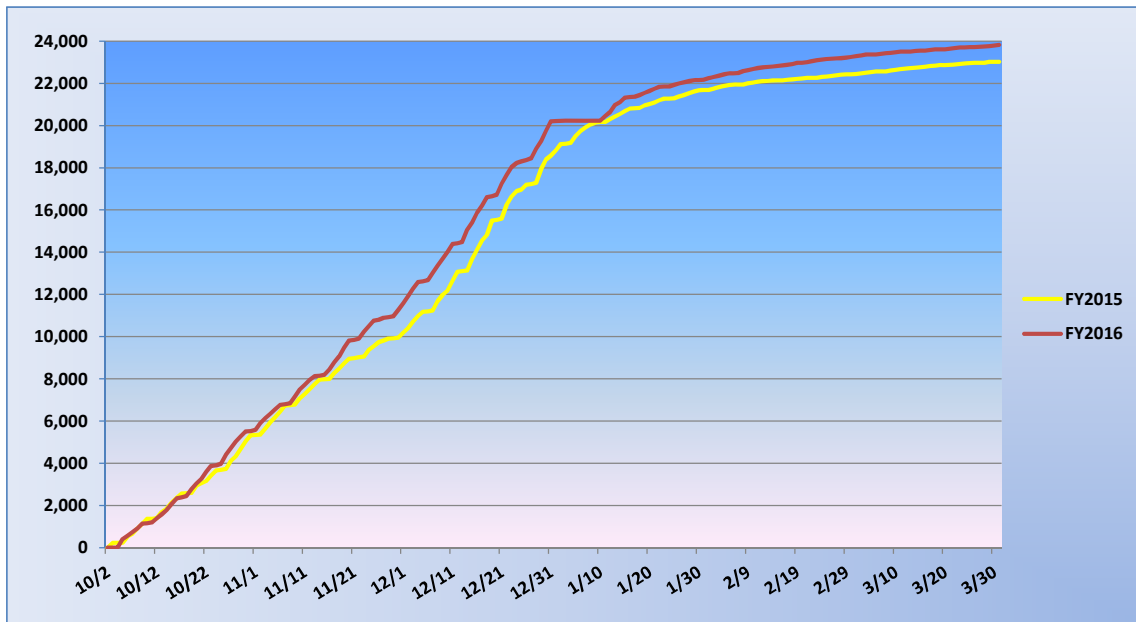
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
MD I	\$21,620,549	\$26,281,779	\$31,790,187	\$34,417,751	\$27,847,812
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
MD II	\$47,714,199	\$57,165,476	\$63,526,947	\$69,754,879	\$65,353,790
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
MD III	\$100,403,003	\$120,554,470	\$134,695,374	\$110,593,830	

Page intentionally left blank

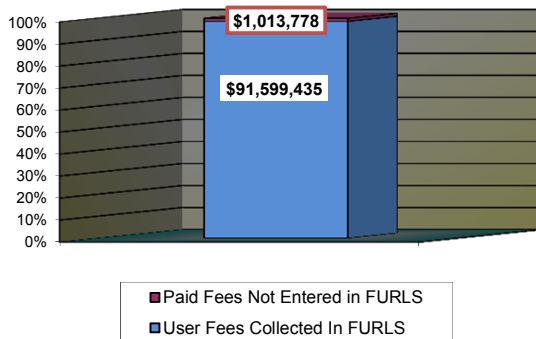
MDUFA III, Registrations, Second Quarter Summary FY2016

