

1st Quarter FY 2016 Package *(in lieu of meeting)*
MDUFA III (FY 2013-2017) Performance
February 18, 2016

Guidance Development

FDA MDUFA Performance — Actions through December 31, 2015

- Report on decisions goals for 1st Quarter of FY 2016.

Qualitative Update on Finances – 1st Quarter of FY 2016

- User fee receipts through the 1st Quarter of FY 2016

CDRH Registration and Listing

- Report on registration and listing

Independent Assessment

CDRH Staff Training Update

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Medical Device Guidance Documents

(Issued in FY 2016)

(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 Public Notification of Emerging Postmarket Medical Device Signals (Emerging Signals) - Draft Guidance for Industry and Food and Drug Administration Staff (12/31/2015)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 Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses - Draft Guidance for Industry, Clinicians and Food and Drug Administration Staff (12/29/15)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 Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (11/02/15)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>

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

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Acronyms and Abbreviations

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

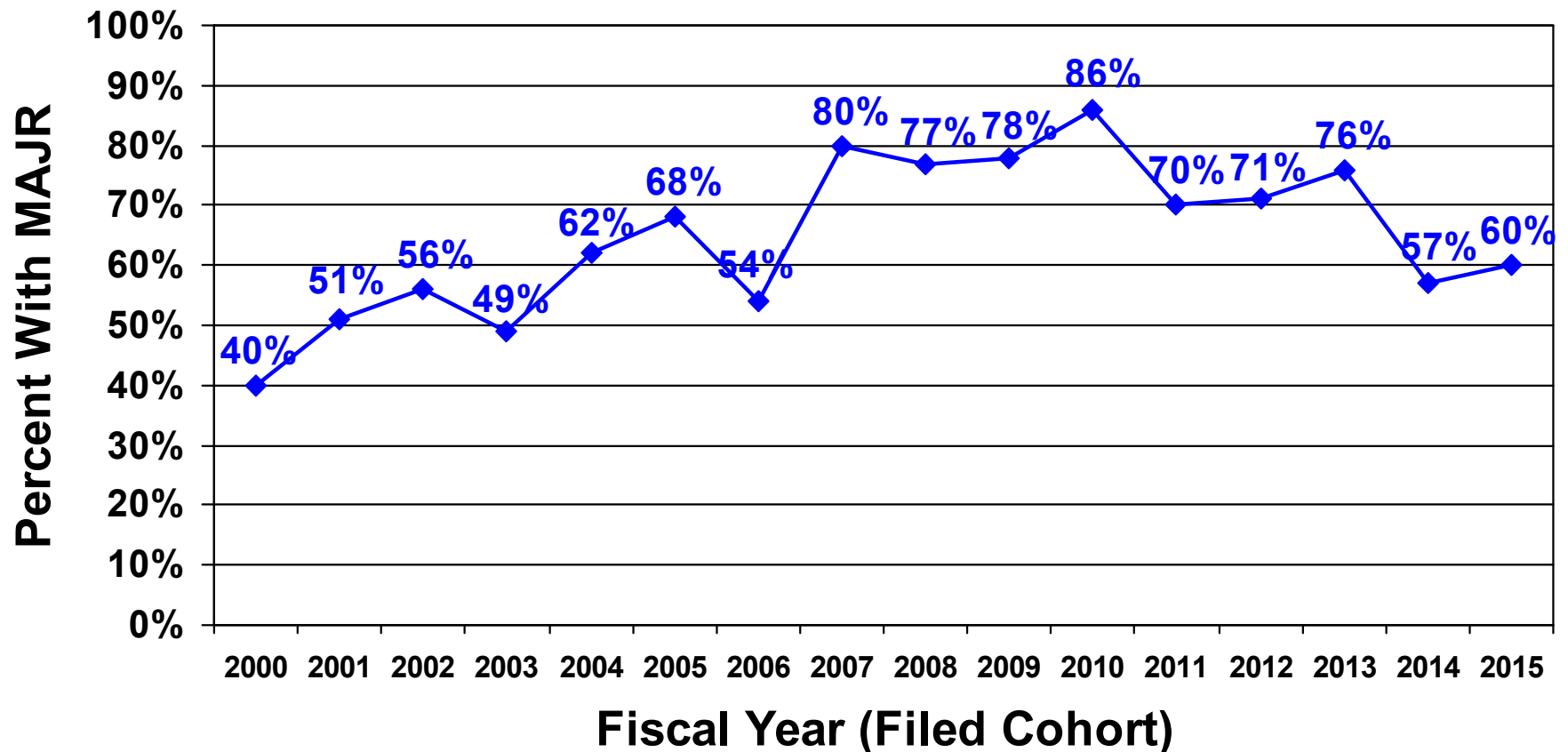
Note: Data may change in subsequent quarterly and annual reports.

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PMA's

1st Q FY 2016

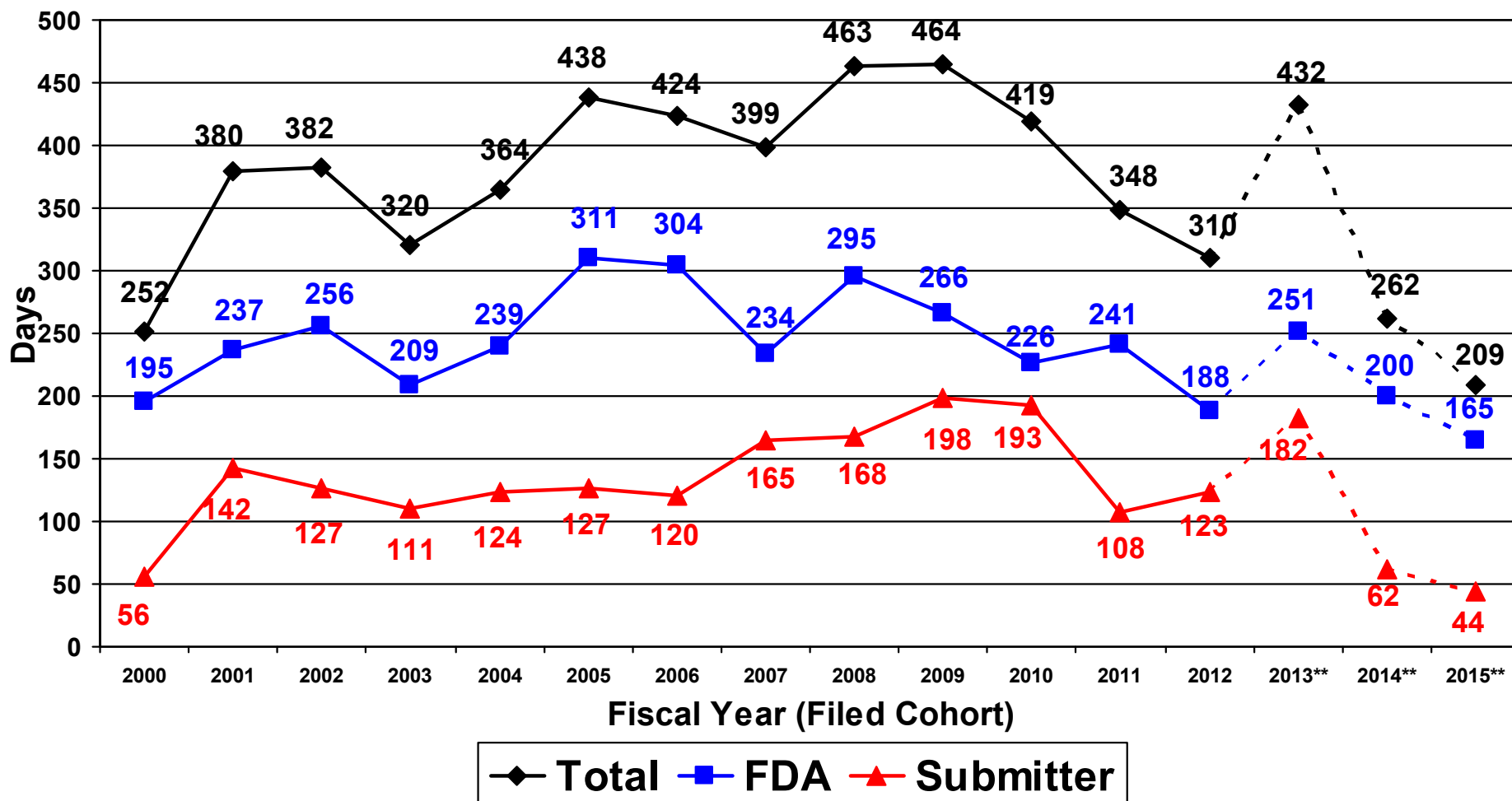
Percent of PMAs With Major Deficiency Letter (MAJR) on 1st FDA Review Cycle*



*Includes original PMAs only; FY 2013 - FY 2015 are receipt cohorts including PMAs filed as of 9/30/2015, prior cohorts are filed cohorts

Average Time to MDUFA Decision: PMAs*

(As of December 31, 2015)

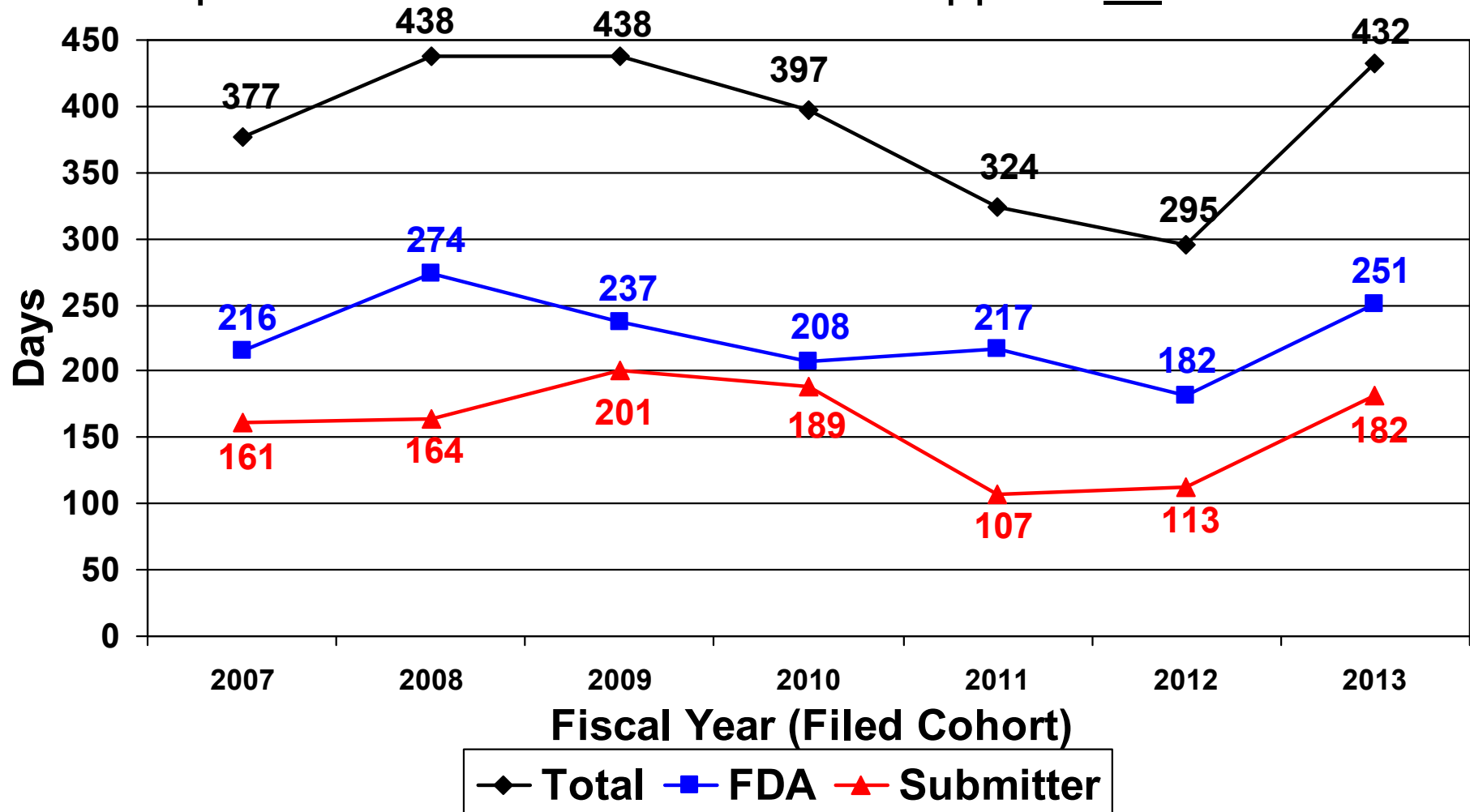


*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 12/31/2015, prior cohorts are filed cohorts; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY13 = 97% (28/29); FY14 = 89% (25/28); FY15 = 45% (19/42)

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

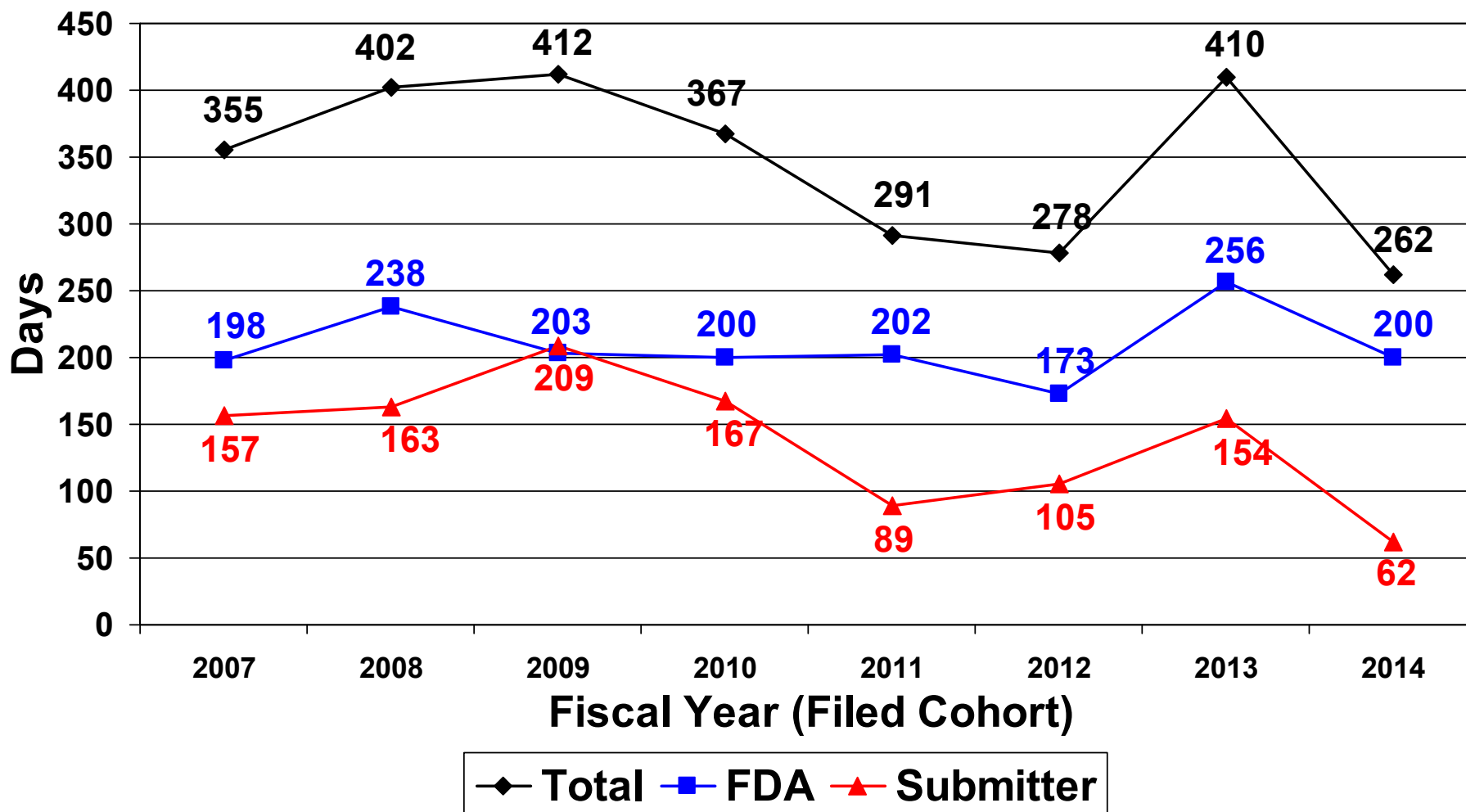
**Proportion of cohort closed (MDUFA decision) in this comparison:

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 12/31/2015)