Registrations by Type	FY16 End of 2nd Quarter Active			FY15 Year End Active Totals			Progress by Est Type
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,789	8,539	14,328	5,943	8,872	14,815	96.71%
Contract Manufacturer	950	1,220	2,170	965	1,194	2,159	100.51%
Contract Sterilizer	75	122	197	78	124	202	97.52%
Specification Developer	1,571	431	2,002	1,657	428	2,085	96.02%
Reprocessor of Single Use Devices	24	1	25	25	1	26	96.15%
U.S. Manufacturer of Export Only Devices	117		117	131	0	131	89.31%
Repackager/Relabeler	1,093	155	1,248	1,143	176	1,319	94.62%
Remanufacturer	19	9	28	21	13	34	82.35%
Foreign Exporter/Private Label Distributor	0	626	626	0	630	630	99.37%
Initial Importer	2,964	0	2,964	3,323	0	3,323	89.20%
Unknown	16	8	24	8	6	14	171.43%
Total:	12,618	11,111	23,729	13,294	11,444	24,738	95.92%

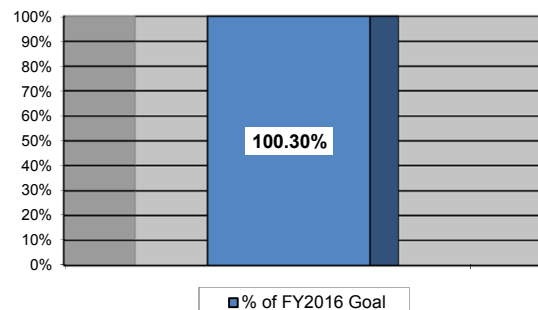
Registration Progress - FY2015 Versus FY2016



User Fees Collected Versus User Fees Paid in Dollars



User Fee Progress - Percent Collected Versus Projections
Goals: \$91,326,440 fees or 23,752 Registrations



Page intentionally left blank

Center for Devices and Radiological Health Internal Training Summary Report

Q2 FY16

October 2015 – March 2016

Prepared by: The Division of Employee Training and Development
(DETD)

As of: 4/8/2015

The FDA continues to invest in internal and external training opportunities supporting the medical device review process. The Division of Employee Training and Development (DETD) is CDRH's internal resource for scientific, regulatory, 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, 2015 and March 31, 2016. DETD offered 243 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.

Table of Contents

Table X - FY15 CDRH Internal Training Conducted:	4
Premarket Reviewer Training - RCP	5
Reviewer Certification Program:	5
RCP Training Completed: <i>October 1, 2015 – March 31, 2016</i>	5
RCP Training by Cohort, Completed: <i>October 1, 2015 – March 31, 2016</i>	6
Premarket Reviewer Training - ELP	7
Experiential Learning Program (ELP):	7
ELP Training Completed: <i>October 1, 2015 – March 31, 2016</i>	7
Leadership Training - LEAD	8
Leadership Enhancement and Development (LEAD) Program:	8
LEAD Training Completed: <i>October 1, 2015 – March 31, 2016</i>	8
LEAD Training for ODE and OIR Completed: <i>October 1, 2015 – March 31, 2016</i>	8
Leadership Training for Non-Managers	9
Leadership Readiness Program (LRP):	9
LRP Participant Data	9
CDRH Training Courses by Category:	10
Regulatory and Law (LAW) Training:	10
Leadership Development Training for Managers and Non-Managers:	12
Professional Development (PRO) Training:	12
Science (SCI) Training:	13
Center-Specific IT (CIT) Training:	13

Table X - FY15 CDRH Internal Training Conducted by DETD:*October 1, 2015 - March 31, 2016*

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA III	6	112	256
	ELP	14	154	1600
	Other LAW	68	1132	3733
<i>LAW Subtotal:</i>		<i>88</i>	<i>1398</i>	<i>5589</i>
Leadership Development Training (LED)	LEAD: Leadership for Managers	37	537	1749
	Leadership for Non-Managers	3	67	67
<i>LED Subtotal:</i>		<i>40</i>	<i>604</i>	<i>1816</i>
Professional Development (PRO) Training	New Employee Orientation (NEO)	2	66	462
	Other PRO	25	328	2457
<i>PRO Subtotal:</i>		<i>27</i>	<i>394</i>	<i>2919</i>
Science (SCI) Training	All SCI	73	2015	6357
Center-Specific Information Technology (CIT) Training	All CIT	15	533	298
Grand Total:		243	4944	16979

Premarket Reviewer Training - RCP

Reviewer Certification Program (RCP):

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 is taught in cohorts of approximately 40 students.