Average Time to MDUFA Decision: PMAs*

- Comparison of Filed Cohorts When Approx. 89% Closed** -



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

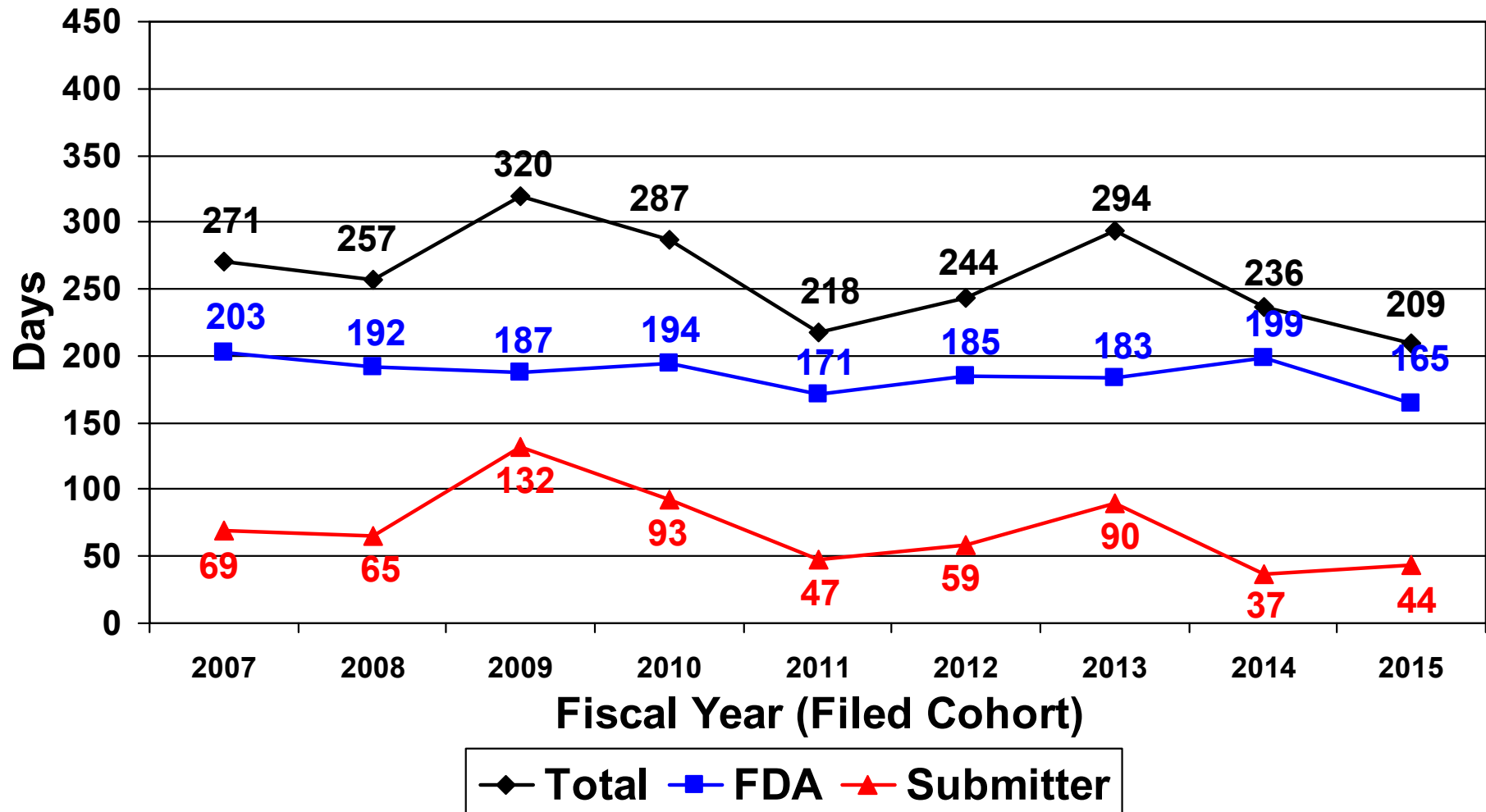
**Proportion of cohort closed (MDUFA decision) in this comparison:

FY07 = 31/35; FY08 = 27/30; FY09 = 29/32; FY10 = 38/43; FY11 = 38/43; FY12 = 21/24;

FY13 = 26/29; FY14 = 25/28

Average Time to MDUFA Decision: PMAs*

- Comparison of Filed Cohorts When Approx. 45% Closed** -



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

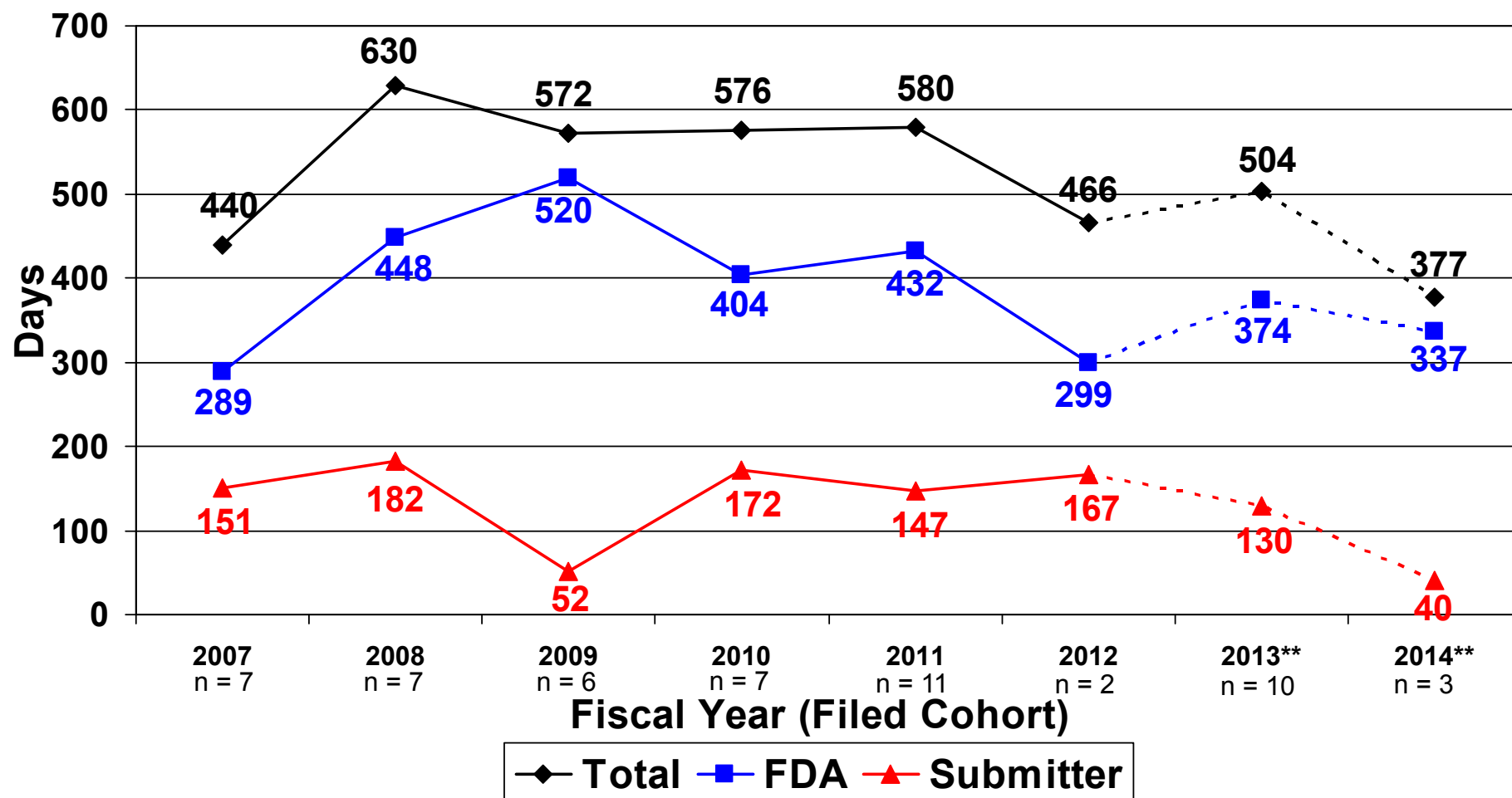
**Proportion of cohort closed (MDUFA decision) in this comparison:

FY07 = 16/35; FY08 = 14/30; FY09 = 14/32; FY10 = 19/43; FY11 = 19/43; FY12 = 11/24;

FY13 = 13/29; FY14 = 13/28; FY15 = 19/42

Average Time to MDUFA Decision: PMAs With Panel Review*

(As of December 31, 2015)

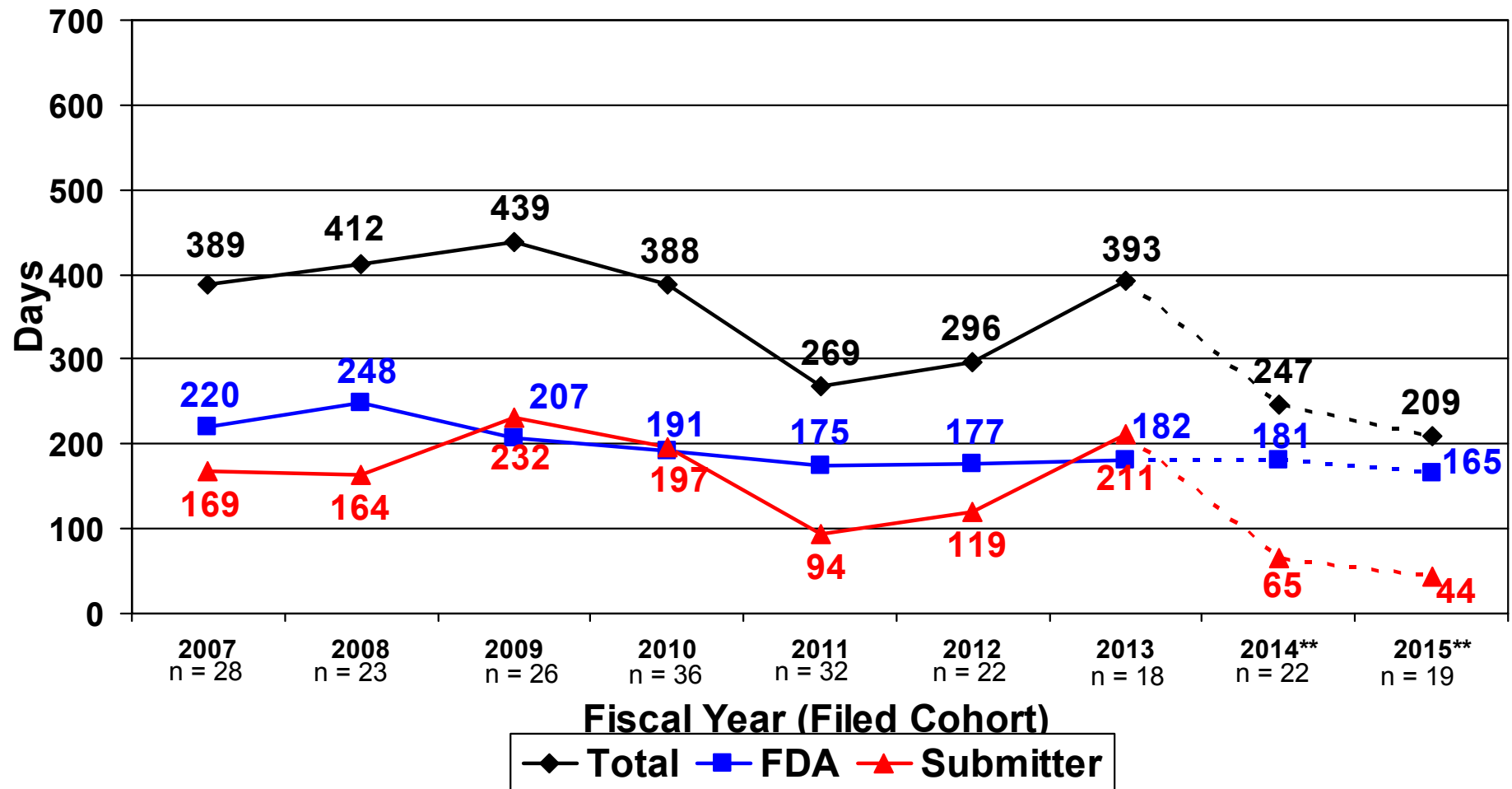


*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 12/31/2015, prior cohorts are filed cohorts; times may not add to total due to rounding;

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

Average Time to MDUFA Decision: PMAs Without Panel Review*

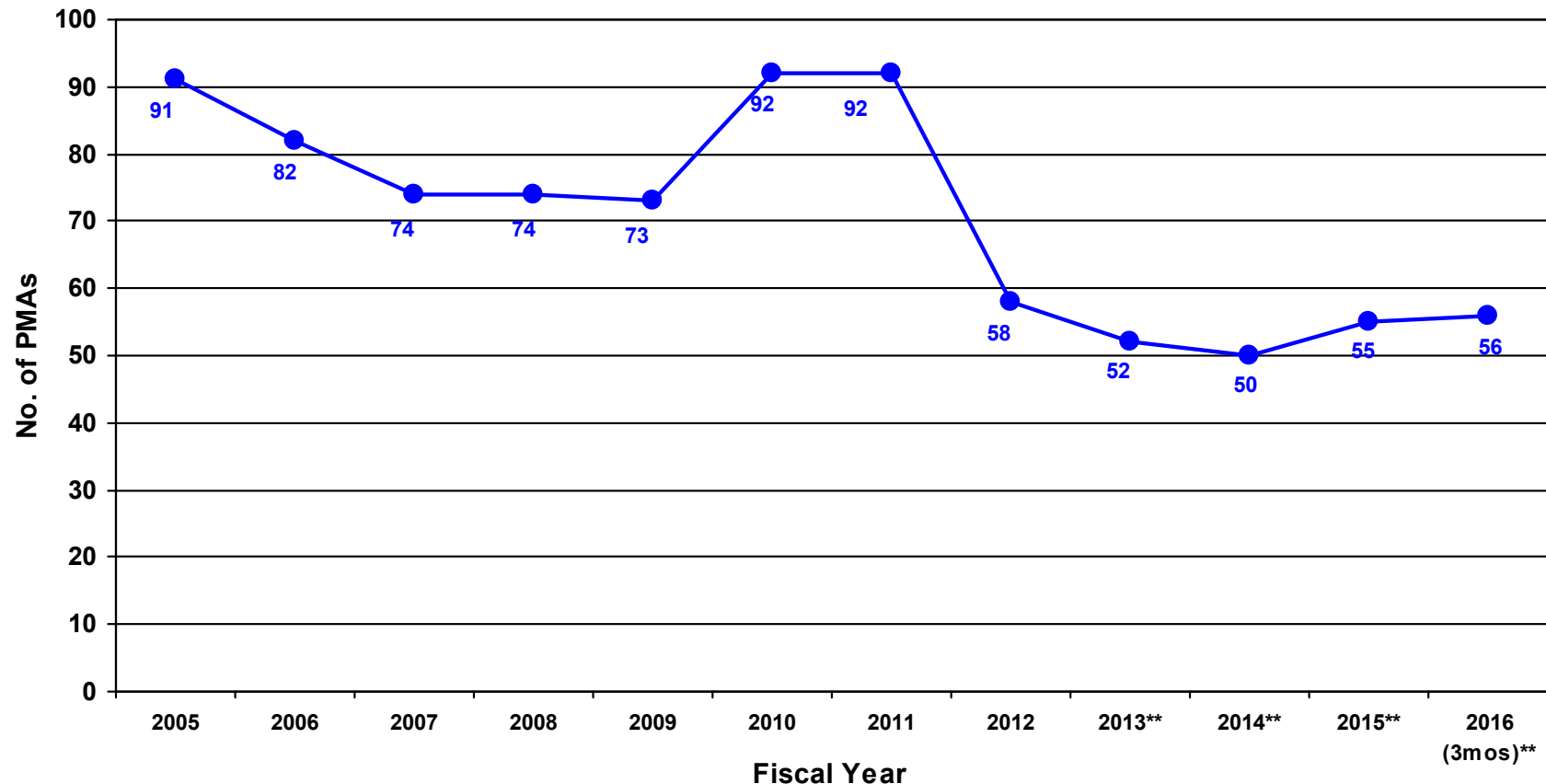
(As of December 31, 2015)



*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 12/31/2015, prior cohorts are filed cohorts; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY14 = 96% (22/23); FY15 = 49% (19/39)

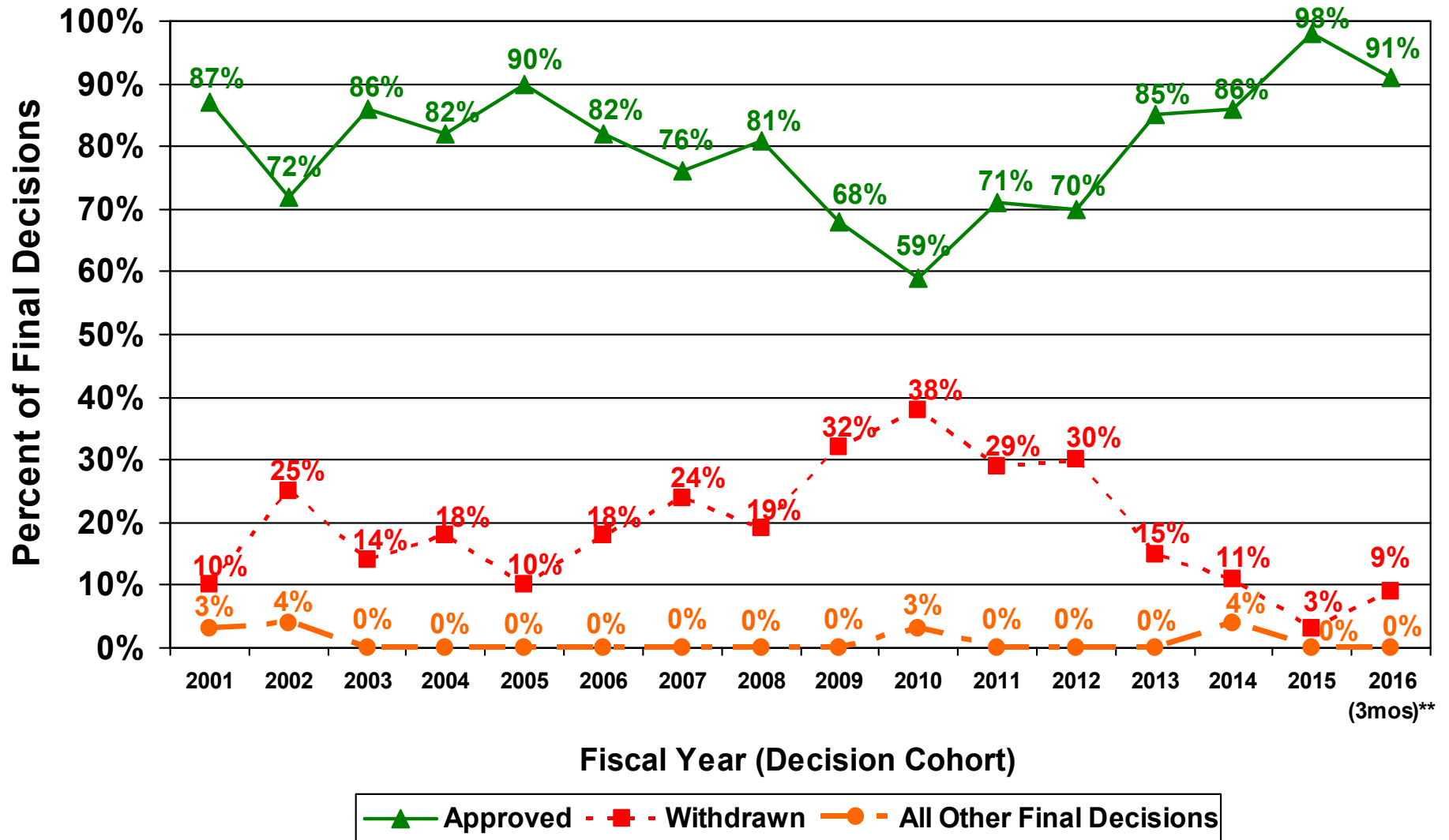
PMAs Pending* at End of Year



*Original PMAs under review or on hold

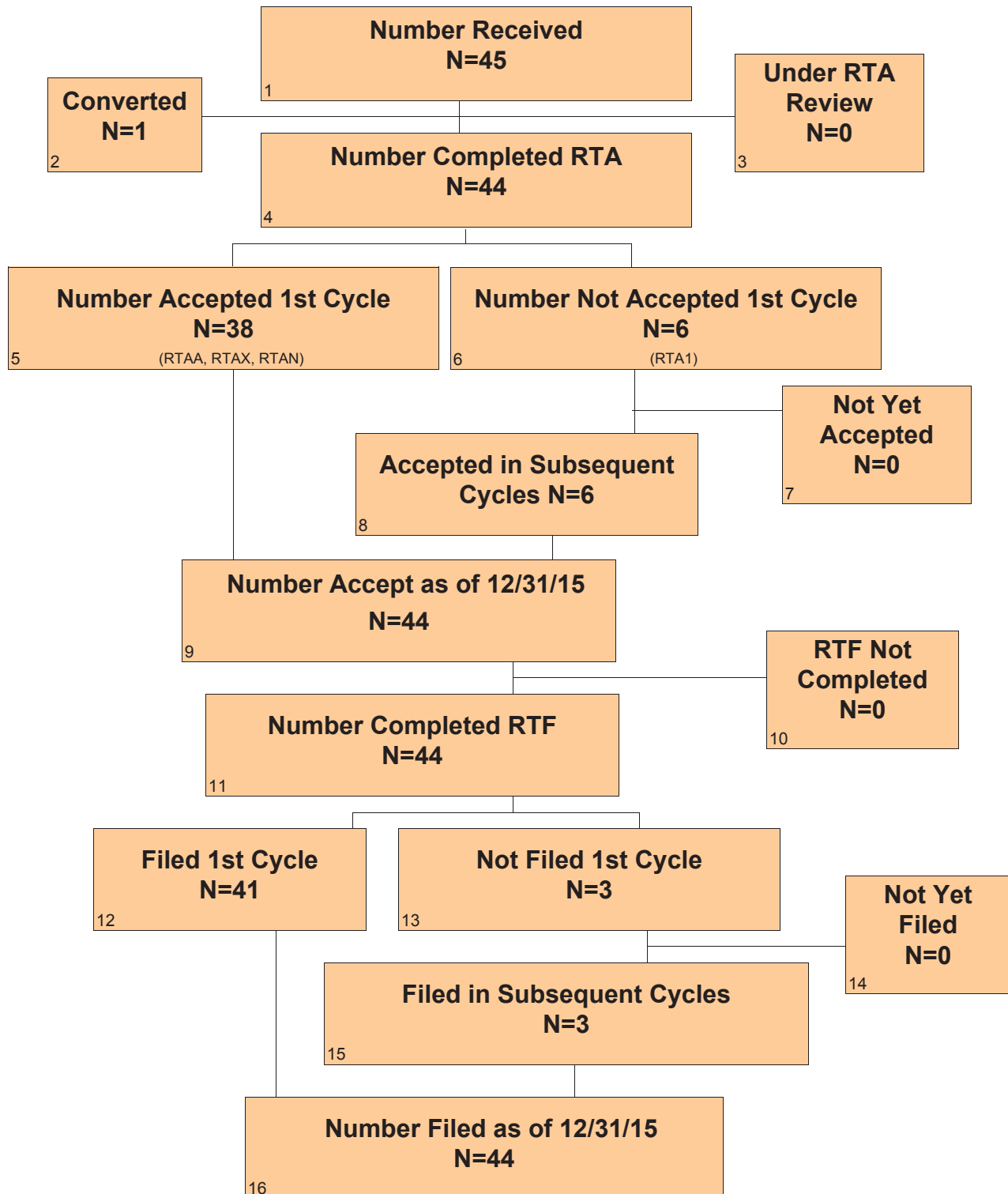
**Excludes FY 2013 - FY 2016 receipts that were not accepted for review at year's end; FY 2015 increase reflects increase in filed PMAs (42 PMAs compared to 24, 29, and 28 for FY 2012 – FY 2014, respectively)

Percent of PMAs Approved*

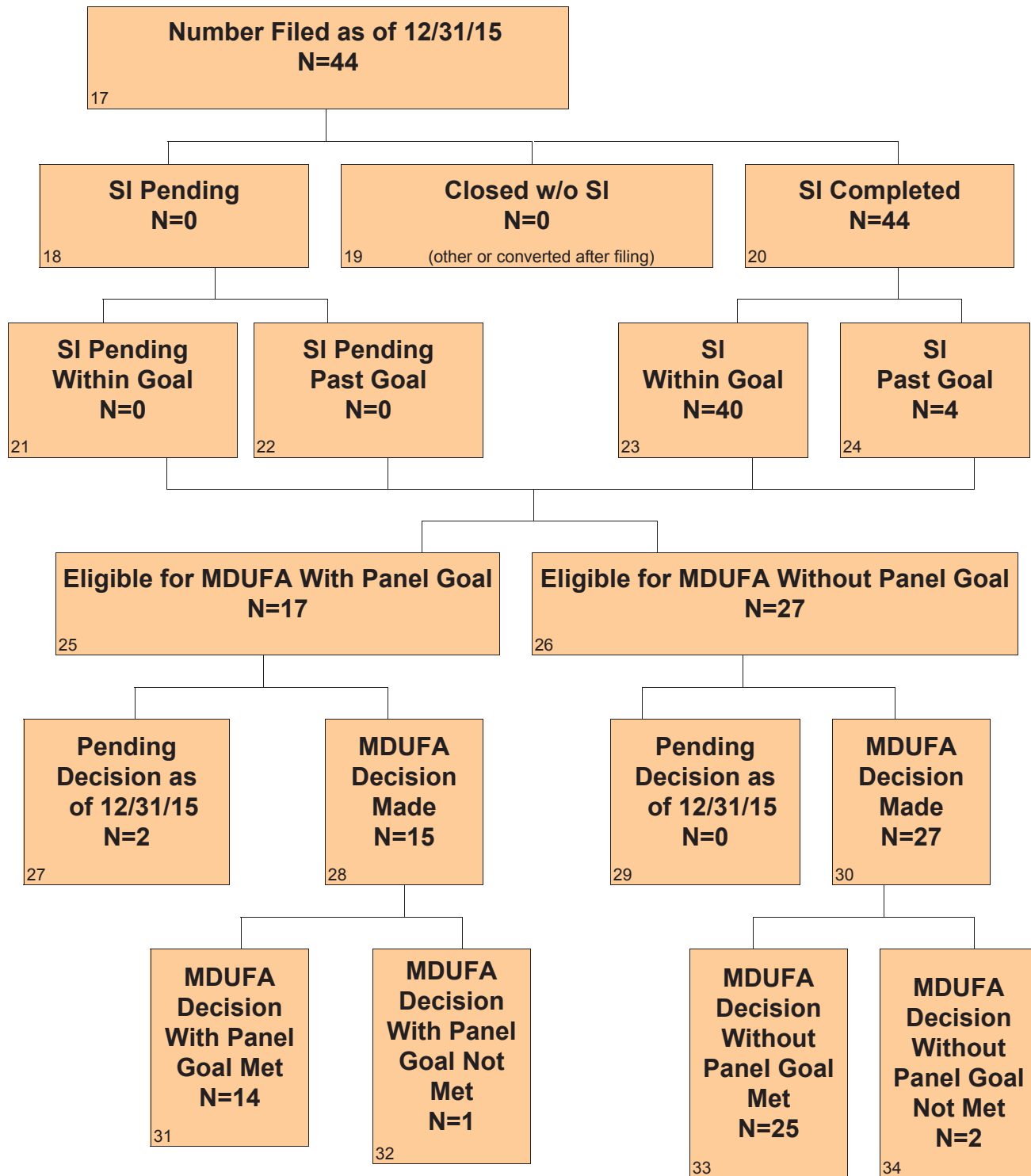


*Based on original PMAs that were accepted for filing as of 12/31/2015; percentages may not add to 100% due to rounding

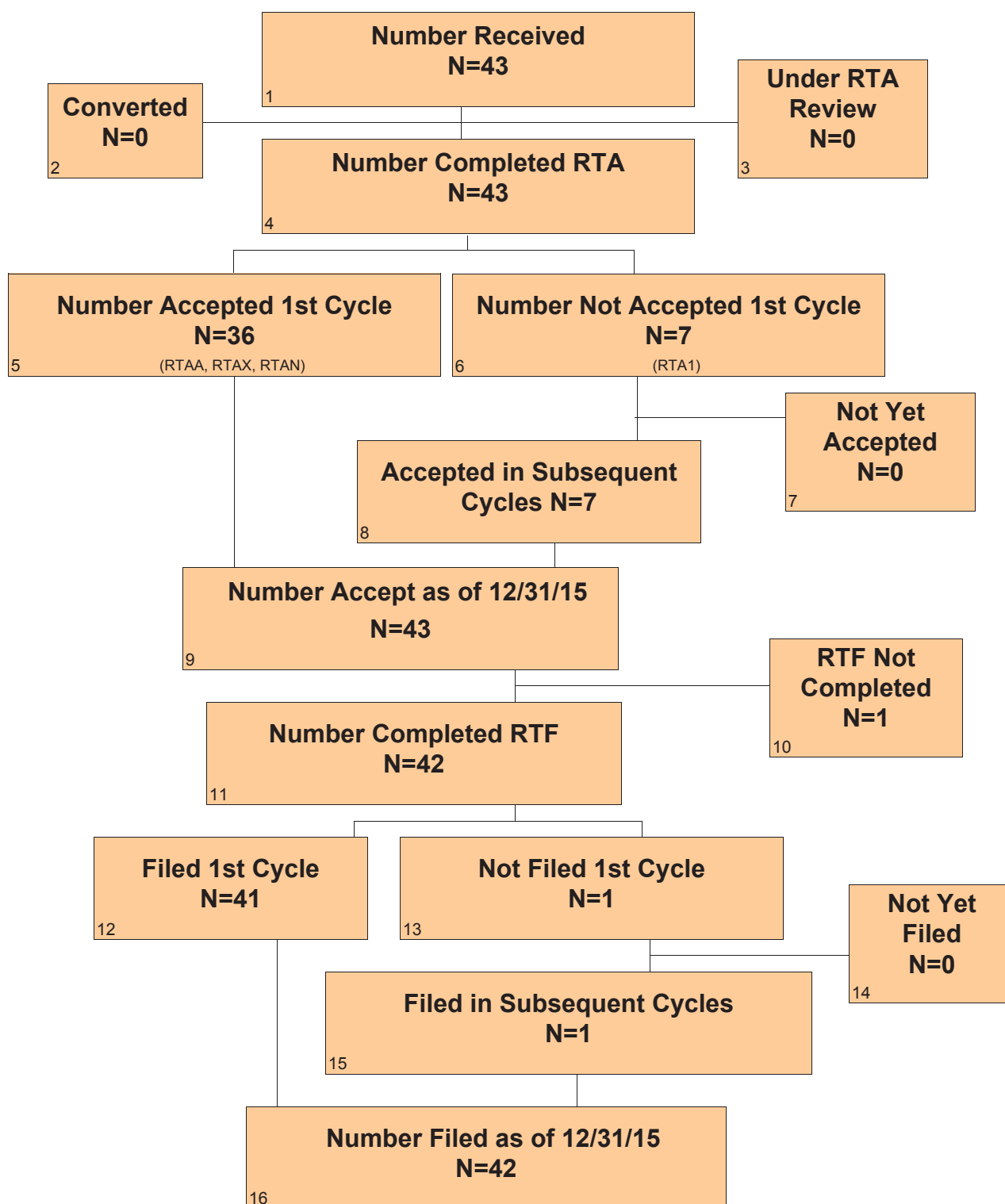
CDRH PMA Original and Panel Track Supplements - FY 2013 As of 12/31/15



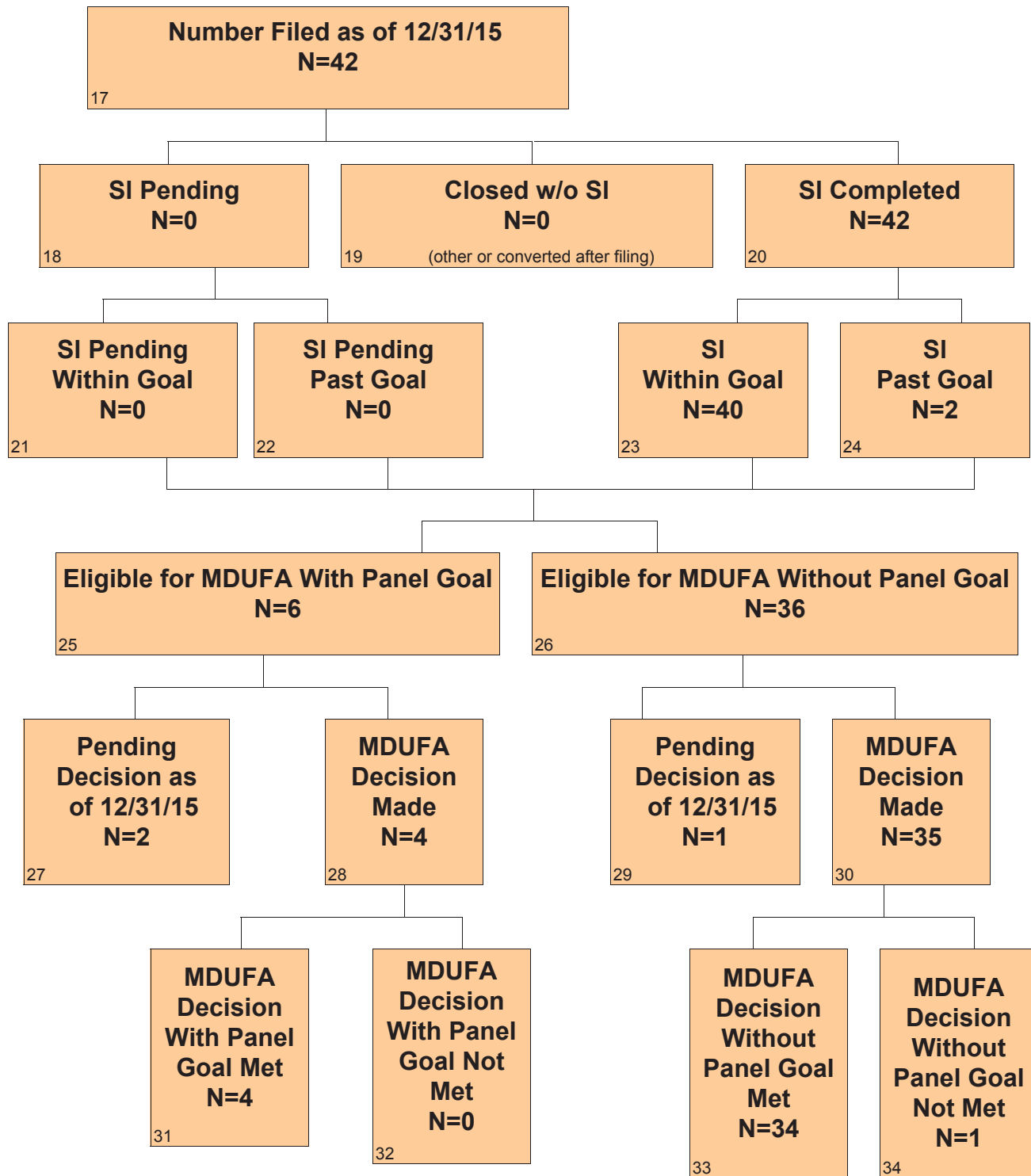
CDRH PMA Original and Panel Track Supplements - FY 2013 As of 12/31/15 Continued