The program components include:

- 37 courses totaling 140 hours of training
- Practical activities and hands-on exercises
- A Submission Review Audit Process
- Knowledge assessments

RCP Training Completed Between: *October 1, 2015 – March 31, 2016*

Category	Total Learning Events	Total Participants	Total Completions	Total Training Hours	Examples of Training Conducted
RCP	44	69	745	4835	<ul style="list-style-type: none">• Basic Food and Drug Law• How to Write Effective Pre-market Consulting Reviews• Freedom of Information (FOI) Training• Using IT Systems in Premarket Review - online• Signal Management Program- online

Premarket Reviewer Training – RCP (Continued)

RCP Training by Cohort: *September 2015* – March 31, 2016*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall 2015 Cohort	13	24	ODE	20	309	1727
			OIR	12	150	946
Spring 2016 Cohort	9	24	ODE	33	286	2107
			OIR	4	46	335
Total:	27	24	-	69	791	5115

*This chart includes data from September 2015, when the Fall 2015 cohort began.

Premarket Reviewer Training - ELP

Experiential Learning Program (ELP):

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 premarket 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: *October 1, 2015 – March 31, 2016*

Office	# of Site Visits	# of Attendees	Total Training Hours	Focus Area
ODE	10	101	1024	<ul style="list-style-type: none">• Solid organ preservation devices• Endovascular grafts for treatment of aortic aneurysms• Diagnostic imaging catheters for cardiovascular diseases• Minimally invasive glaucoma surgery devices
OIR	4	53	576	<ul style="list-style-type: none">• TPLC of auto antibody assays, including ELISA• Next Generation Sequencing (NGS) on tumor specimen
Total:	14	154	1600	

Leadership Training - LEAD

Leadership Enhancement and Development (LEAD) Program:

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: *October 1, 2015 – March 31, 2016*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	37	537	1749	<ul style="list-style-type: none"> • Meetings that Work • Media Relations Training • Conflict Management Skills for Leaders • OMO Seminar Series for Managers • Annual Supervisory Safety Training • Championing Diversity • Active Shooter Preparedness

LEAD Training for ODE and OIR Completed: *October 1, 2015 – March 31, 2016*

Office	Total # of Managers/Supervisors	# of Training Participants	Training Hours Completed	Training Hours Required*	% of Required Training Hours Completed
ODE	75	55	476	1200	40%
OIR	39	32	169	624	27%
Total:	114	87	645	1824	34%

*This data is based on the 16 hour minimum annual management training requirement for managers with more than 3 years of experience. New managers have an additional 24 hour training requirement, for a total of 40 hours.

Leadership Training - LRP

Leadership Readiness Program (LRP):

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 audience for this program is 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
2006 - 2007	OIVD	3	3
	ODE	13	12
2008 - 2009	OIVD	3	3
	ODE	10	10
	Other	17	16
2010 - 2011	OIVD	3	3
	ODE	9	8
	Other	8	8
2012 - 2013	OIR	3	3
	ODE	6	6
	Other	11	11
2014 - 2015	OIR	2	2
	ODE	6	6
	Other	12	12
Total:		106	103

CDRH Training Courses by Category:

The following section contains a sampling of DETD courses that occurred through 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.
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.

Leadership Development Training for Managers and Non-Managers:

Handling People with Diplomacy & Tact	Employees will learn the critically important big-picture mentality of their work, a blueprint for mega productivity, and a brand new sense of unity. Participants will also learn techniques to empower their team, and make each team member responsible and accountable for their actions.
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 Other 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.

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.

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.