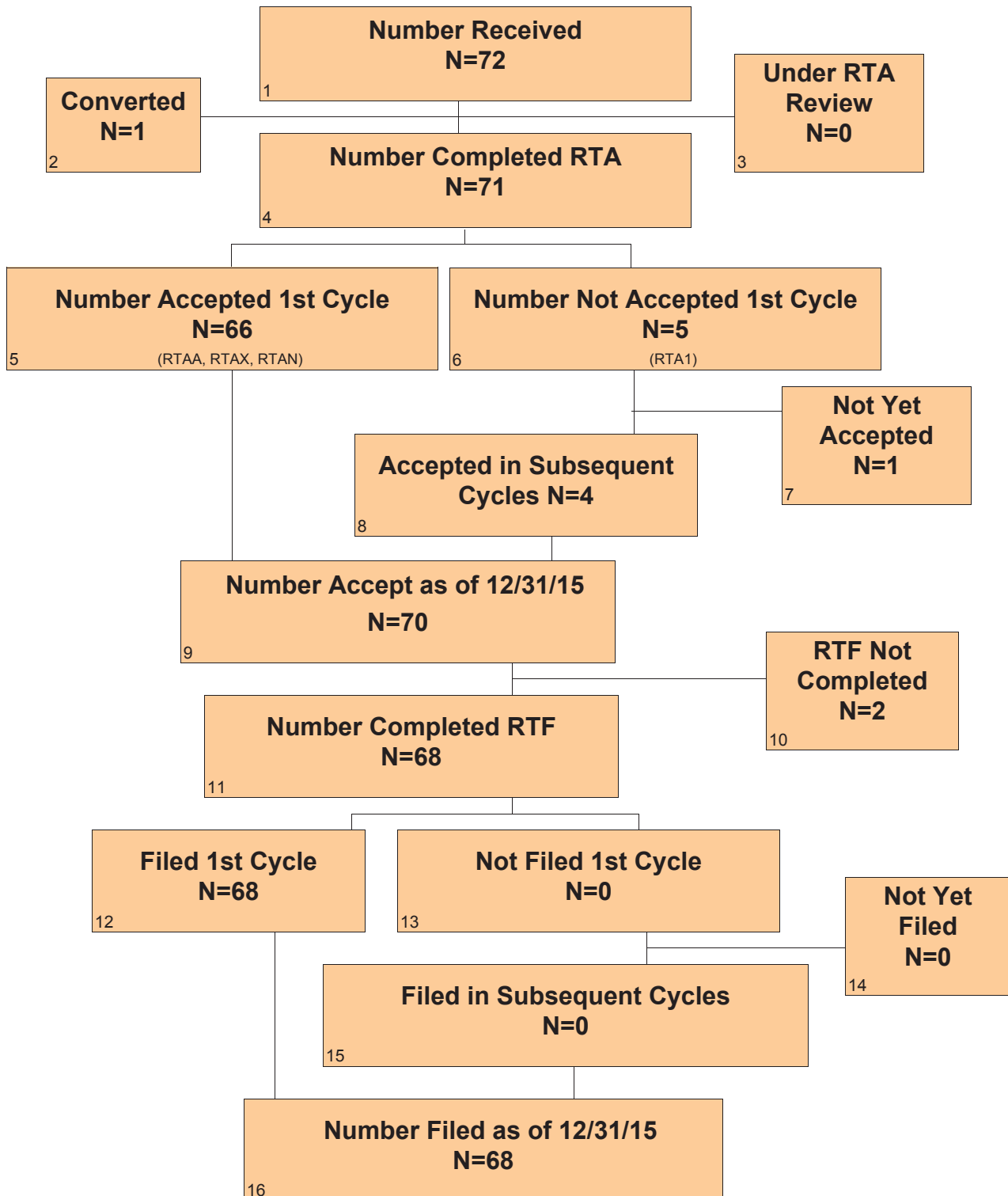
CDRH PMA Original and Panel Track Supplements - FY 2014 As of 12/31/15



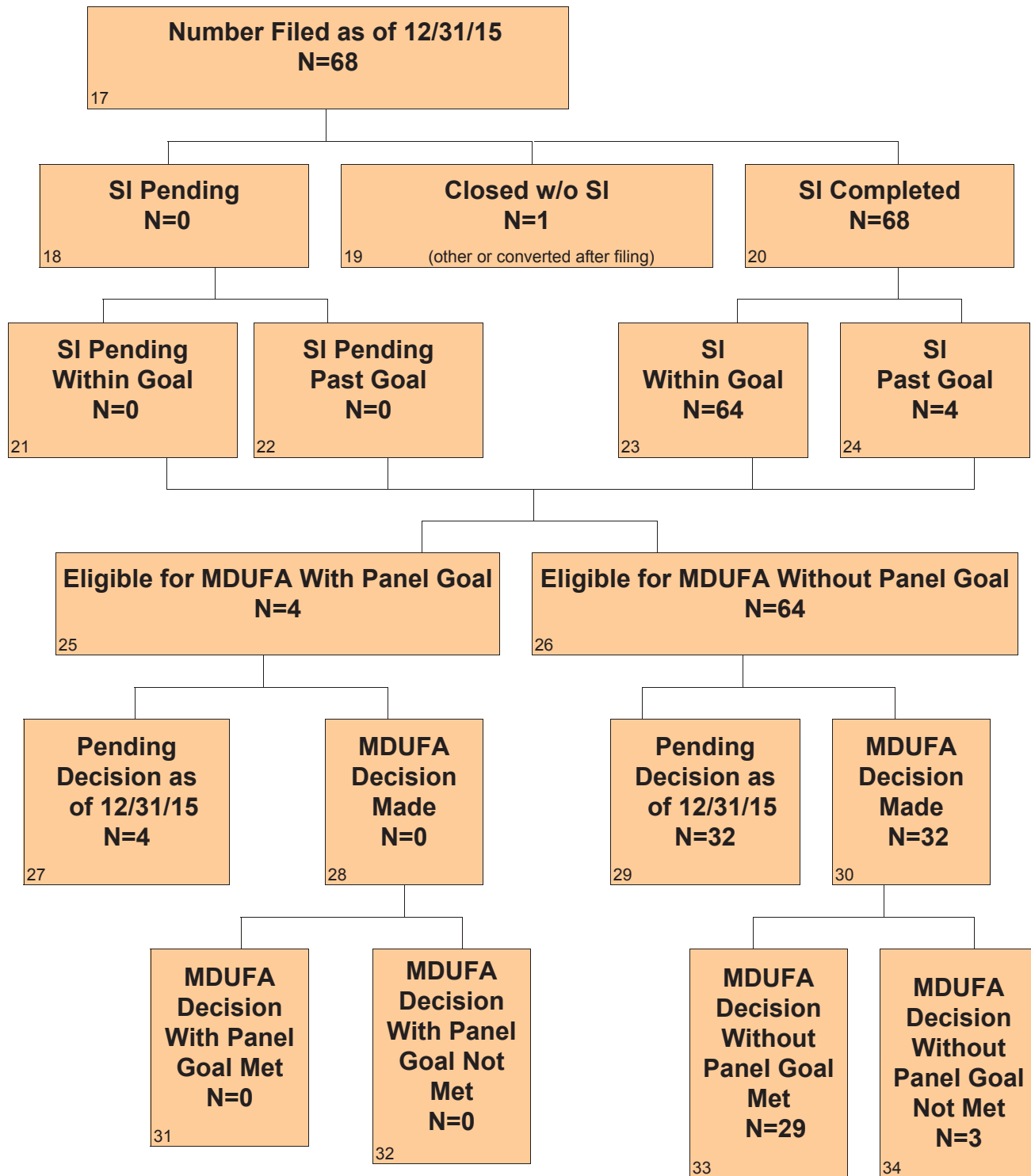
CDRH PMA Original and Panel Track Supplements - FY 2014 As of 12/31/15 Continued



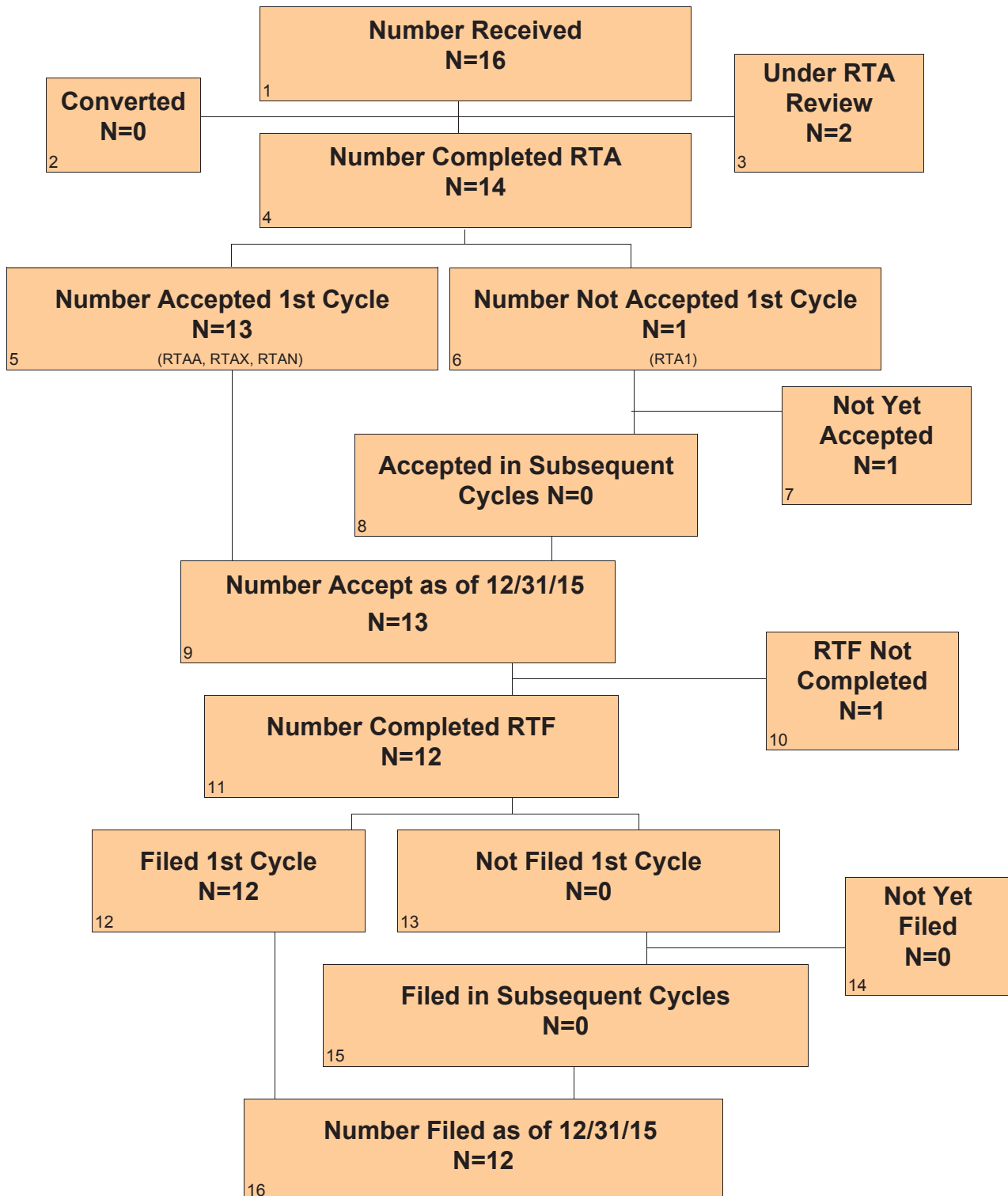
CDRH PMA Original and Panel Track Supplements - FY 2015 As of 12/31/15



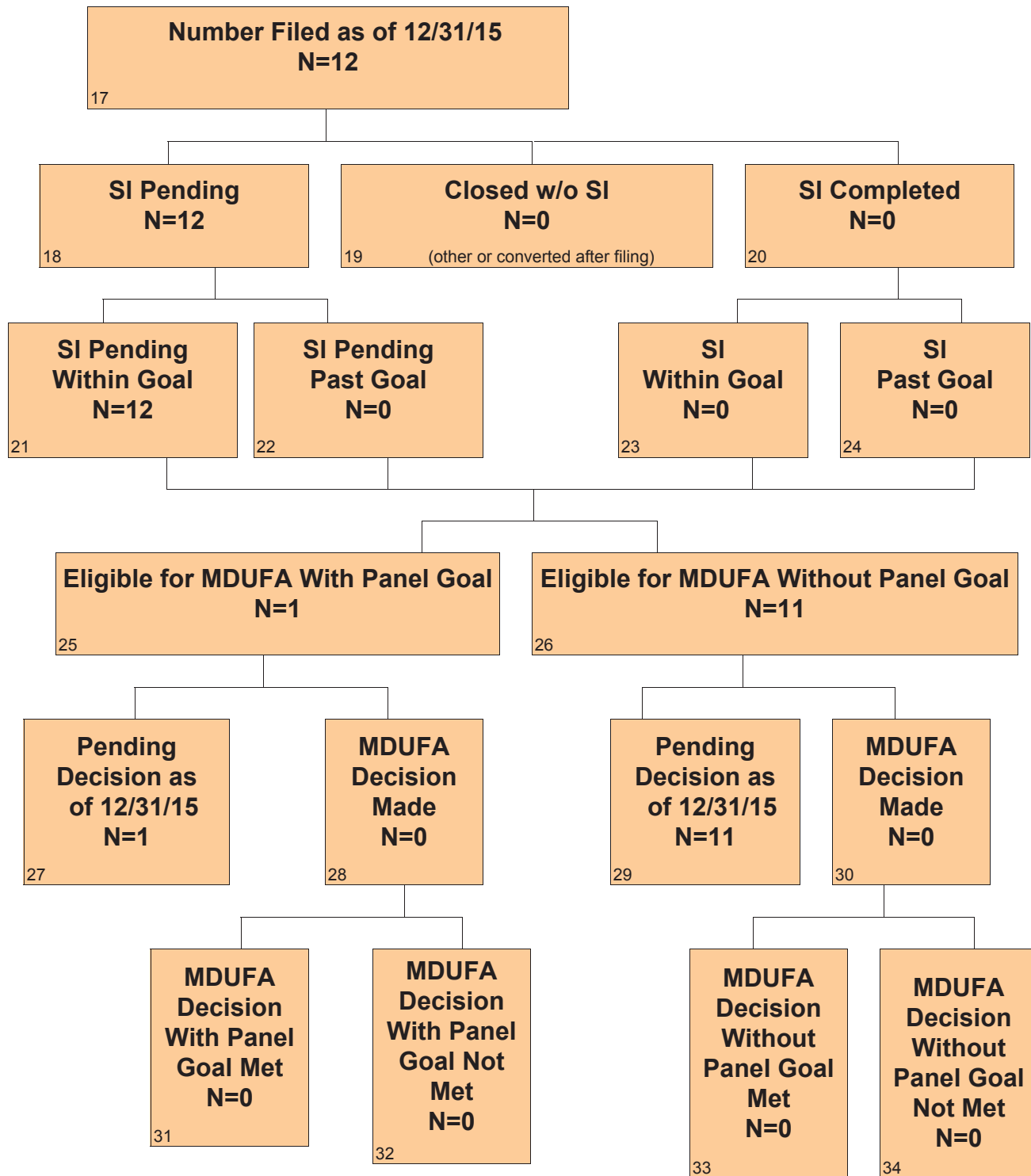
CDRH PMA Original and Panel Track Supplements - FY 2015 As of 12/31/15 Continued



CDRH PMA Original and Panel Track Supplements - FY 2016 As of 12/31/15



CDRH PMA Original and Panel Track Supplements - FY 2016 As of 12/31/15 Continued



Section 1 PMA Original and Panel Track Supplements - Center Level

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	35	43	72	16	
Closed before RTA action	1	0	1	0	
Number with accepted RTA review	27	35	64	13	
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	2	
Number Not Accepted for Filing Review	6	7	5	1	
Rate of submissions not accepted for filing review	17.6%	16.3%	7%	7.1%	

*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	16	
Number Accepted	38	36	66	13	
Completed RTF	44	42	68	12	
Number Not Filed	3	1	0	0	
Rate of submissions Not Filed	6.8%	2.4%	0%	0%	

Table 1.3 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	44	42	68	12	
SI Goal Met	40	40	64	0	
SI Goal Not Met	4	2	4	0	
SI Pending Within Goal	0	0	0	12	
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%	N/A	

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	0	
Average number of FDA days to Substantive Interaction	109.73	90.02	91.81	0.00	
20th Percentile FDA days to Substantive Interaction	86	87	85	0	
40th Percentile FDA days to Substantive Interaction	88	88	88	0	
60th Percentile FDA days to Substantive Interaction	90	89	90	0	
80th Percentile FDA days to Substantive Interaction	90	90	90	0	
Maximum FDA days to Substantive Interaction	1031	136	168	0	

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
	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	27	36	64	11	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	27	35	32	0	
MDUFA III Decisions Goal Met	25	34	29	0	
PMAs pending MDUFA III Decision	0	1	32	11	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	92.6%	97.1%	90.6%	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
	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	17	6	4	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	15	4	0	0	
MDUFA III Decisions Goal Met	14	4	0	0	
PMAs pending MDUFA III Decision	2	2	4	1	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	93.3%	100%	N/A	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	35	32	0	
Average FDA days to MDUFA III decision	208.81	178.34	167.50	0.00	
20th Percentile FDA days to MDUFA III decision	175	177	164	0	
40th Percentile FDA days to MDUFA III decision	178	179	176	0	
60th Percentile FDA days to MDUFA III decision	180	179	178	0	
80th Percentile FDA days to MDUFA III decision	180	180	180	0	
Maximum FDA days to MDUFA III decision	1031	359	189	0	
Average Industry days to MDUFA III decision	163.81	50.11	35.28	0.00	
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	46	42	0	
80th Percentile Industry days to MDUFA III decision	337	92	77	0	
Maximum Industry days to MDUFA III decision	563	238	140	0	
Average Total days to MDUFA III decision	372.63	228.46	202.78	0.00	
20th Percentile Total days to MDUFA III decision	181	179	177	0	
40th Percentile Total days to MDUFA III decision	253	180	179	0	
60th Percentile Total days to MDUFA III decision	345	238	197	0	
80th Percentile Total days to MDUFA III decision	538	284	244	0	
Maximum Total days to MDUFA III decision	1031	418	315	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	0	0	
Average FDA days to MDUFA III decision	339.60	332.75	0.00	0.00	
20th Percentile FDA days to MDUFA III decision	276	316	0	0	
40th Percentile FDA days to MDUFA III decision	314	318	0	0	
60th Percentile FDA days to MDUFA III decision	316	320	0	0	
80th Percentile FDA days to MDUFA III decision	360	344	0	0	
Maximum FDA days to MDUFA III decision	668	379	0	0	
Average Industry days to MDUFA III decision	98.87	74.75	0.00	0.00	
20th Percentile Industry days to MDUFA III decision	0	12	0	0	
40th Percentile Industry days to MDUFA III decision	17	36	0	0	
60th Percentile Industry days to MDUFA III decision	119	85	0	0	
80th Percentile Industry days to MDUFA III decision	187	132	0	0	
Maximum Industry days to MDUFA III decision	295	178	0	0	
Average Total days to MDUFA III decision	438.47	407.50	0.00	0.00	
20th Percentile Total days to MDUFA III decision	312	367	0	0	
40th Percentile Total days to MDUFA III decision	338	402	0	0	
60th Percentile Total days to MDUFA III decision	454	412	0	0	
80th Percentile Total days to MDUFA III decision	577	448	0	0	
Maximum Total days to MDUFA III decision	805	498	0	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	11	
Number with MDUFA decision	27	35	32	0	
Number of Withdrawals	1	0	0	0	
Number of Not Approvable	4	2	5	0	
Rate of Withdrawals	3.7%	0%	0%	N/A	
Rate of Not Approvable	14.8%	5.7%	15.6%	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	0	0	
Number of Withdrawals	1	0	0	0	
Number of Not Approvable	3	0	0	0	
Rate of Withdrawals	6.7%	0%	N/A	N/A	
Rate of Not Approvable	20%	0%	N/A	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	3	0	
Mean FDA days for submissions that missed goal	661	201	186	0	
Mean industry days for submissions that missed goal	57	43	93	0	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0	0	
Mean FDA days for submissions that missed goal	668	0	0	0	
Mean industry days for submissions that missed goal	0	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	10	
Closed before RTA action	1	0	1	0	
Number with accepted RTA review	20	30	47	7	
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	2	
Number Not Accepted for Filing Review	6	6	5	1	
Rate of submissions not accepted for filing review	22.2%	16.2%	9.3%	12.5%	

*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	10	
Number Accepted	28	31	49	7	
Completed RTF	34	36	51	6	
Number Not Filed	3	1	0	0	
Rate of submissions Not Filed	8.8%	2.8%	0%	0%	

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	6	
SI Goal Met	31	34	48	0	
SI Goal Not Met	3	2	3	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	91.2%	94.4%	94.1%	N/A	

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	0	
Average number of FDA days to Substantive Interaction	115.88	90.64	94.39	0.00	
20th Percentile FDA days to Substantive Interaction	86	87	86	0	
40th Percentile FDA days to Substantive Interaction	88	88	88	0	
60th Percentile FDA days to Substantive Interaction	89	89	89	0	
80th Percentile FDA days to Substantive Interaction	90	90	90	0	
Maximum FDA days to Substantive Interaction	1031	136	168	0	

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	5	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	21	29	19	0	
MDUFA III Decisions Goal Met	19	28	16	0	
PMAs pending MDUFA III Decision	0	1	28	5	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	90.5%	96.6%	84.2%	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	0	0	
MDUFA III Decisions Goal Met	10	4	0	0	
PMAs pending MDUFA III Decision	2	2	4	1	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	90.9%	100%	N/A	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	29	19	0	
Average FDA days to MDUFA III decision	225.05	181.45	174.63	0.00	
20th Percentile FDA days to MDUFA III decision	177	177	177	0	
40th Percentile FDA days to MDUFA III decision	180	179	178	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	189	0	
Average Industry days to MDUFA III decision	167.29	44.48	31.47	0.00	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	68	4	0	0	
60th Percentile Industry days to MDUFA III decision	113	44	38	0	
80th Percentile Industry days to MDUFA III decision	356	80	70	0	
Maximum Industry days to MDUFA III decision	563	168	135	0	
Average Total days to MDUFA III decision	392.33	225.93	206.11	0.00	
20th Percentile Total days to MDUFA III decision	180	179	178	0	
40th Percentile Total days to MDUFA III decision	260	183	179	0	
60th Percentile Total days to MDUFA III decision	397	232	215	0	
80th Percentile Total days to MDUFA III decision	540	262	252	0	
Maximum Total days to MDUFA III decision	1031	392	314	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	0	0	
Average FDA days to MDUFA III decision	359.18	332.75	0.00	0.00	
20th Percentile FDA days to MDUFA III decision	290	316	0	0	
40th Percentile FDA days to MDUFA III decision	315	318	0	0	
60th Percentile FDA days to MDUFA III decision	316	320	0	0	
80th Percentile FDA days to MDUFA III decision	501	344	0	0	
Maximum FDA days to MDUFA III decision	668	379	0	0	
Average Industry days to MDUFA III decision	108.09	74.75	0.00	0.00	
20th Percentile Industry days to MDUFA III decision	0	12	0	0	
40th Percentile Industry days to MDUFA III decision	28	36	0	0	
60th Percentile Industry days to MDUFA III decision	141	85	0	0	
80th Percentile Industry days to MDUFA III decision	186	132	0	0	
Maximum Industry days to MDUFA III decision	295	178	0	0	
Average Total days to MDUFA III decision	467.27	407.50	0.00	0.00	
20th Percentile Total days to MDUFA III decision	316	367	0	0	
40th Percentile Total days to MDUFA III decision	348	402	0	0	
60th Percentile Total days to MDUFA III decision	490	412	0	0	
80th Percentile Total days to MDUFA III decision	610	448	0	0	
Maximum Total days to MDUFA III decision	805	498	0	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	5	
Number with MDUFA decision	21	29	19	0	
Number of Withdrawals	1	0	0	0	
Number of Not Approvable	3	2	4	0	
Rate of Withdrawals	4.8%	0%	0%	N/A	
Rate of Not Approvable	14.3%	6.9%	21.1%	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	0	0	
Number of Withdrawals	1	0	0	0	
Number of Not Approvable	2	0	0	0	
Rate of Withdrawals	9.1%	0%	N/A	N/A	
Rate of Not Approvable	18.2%	0%	N/A	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	3	0	
Mean FDA days for submissions that missed goal	661	201	186	0	
Mean industry days for submissions that missed goal	57	43	93	0	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0	0	
Mean FDA days for submissions that missed goal	668	0	0	0	
Mean industry days for submissions that missed goal	0	0	0	0	
	0	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	6	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	7	5	17	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	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	6	
Number Accepted	10	5	17	6	
Completed RTF	10	6	17	6	
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	6	
SI Goal Met	9	6	16	0	
SI Goal Not Met	1	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	90%	100%	94.1%	N/A	

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	0	
Average number of FDA days to Substantive Interaction	88.80	86.33	84.06	0.00	
20th Percentile FDA days to Substantive Interaction	86	85	84	0	
40th Percentile FDA days to Substantive Interaction	90	86	87	0	
60th Percentile FDA days to Substantive Interaction	90	87	90	0	
80th Percentile FDA days to Substantive Interaction	90	88	90	0	
Maximum FDA days to Substantive Interaction	112	89	91	0	

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	6	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	6	6	13	0	
MDUFA III Decisions Goal Met	6	6	13	0	
PMAs pending MDUFA III Decision	0	0	4	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 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	13	0	
Average FDA days to MDUFA III decision	152.00	163.33	157.08	0	
20th Percentile FDA days to MDUFA III decision	116	177	143	0	
40th Percentile FDA days to MDUFA III decision	167	179	169	0	
60th Percentile FDA days to MDUFA III decision	174	179	173	0	
80th Percentile FDA days to MDUFA III decision	177	179	177	0	
Maximum FDA days to MDUFA III decision	179	180	180	0	
Average Industry days to MDUFA III decision	151.67	77.33	40.85	0	
20th Percentile Industry days to MDUFA III decision	81	0	0	0	
40th Percentile Industry days to MDUFA III decision	107	0	0	0	
60th Percentile Industry days to MDUFA III decision	118	106	45	0	
80th Percentile Industry days to MDUFA III decision	133	120	182	0	
Maximum Industry days to MDUFA III decision	400	238	140	0	
Average Total days to MDUFA III decision	303.67	240.67	197.92	0	
20th Percentile Total days to MDUFA III decision	217	179	171	0	
40th Percentile Total days to MDUFA III decision	248	179	179	0	
60th Percentile Total days to MDUFA III decision	284	283	196	0	
80th Percentile Total days to MDUFA III decision	307	299	226	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	0.00	0.00	0.00	
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	0.00	0.00	0.00	
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	0.00	0.00	0.00	
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	6	
Number with MDUFA decision	6	6	13	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%	7.7%	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	

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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	85.00	87.00	128.00	0.00	
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	0	0	
MDUFA III Decisions Goal Met	1	1	0	0	
PMAs pending MDUFA III Decision	0	0	2	0	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	N/A	N/A	

Table 1.6.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	0	0	
Average FDA days to MDUFA III decision	180.00	179.00	0	0	
20th Percentile FDA days to MDUFA III decision	180	179	0	0	
40th Percentile FDA days to MDUFA III decision	180	179	0	0	
60th Percentile FDA days to MDUFA III decision	180	179	0	0	
80th Percentile FDA days to MDUFA III decision	180	179	0	0	
Maximum FDA days to MDUFA III decision	180	179	0	0	
Average Industry days to MDUFA III decision	360.00	0.00	0	0	
20th Percentile Industry days to MDUFA III decision	360	0	0	0	
40th Percentile Industry days to MDUFA III decision	360	0	0	0	
60th Percentile Industry days to MDUFA III decision	360	0	0	0	
80th Percentile Industry days to MDUFA III decision	360	0	0	0	
Maximum Industry days to MDUFA III decision	360	0	0	0	
Average Total days to MDUFA III decision	540.00	179.00	0	0	
20th Percentile Total days to MDUFA III decision	540	179	0	0	
40th Percentile Total days to MDUFA III decision	540	179	0	0	
60th Percentile Total days to MDUFA III decision	540	179	0	0	
80th Percentile Total days to MDUFA III decision	540	179	0	0	
Maximum Total days to MDUFA III decision	540	179	0	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	320.00	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	28.00	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	348.00	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	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 1.10.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	5	
Closed before RTA action	1	0	1	0	
Number with accepted RTA review	15	15	25	4	
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	1	
Number Not Accepted for Filing Review	0	1	2	0	
Rate of submissions not accepted for filing review	0%	5.9%	7.4%	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.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	5	
Number Accepted	19	16	25	4	
Completed RTF	19	17	27	3	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	0%	0%	0%	0%	

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	3	
SI Goal Met	17	16	26	0	
SI Goal Not Met	2	1	1	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	89.5%	94.1%	96.3%	N/A	

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	0	
Average number of FDA days to Substantive Interaction	137.95	87.71	91.85	0	
20th Percentile FDA days to Substantive Interaction	85	87	85	0	
40th Percentile FDA days to Substantive Interaction	88	88	88	0	
60th Percentile FDA days to Substantive Interaction	90	89	89	0	
80th Percentile FDA days to Substantive Interaction	90	90	90	0	
Maximum FDA days to Substantive Interaction	1031	91	145	0	

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	24	2	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	15	16	12	0	
MDUFA III Decisions Goal Met	13	15	9	0	
PMAs pending MDUFA III Decision	0	0	12	2	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	86.7%	93.8%	75%	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	3	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	3	1	
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	66.7%	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	12	0	
Average FDA days to MDUFA III decision	243.60	174.25	174.67	0.00	
20th Percentile FDA days to MDUFA III decision	180	177	177	0	
40th Percentile FDA days to MDUFA III decision	180	178	178	0	
60th Percentile FDA days to MDUFA III decision	180	179	180	0	
80th Percentile FDA days to MDUFA III decision	259	180	184	0	
Maximum FDA days to MDUFA III decision	1031	201	189	0	
Average Industry days to MDUFA III decision	154.67	29.31	35.42	0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	48	0	0	0	
60th Percentile Industry days to MDUFA III decision	110	0	44	0	
80th Percentile Industry days to MDUFA III decision	464	43	69	0	
Maximum Industry days to MDUFA III decision	563	161	135	0	
Average Total days to MDUFA III decision	398.27	212.43	210.08	0	
20th Percentile Total days to MDUFA III decision	222	179	178	0	
40th Percentile Total days to MDUFA III decision	281	180	184	0	
60th Percentile Total days to MDUFA III decision	391	193	222	0	
80th Percentile Total days to MDUFA III decision	714	252	255	0	
Maximum Total days to MDUFA III decision	1031	338	314	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	318.00	0.00	0.00	
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	0.00	0.00	0.00	0.00	
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	318.00	0.00	0.00	
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	24	2	
Number with MDUFA decision	15	16	12	2	
Number of Withdrawals	1	0	0	0	
Number of Not Approvable	2	0	3	0	
Rate of Withdrawals	6.7%	0%	0%	0%	
Rate of Not Approvable	13.3%	0%	25%	0%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4	1	3	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	3	0	
Mean FDA days for submissions that missed goal	661	201	186	0	
Mean industry days for submissions that missed goal	57	43	93	0	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0	0	
Mean FDA days for submissions that missed goal	668	0	0	0	
Mean industry days for submissions that missed goal	0	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	0	
SI Goal Not Met	1	1	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	0%	66.7%	100%	N/A	

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	0	
Average number of FDA days to Substantive Interaction	92.00	90.33	108.25	0.00	
20th Percentile FDA days to Substantive Interaction	92	90	89	0	
40th Percentile FDA days to Substantive Interaction	92	90	90	0	
60th Percentile FDA days to Substantive Interaction	92	90	90	0	
80th Percentile FDA days to Substantive Interaction	92	91	120	0	
Maximum FDA days to Substantive Interaction	92	91	166	0	

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	3	4	1	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	3	2	0	
MDUFA III Decisions Goal Met	1	3	2	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	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	2	0	
Average FDA days to MDUFA III decision	180.00	182.33	171.00	0	
20th Percentile FDA days to MDUFA III decision	180	178	167	0	
40th Percentile FDA days to MDUFA III decision	180	179	170	0	
60th Percentile FDA days to MDUFA III decision	180	182	172	0	
80th Percentile FDA days to MDUFA III decision	180	186	175	0	
Maximum FDA days to MDUFA III decision	180	190	178	0	
Average Industry days to MDUFA III decision	0.00	91.67	7.00	0	
20th Percentile Industry days to MDUFA III decision	0	48	3	0	
40th Percentile Industry days to MDUFA III decision	0	69	6	0	
60th Percentile Industry days to MDUFA III decision	0	97	8	0	
80th Percentile Industry days to MDUFA III decision	0	132	11	0	
Maximum Industry days to MDUFA III decision	0	168	14	0	
Average Total days to MDUFA III decision	180.00	274.00	178.00	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	178	0	
80th Percentile Total days to MDUFA III decision	180	317	178	0	
Maximum Total days to MDUFA III decision	180	358	178	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	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.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	0%	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	86.00	100.00	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	6	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	4	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	0	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	0	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	175.00	179.50	171.50	0.00	
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	356.00	79.00	0.00	0.00	
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	531.00	258.50	171.50	0.00	
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	219.00	314.00	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	186.00	101.00	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	405.00	415.00	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	6	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	0	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	3	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	4	1	5	2	
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	1	
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	3	
Number Accepted	5	1	5	2	
Completed RTF	6	1	5	2	
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	2	
SI Goal Met	6	1	4	0	
SI Goal Not Met	0	0	1	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%	80%	N/A	

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	0	
Average number of FDA days to Substantive Interaction	88.50	81.00	87.40	0	
20th Percentile FDA days to Substantive Interaction	88	81	86	0	
40th Percentile FDA days to Substantive Interaction	88	81	88	0	
60th Percentile FDA days to Substantive Interaction	89	81	88	0	
80th Percentile FDA days to Substantive Interaction	90	81	90	0	
Maximum FDA days to Substantive Interaction	90	81	93	0	

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	2	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	2	1	1	0	
MDUFA III Decisions Goal Met	2	1	1	0	
PMAs pending MDUFA III Decision	0	0	4	2	
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	1	0	
Average FDA days to MDUFA III decision	178.50	170.00	177.00	0	
20th Percentile FDA days to MDUFA III decision	178	170	177	0	
40th Percentile FDA days to MDUFA III decision	178	170	177	0	
60th Percentile FDA days to MDUFA III decision	179	170	177	0	
80th Percentile FDA days to MDUFA III decision	179	170	177	0	
Maximum FDA days to MDUFA III decision	180	170	177	0	
Average Industry days to MDUFA III decision	108.50	0.00	0.00	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	287.00	170.00	177.00	0	
20th Percentile Total days to MDUFA III decision	221	170	177	0	
40th Percentile Total days to MDUFA III decision	265	170	177	0	
60th Percentile Total days to MDUFA III decision	309	170	177	0	
80th Percentile Total days to MDUFA III decision	353	170	177	0	
Maximum Total days to MDUFA III decision	397	170	177	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	328.00	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	2	
Number with MDUFA decision	2	1	1	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	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.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	0	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	1	3	2	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	3	2	0	0	
Rate of submissions not accepted for filing review	75%	40%	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.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	0	
Number Accepted	1	3	3	0	
Completed RTF	4	5	2	0	
Number Not Filed	2	0	0	0	
Rate of submissions Not Filed	50%	0%	0%	N/A	

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	0	
SI Goal Met	4	5	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.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	122.00	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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	1	3	0	0	
MDUFA III Decisions Goal Met	1	3	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 1.6.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	0	0	
MDUFA III Decisions Goal Met	3	0	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%	N/A	N/A	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	3	0	0	
Average FDA days to MDUFA III decision	180.00	229.00	0	0	
20th Percentile FDA days to MDUFA III decision	180	161	0	0	
40th Percentile FDA days to MDUFA III decision	180	174	0	0	
60th Percentile FDA days to MDUFA III decision	180	216	0	0	
80th Percentile FDA days to MDUFA III decision	180	287	0	0	
Maximum FDA days to MDUFA III decision	180	359	0	0	
Average Industry days to MDUFA III decision	260.00	80.33	0	0	
20th Percentile Industry days to MDUFA III decision	260	47	0	0	
40th Percentile Industry days to MDUFA III decision	260	61	0	0	
60th Percentile Industry days to MDUFA III decision	260	82	0	0	
80th Percentile Industry days to MDUFA III decision	260	111	0	0	
Maximum Industry days to MDUFA III decision	260	140	0	0	
Average Total days to MDUFA III decision	440.00	340.00	0	0	
20th Percentile Total days to MDUFA III decision	440	309	0	0	
40th Percentile Total days to MDUFA III decision	440	330	0	0	
60th Percentile Total days to MDUFA III decision	440	350	0	0	
80th Percentile Total days to MDUFA III decision	440	371	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	0	0	
Average FDA days to MDUFA III decision	376.00	0	0	0	
20th Percentile FDA days to MDUFA III decision	313	0	0	0	
40th Percentile FDA days to MDUFA III decision	314	0	0	0	
60th Percentile FDA days to MDUFA III decision	352	0	0	0	
80th Percentile FDA days to MDUFA III decision	427	0	0	0	
Maximum FDA days to MDUFA III decision	501	0	0	0	
Average Industry days to MDUFA III decision	180.33	0	0	0	
20th Percentile Industry days to MDUFA III decision	112	0	0	0	
40th Percentile Industry days to MDUFA III decision	156	0	0	0	
60th Percentile Industry days to MDUFA III decision	201	0	0	0	
80th Percentile Industry days to MDUFA III decision	248	0	0	0	
Maximum Industry days to MDUFA III decision	295	0	0	0	
Average Total days to MDUFA III decision	556.33	0	0	0	
20th Percentile Total days to MDUFA III decision	522	0	0	0	
40th Percentile Total days to MDUFA III decision	553	0	0	0	
60th Percentile Total days to MDUFA III decision	577	0	0	0	
80th Percentile Total days to MDUFA III decision	594	0	0	0	
Maximum Total days to MDUFA III decision	610	0	0	0	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	4	1	0	
Number with MDUFA decision	1	3	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	0	1	0	0	
Rate of Withdrawals	0%	0%	N/A	N/A	
Rate of Not Approvable	0%	33.3%	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	0	0	
Number of Withdrawals	0	0	0	0	
Number of Not Approvable	2	0	0	0	
Rate of Withdrawals	0%	N/A	N/A	N/A	
Rate of Not Approvable	66.7%	N/A	N/A	N/A	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	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	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.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	0	
Number Not Filed	0	0	0	0	
Rate of submissions Not Filed	N/A	0%	0%	N/A	

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	0	
SI Goal Met	0	5	5	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	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	0	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	0	3	2	0	
MDUFA III Decisions Goal Met	0	3	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	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	2	0	
Average FDA days to MDUFA III decision	0	177.33	180.00	0	
20th Percentile FDA days to MDUFA III decision	0	175	180	0	
40th Percentile FDA days to MDUFA III decision	0	178	180	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	49.00	79.50	0	
20th Percentile Industry days to MDUFA III decision	0	46	71	0	
40th Percentile Industry days to MDUFA III decision	0	47	77	0	
60th Percentile Industry days to MDUFA III decision	0	49	82	0	
80th Percentile Industry days to MDUFA III decision	0	52	88	0	
Maximum Industry days to MDUFA III decision	0	55	93	0	
Average Total days to MDUFA III decision	0	226.33	259.50	0	
20th Percentile Total days to MDUFA III decision	0	222	251	0	
40th Percentile Total days to MDUFA III decision	0	223	257	0	
60th Percentile Total days to MDUFA III decision	0	226	262	0	
80th Percentile Total days to MDUFA III decision	0	230	268	0	
Maximum Total days to MDUFA III decision	0	234	273	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	99.00	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	0	
Number with MDUFA decision	0	3	2	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%	20%	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	0	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	2	2	8	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%	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.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	0	
Number Accepted	2	2	8	0	
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	90.00	88.00	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	119.00	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	443.00	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%	N/A	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	2	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	2	1	3	2	
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	2	
Number Accepted	2	1	3	2	
Completed RTF	2	1	3	2	
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	2	
SI Goal Met	2	1	2	0	
SI Goal Not Met	0	0	1	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%	66.7%	N/A	

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	0	
Average number of FDA days to Substantive Interaction	86.00	83.00	88.67	0	
20th Percentile FDA days to Substantive Interaction	86	83	87	0	
40th Percentile FDA days to Substantive Interaction	86	83	88	0	
60th Percentile FDA days to Substantive Interaction	86	83	89	0	
80th Percentile FDA days to Substantive Interaction	86	83	90	0	
Maximum FDA days to Substantive Interaction	86	83	91	0	

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	2	
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	2	
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	177.00	179.00	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	107.00	0	26.00	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	284.00	179.00	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	297.00	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	0.00	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	297.00	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	2	
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	3	
Closed before RTA action	0	0	0	0	
Number with accepted RTA review	2	1	6	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.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	3	
Number Accepted	4	1	6	3	
Completed RTF	4	1	6	3	
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	3	
SI Goal Met	3	1	6	0	
SI Goal Not Met	1	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	75%	100%	100%	N/A	

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	0	
Average number of FDA days to Substantive Interaction	95.25	86.00	86.83	0	
20th Percentile FDA days to Substantive Interaction	90	86	90	0	
40th Percentile FDA days to Substantive Interaction	90	86	90	0	
60th Percentile FDA days to Substantive Interaction	90	86	90	0	
80th Percentile FDA days to Substantive Interaction	99	86	90	0	
Maximum FDA days to Substantive Interaction	112	86	90	0	

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	3	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	2	1	5	0	
MDUFA III Decisions Goal Met	2	1	5	0	
PMAs pending MDUFA III Decision	0	0	1	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.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	5	0	
Average FDA days to MDUFA III decision	107.50	86.00	130.60	0	
20th Percentile FDA days to MDUFA III decision	102	86	94	0	
40th Percentile FDA days to MDUFA III decision	106	86	118	0	
60th Percentile FDA days to MDUFA III decision	109	86	145	0	
80th Percentile FDA days to MDUFA III decision	113	86	165	0	
Maximum FDA days to MDUFA III decision	116	86	170	0	
Average Industry days to MDUFA III decision	94.50	0.00	37.40	0	
20th Percentile Industry days to MDUFA III decision	80	0	0	0	
40th Percentile Industry days to MDUFA III decision	90	0	24	0	
60th Percentile Industry days to MDUFA III decision	99	0	49	0	
80th Percentile Industry days to MDUFA III decision	109	0	67	0	
Maximum Industry days to MDUFA III decision	118	0	84	0	
Average Total days to MDUFA III decision	202.00	86.00	168.00	0	
20th Percentile Total days to MDUFA III decision	193	86	149	0	
40th Percentile Total days to MDUFA III decision	199	86	173	0	
60th Percentile Total days to MDUFA III decision	205	86	186	0	
80th Percentile Total days to MDUFA III decision	211	86	199	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	320.00	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	147.00	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	467.00	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	3	
Number with MDUFA decision	2	1	5	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	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%	N/A	N/A	

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	0	
Average number of FDA days to Substantive Interaction	77.50	86.50	0	0	
20th Percentile FDA days to Substantive Interaction	70	86	0	0	
40th Percentile FDA days to Substantive Interaction	75	86	0	0	
60th Percentile FDA days to Substantive Interaction	80	87	0	0	
80th Percentile FDA days to Substantive Interaction	85	87	0	0	
Maximum FDA days to Substantive Interaction	90	88	0	0	

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	2	0	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	167.00	178.00	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	81.00	113.00	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	248.00	291.00	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	206.00	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	0.00	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	206.00	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	

**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	5	0	
Average FDA days to MDUFA III decision	107.50	86.00	130.60	0	
20th Percentile FDA days to MDUFA III decision	102	86	94	0	
40th Percentile FDA days to MDUFA III decision	106	86	118	0	
60th Percentile FDA days to MDUFA III decision	109	86	145	0	
80th Percentile FDA days to MDUFA III decision	113	86	165	0	
Maximum FDA days to MDUFA III decision	116	86	170	0	
Average Industry days to MDUFA III decision	94.50	0.00	37.40	0	
20th Percentile Industry days to MDUFA III decision	80	0	0	0	
40th Percentile Industry days to MDUFA III decision	90	0	24	0	
60th Percentile Industry days to MDUFA III decision	99	0	49	0	
80th Percentile Industry days to MDUFA III decision	109	0	67	0	
Maximum Industry days to MDUFA III decision	118	0	84	0	
Average Total days to MDUFA III decision	202.00	86.00	168.00	0	
20th Percentile Total days to MDUFA III decision	193	86	149	0	
40th Percentile Total days to MDUFA III decision	199	86	173	0	
60th Percentile Total days to MDUFA III decision	205	86	186	0	
80th Percentile Total days to MDUFA III decision	211	86	199	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	320.00	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	147.00	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	467.00	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	3	
Number with MDUFA decision	2	1	5	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	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%	N/A	N/A	

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	0	
Average number of FDA days to Substantive Interaction	77.50	86.50	0	0	
20th Percentile FDA days to Substantive Interaction	70	86	0	0	
40th Percentile FDA days to Substantive Interaction	75	86	0	0	
60th Percentile FDA days to Substantive Interaction	80	87	0	0	
80th Percentile FDA days to Substantive Interaction	85	87	0	0	
Maximum FDA days to Substantive Interaction	90	88	0	0	

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	2	0	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	167.00	178.00	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	81.00	113.00	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	248.00	291.00	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	206.00	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	0.00	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	206.00	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

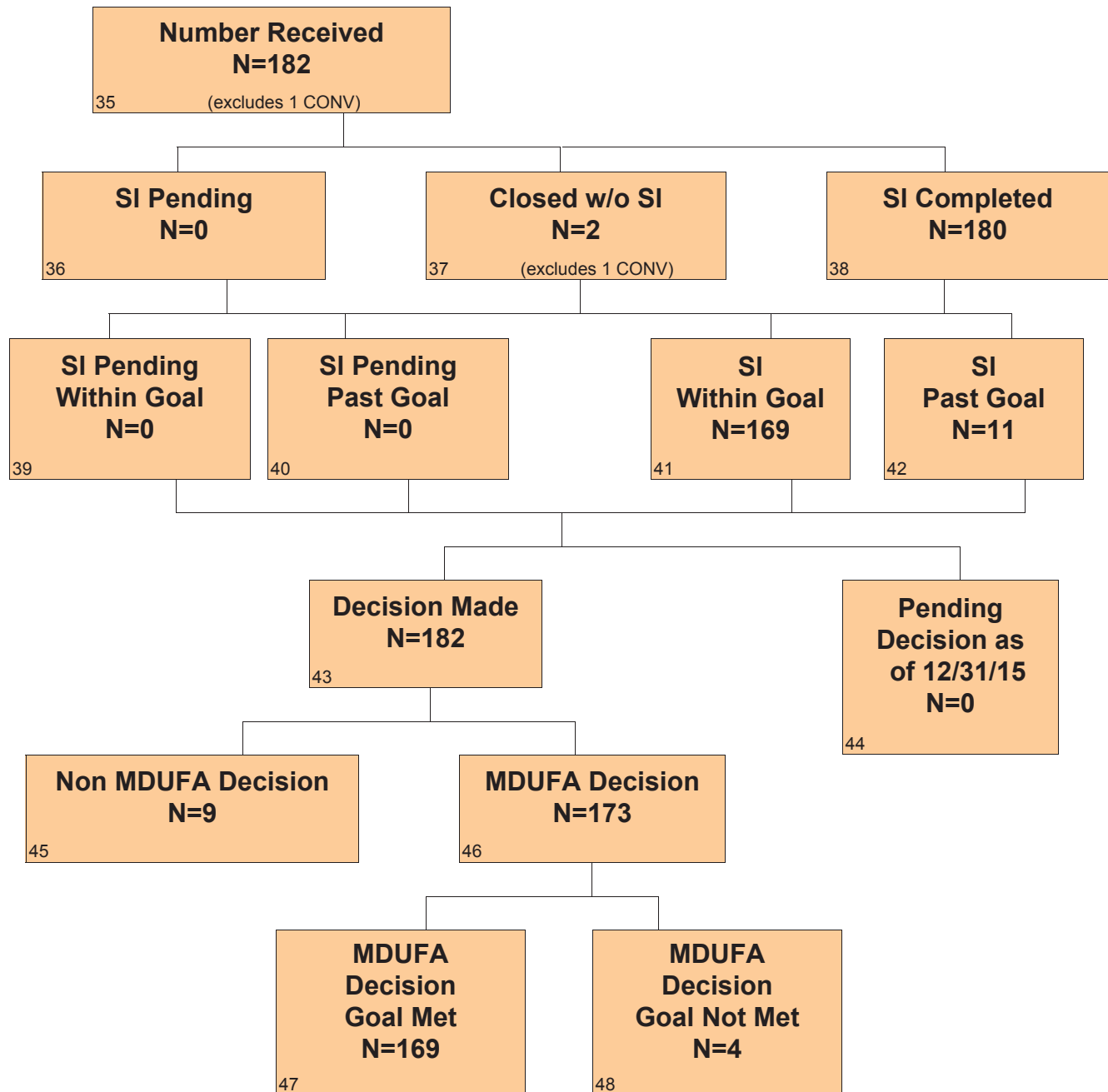
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	0	0	0	

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

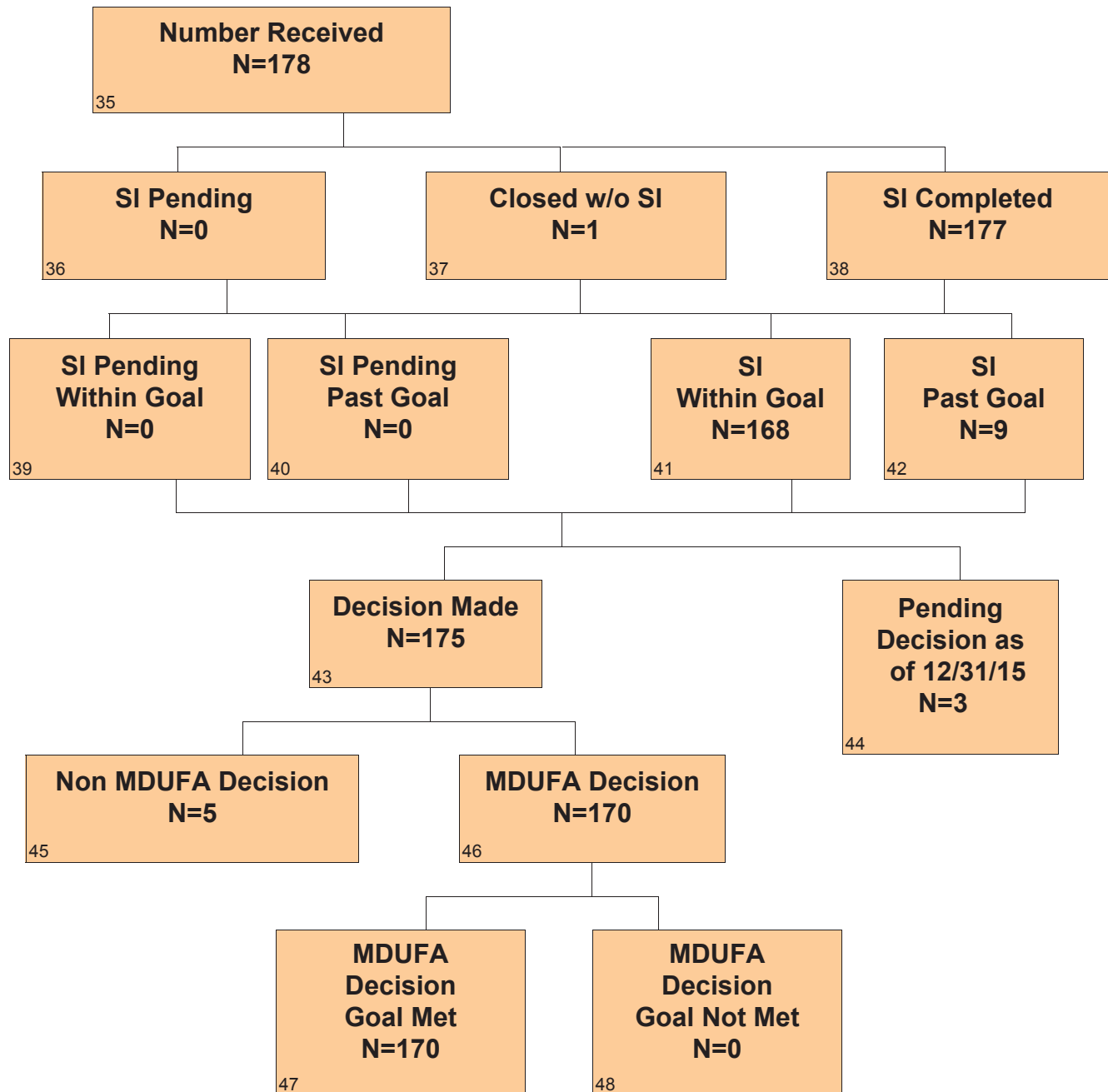
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	
Mean FDA days for submissions that missed goal	0	0	0	0	
Mean industry days for submissions that missed goal	0	0	0	0	

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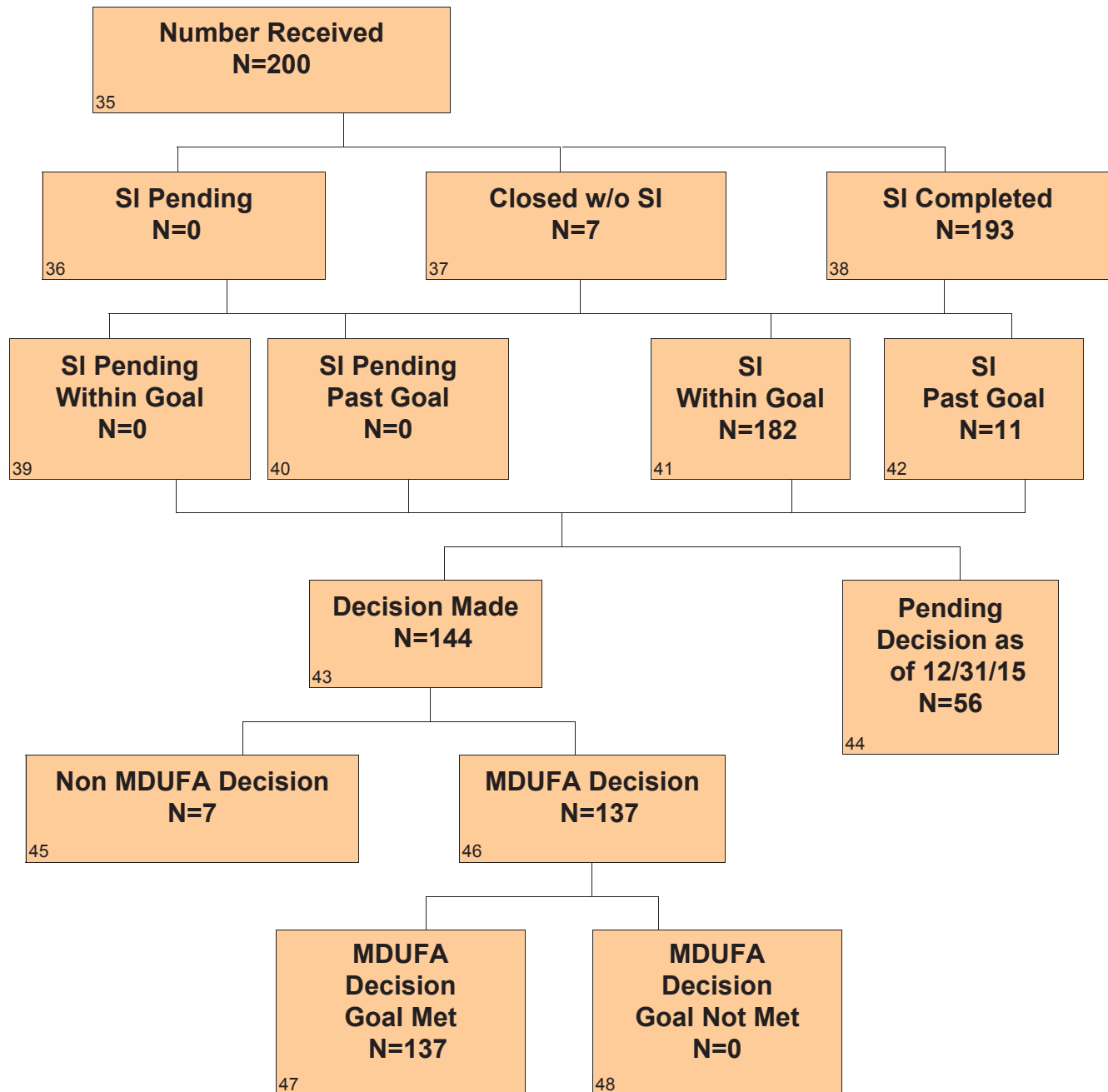
CDRH PMA 180 Day Supplements - FY 2013 As of 12/31/15



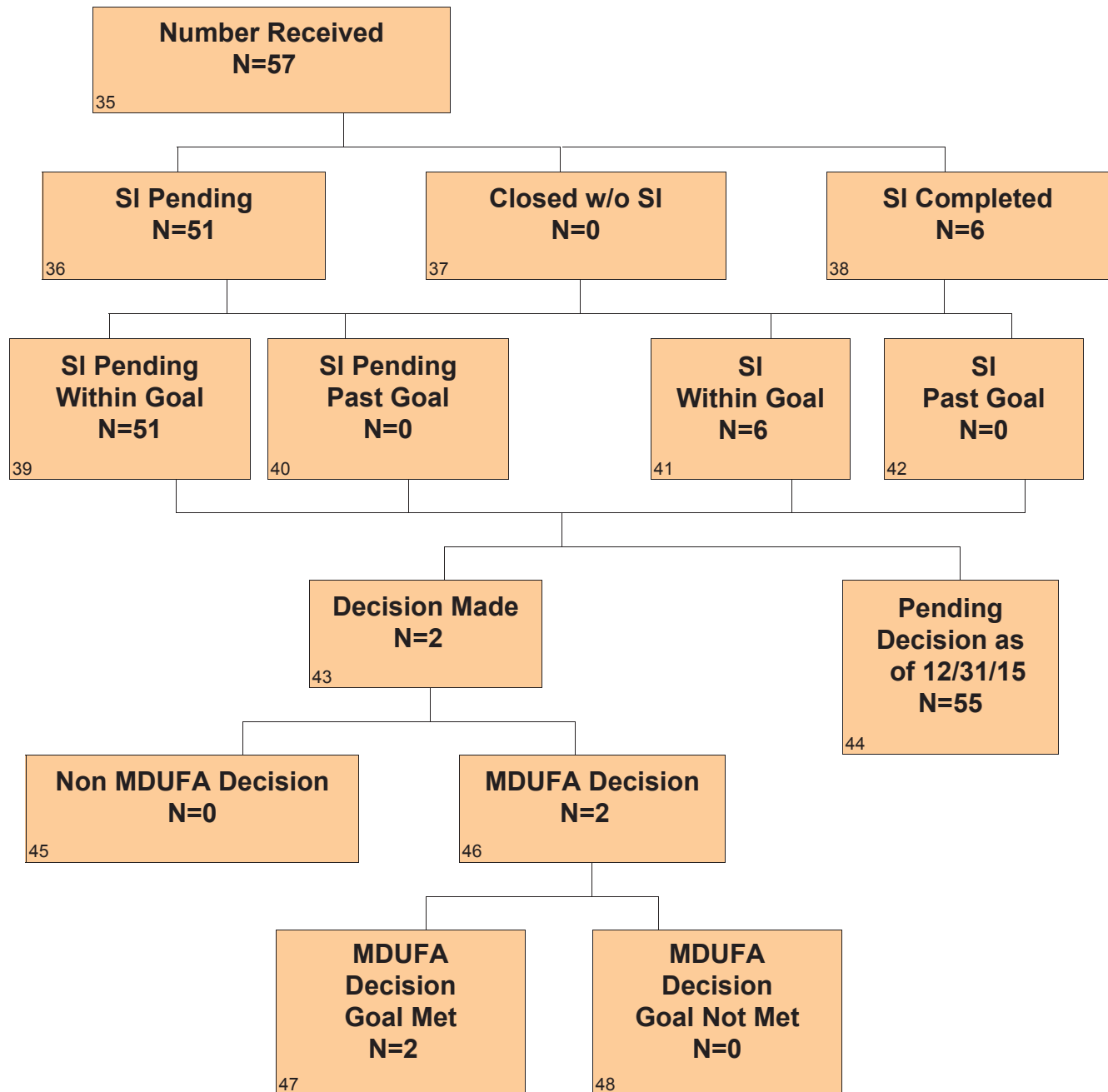
CDRH PMA 180 Day Supplements - FY 2014 As of 12/31/15



CDRH PMA 180 Day Supplements - FY 2015 As of 12/31/15



CDRH PMA 180 Day Supplements - FY 2016 As of 12/31/15



Section 2 PMA 180 Day Supplements - Center Level

Table 2.1 CDRH – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	183	178	200	57	
SI Goal Met	169	168	182	6	
SI Goal Not Met	11	9	11	0	
SI Pending Within Goal	0	0	0	51	
SI Pending Past Goal	0	0	0	0	
Closed without SI	3	1	7	0	
Current SI Performance Percent Goal Met	93.9%	94.9%	94.3%	100%	

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	183	178	200	57	
Non-MDUFA III Decisions	10	5	7	0	
MDUFA III Decisions	173	170	137	2	
MDUFA III Decisions Goal Met	169	170	137	2	
Supplements pending MDUFA III Decision	0	3	56	55	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	97.7%	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	183	178	200	57	
Number with MDUFA decision	173	170	137	2	
Number of Not Approvable	11	5	7	0	
Rate of Not Approvable	6.4%	2.9%	5.1%	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	4	0	0	0	
Mean FDA days for submissions that missed goal	209	0	0	0	
Mean Industry days for submissions that missed goal	246	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	162	165	164	51	
SI Goal Met	148	155	149	5	
SI Goal Not Met	11	9	10	0	
SI Pending Within Goal	0	0	0	46	
SI Pending Past Goal	0	0	0	0	
Closed without SI	3	1	5	0	
Current SI Performance Percent Goal Met	93.1%	94.5%	93.7%	100%	

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	162	165	164	51	
Non-MDUFA III Decisions	9	4	5	0	
MDUFA III Decisions	153	158	118	2	
MDUFA III Decisions Goal Met	149	158	118	2	
Supplements pending MDUFA III Decision	0	3	41	49	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	97.4%	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	162	165	164	51	
Number with MDUFA decision	153	158	118	2	
Number of Not Approvable	11	5	5	0	
Rate of Not Approvable	7.2%	3.2%	4.2%	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	4	0	0	0	
Mean FDA days for submissions that missed goal	209	0	0	0	
Mean Industry days for submissions that missed goal	246	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	36	6	
SI Goal Met	21	13	33	1	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	5	
SI Pending Past Goal	0	0	0	0	
Closed without SI	0	0	2	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	36	6	
Non-MDUFA III Decisions	1	1	2	0	
MDUFA III Decisions	20	12	19	0	
MDUFA III Decisions Goal Met	20	12	19	0	
Supplements pending MDUFA III Decision	0	0	15	6	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	36	6	
Number with MDUFA decision	20	12	19	0	
Number of Not Approvable	0	0	2	0	
Rate of Not Approvable	0%	0%	10.5%	N/A	

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	2	
SI Goal Met	8	7	6	1	
SI Goal Not Met	2	2	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	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	2	
Non-MDUFA III Decisions	2	1	0	0	
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	2	
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	30	
SI Goal Met	108	93	96	4	
SI Goal Not Met	5	1	3	0	
SI Pending Within Goal	0	0	0	26	
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%	97%	100%	

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	116	94	104	30	
Non-MDUFA III Decisions	4	1	5	0	
MDUFA III Decisions	112	93	72	2	
MDUFA III Decisions Goal Met	111	93	72	2	
Supplements pending MDUFA III Decision	0	0	27	28	
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	30	
Number with MDUFA decision	112	93	72	2	
Number of Not Approvable	6	0	4	0	
Rate of Not Approvable	5.4%	0%	5.6%	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	8	
SI Goal Met	7	13	13	0	
SI Goal Not Met	1	0	1	0	
SI Pending Within Goal	0	0	0	8	
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%	N/A	

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	8	
Non-MDUFA III Decisions	2	1	0	0	
MDUFA III Decisions	6	13	9	0	
MDUFA III Decisions Goal Met	6	13	9	0	
Supplements pending MDUFA III Decision	0	0	5	8	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	8	
Number with MDUFA decision	6	13	9	0	
Number of Not Approvable	1	0	0	0	
Rate of Not Approvable	16.7%	0%	0%	N/A	

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	1	
SI Goal Met	2	2	5	0	
SI Goal Not Met	0	2	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%	50%	83.3%	N/A	

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	4	6	1	
Number with MDUFA decision	2	4	4	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	0%	0%	N/A	

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	24	18	6	
SI Goal Met	11	24	17	0	
SI Goal Not Met	1	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	91.7%	100%	94.4%	N/A	

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	12	24	18	6	
Non-MDUFA III Decisions	0	1	0	0	
MDUFA III Decisions	12	21	15	0	
MDUFA III Decisions Goal Met	12	21	15	0	
Supplements pending MDUFA III Decision	0	2	3	6	
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	24	18	6	
Number with MDUFA decision	12	21	15	0	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	8.3%	4.8%	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	2	
SI Goal Met	9	7	8	0	
SI Goal Not Met	1	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	90%	100%	100%	N/A	

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	2	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	10	7	8	0	
MDUFA III Decisions Goal Met	10	7	8	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 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	2	
Number with MDUFA decision	10	7	8	0	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	10%	14.3%	0%	N/A	

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	4	13	7	2	
SI Goal Met	3	9	4	0	
SI Goal Not Met	1	4	3	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	75%	69.2%	57.1%	N/A	

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	4	13	7	2	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	3	12	5	0	
MDUFA III Decisions Goal Met	2	12	5	0	
Supplements pending MDUFA III Decision	0	1	2	2	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	66.7%	100%	100%	N/A	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	13	7	2	
Number with MDUFA decision	3	12	5	0	
Number of Not Approvable	1	1	1	0	
Rate of Not Approvable	33.3%	8.3%	20%	N/A	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0	0	
Mean FDA days for submissions that missed goal	261	0	0	0	
Mean Industry days for submissions that missed goal	358	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	0	
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%	75%	N/A	

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	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	0	
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%	N/A	

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	1	1	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	2	
SI Goal Met	7	4	14	1	
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	2	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	6	4	5	0	
MDUFA III Decisions Goal Met	6	4	5	0	
Supplements pending MDUFA III Decision	0	0	9	2	
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	2	
Number with MDUFA decision	6	4	5	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	11	0	
SI Goal Met	5	4	9	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	2	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	11	0	
Non-MDUFA III Decisions	0	0	2	0	
MDUFA III Decisions	5	4	7	0	
MDUFA III Decisions Goal Met	5	4	7	0	
Supplements pending MDUFA III Decision	0	0	2	0	
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	11	0	
Number with MDUFA decision	5	4	7	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	1	
SI Goal Met	5	1	4	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 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	1	
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	1	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

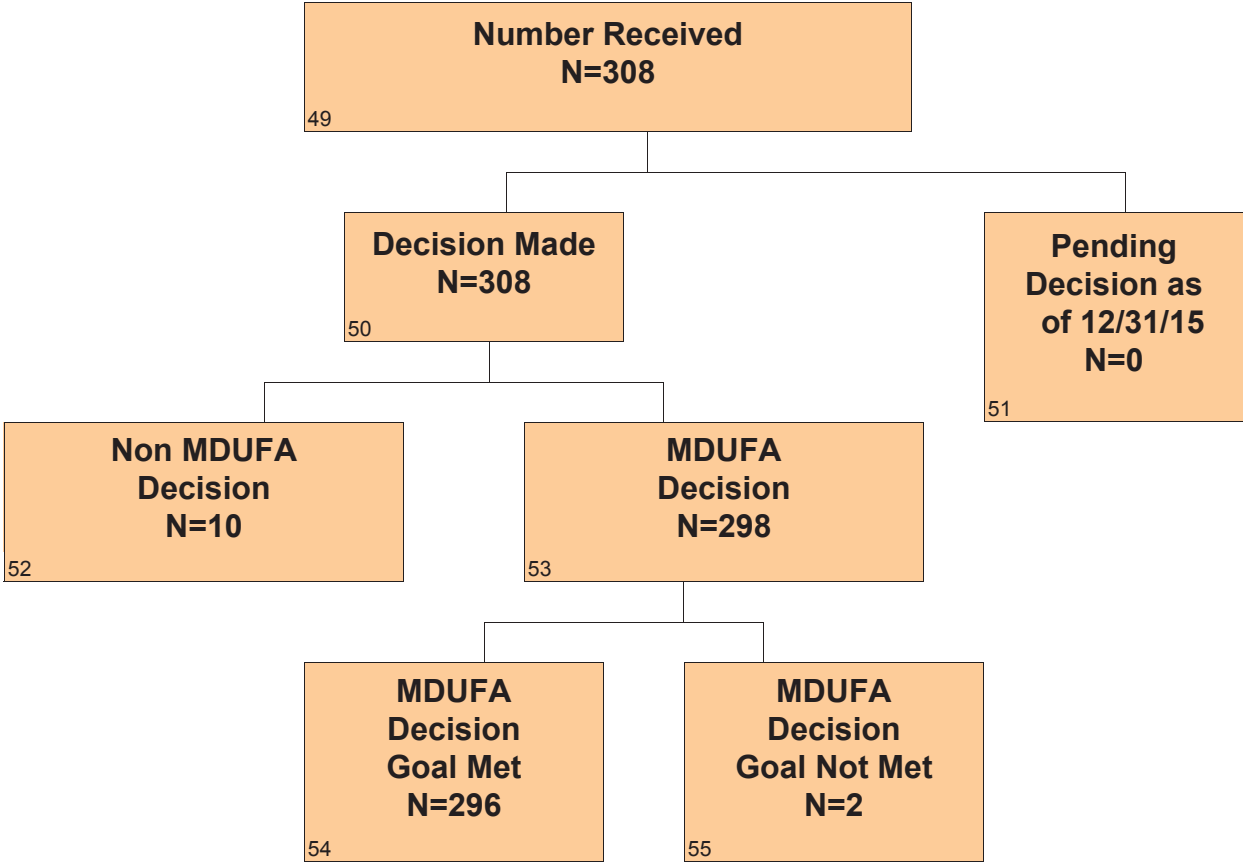
Table 2.3.DRH DRH - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1	4	1	
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	

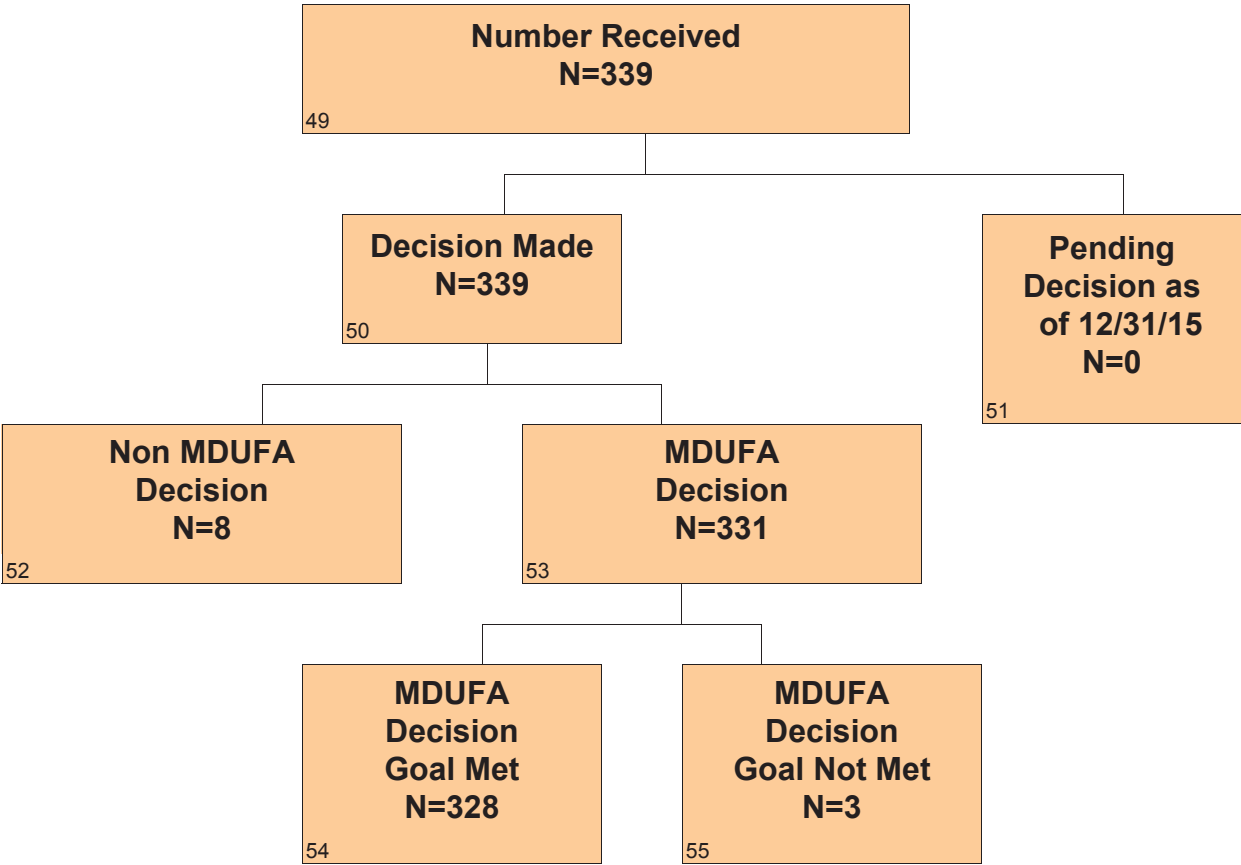
Table 2.4.DRH - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

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	

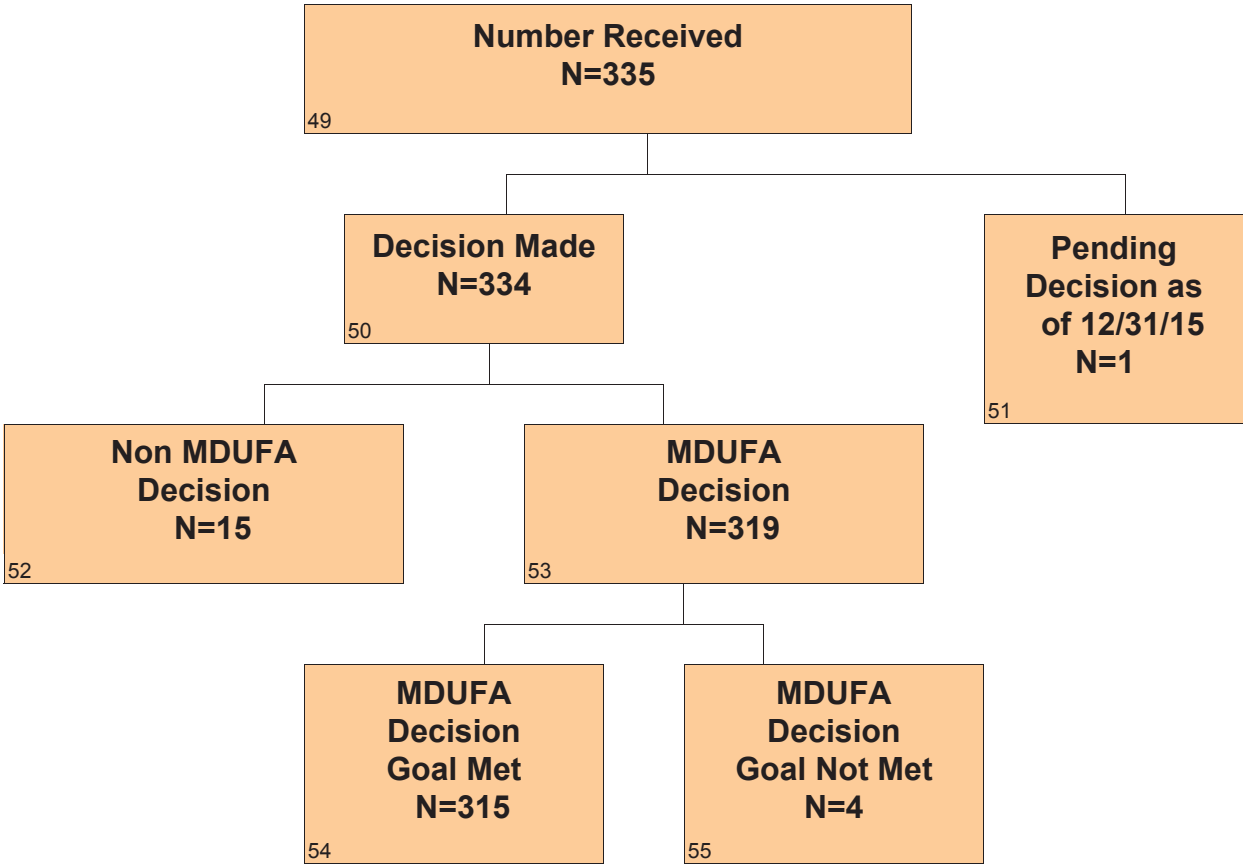
CDRH PMA Real Time Supplements - FY 2013 As of 12/31/15



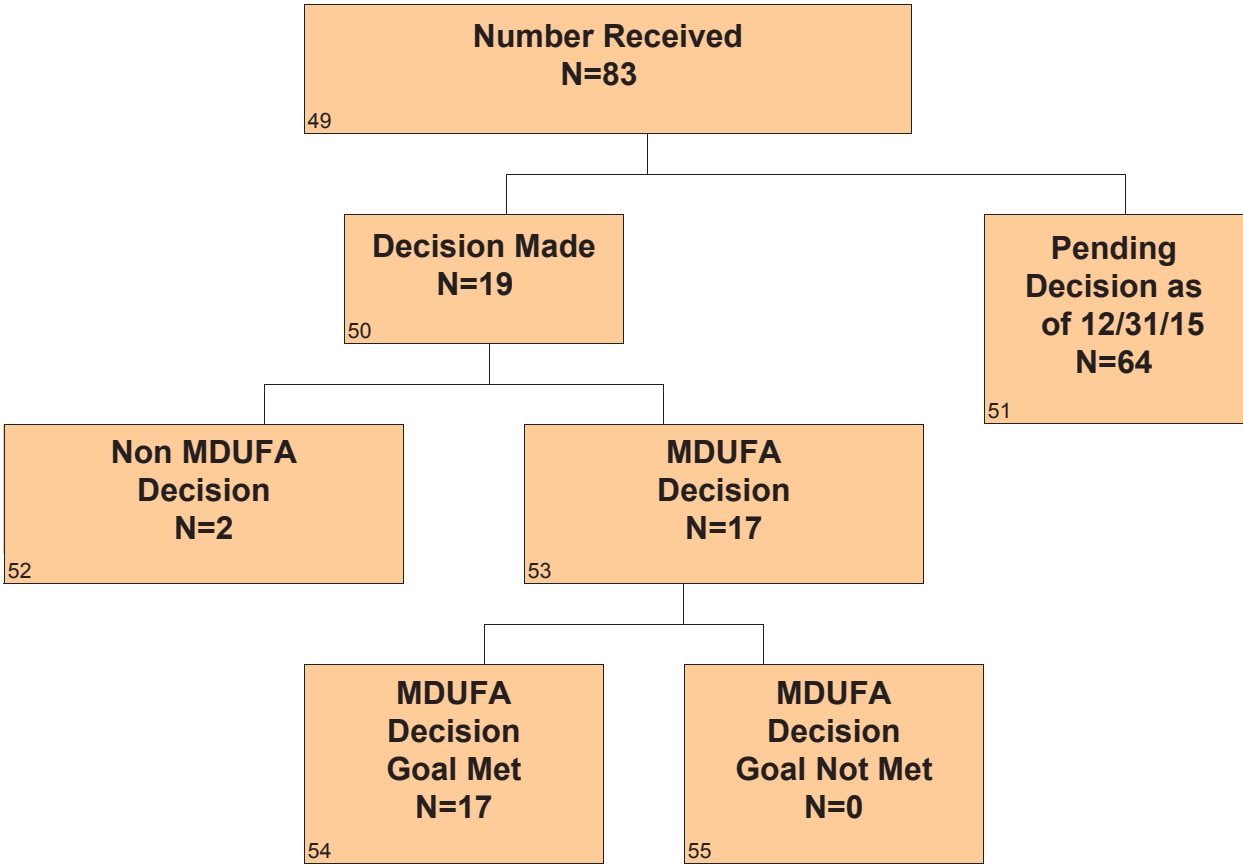
CDRH PMA Real Time Supplements - FY 2014 As of 12/31/15



CDRH PMA Real Time Supplements - FY 2015 As of 12/31/15



CDRH PMA Real Time Supplements - FY 2016 As of 12/31/15



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	335	83	
Non-MDUFA III Decisions	10	8	15	2	
MDUFA III Decisions	298	331	319	17	
MDUFA III Decisions Goal Met	296	328	315	17	
Supplements pending MDUFA III Decision	0	0	1	64	
Supplements pending MDUFA III Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	99.3%	99.1%	98.4%	100%	

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	335	83	
Number with MDUFA decision	298	331	319	17	
Number of Not Approvable	20	3	20	0	
Rate of Not Approvable	6.7%	0.9%	6.3%	0%	

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	4	0	
Mean FDA days for submissions that missed goal	143	100	148	0	
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	283	74	
Non-MDUFA III Decisions	9	6	14	2	
MDUFA III Decisions	260	277	268	17	
MDUFA III Decisions Goal Met	258	274	264	17	
Supplements pending MDUFA III Decision	0	0	1	55	
Supplements pending MDUFA III Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	99.2%	98.9%	98.1%	100%	

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	283	74	
Number with MDUFA decision	260	277	268	17	
Number of Not Approvable	15	3	14	0	
Rate of Not Approvable	5.8%	1.1%	5.2%	0%	

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	4	0	
Mean FDA days for submissions that missed goal	143	100	148	0	
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	9	
Non-MDUFA III Decisions	1	2	1	0	
MDUFA III Decisions	38	54	51	0	
MDUFA III Decisions Goal Met	38	54	51	0	
Supplements pending MDUFA III Decision	0	0	0	9	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	9	
Number with MDUFA decision	38	54	51	0	
Number of Not Approvable	5	0	6	0	
Rate of Not Approvable	13.2%	0%	11.8%	N/A	

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	4	
Non-MDUFA III Decisions	0	1	0	0	
MDUFA III Decisions	13	7	6	0	
MDUFA III Decisions Goal Met	13	5	5	0	
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%	71.4%	83.3%	N/A	

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	4	
Number with MDUFA decision	13	7	6	0	
Number of Not Approvable	1	1	2	0	
Rate of Not Approvable	7.7%	14.3%	33.3%	N/A	

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	0	
Mean FDA days for submissions that missed goal	0	101	183	0	
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	200	50	
Non-MDUFA III Decisions	6	3	11	1	
MDUFA III Decisions	170	215	188	16	
MDUFA III Decisions Goal Met	170	215	185	16	
Supplements pending MDUFA III Decision	0	0	1	33	
Supplements pending MDUFA III Decision Past Goal	0	0	1	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	200	50	
Number with MDUFA decision	170	215	188	16	
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	3	0	
Mean FDA days for submissions that missed goal	0	0	136	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	4	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	23	17	23	0	
MDUFA III Decisions Goal Met	23	16	23	0	
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%	94.1%	100%	N/A	

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	4	
Number with MDUFA decision	23	17	23	0	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	4.3%	5.9%	0%	N/A	

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	14	0	
Non-MDUFA III Decisions	0	2	2	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	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.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	14	0	
Number with MDUFA decision	8	8	12	0	
Number of Not Approvable	2	0	0	0	
Rate of Not Approvable	25%	0%	0%	N/A	

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	22	9	
Non-MDUFA III Decisions	0	0	1	1	
MDUFA III Decisions	16	17	21	0	
MDUFA III Decisions Goal Met	16	17	21	0	
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%	N/A	

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	22	9	
Number with MDUFA decision	16	17	21	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	0%	0%	N/A	

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	3	
Non-MDUFA III Decisions	2	0	0	0	
MDUFA III Decisions	17	2	11	0	
MDUFA III Decisions Goal Met	17	2	11	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 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	3	
Number with MDUFA decision	17	2	11	0	
Number of Not Approvable	1	0	0	0	
Rate of Not Approvable	5.9%	0%	0%	N/A	

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	4	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	13	11	7	1	
MDUFA III Decisions Goal Met	11	11	7	1	
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	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	4	
Number with MDUFA decision	13	11	7	1	
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	3	
Non-MDUFA III Decisions	0	2	0	0	
MDUFA III Decisions	6	17	20	0	
MDUFA III Decisions Goal Met	6	17	20	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 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	3	
Number with MDUFA decision	6	17	20	0	
Number of Not Approvable	0	0	4	0	
Rate of Not Approvable	0%	0%	20%	N/A	

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	5	
Non-MDUFA III Decisions	0	0	0	0	
MDUFA III Decisions	13	12	13	0	
MDUFA III Decisions Goal Met	13	12	13	0	
Supplements pending MDUFA III Decision	0	0	0	5	
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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	5	
Number with MDUFA decision	13	12	13	0	
Number of Not Approvable	3	0	0	0	
Rate of Not Approvable	23.1%	0%	0%	N/A	

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	1	
Non-MDUFA III Decisions	1	0	0	0	
MDUFA III Decisions	7	13	12	0	
MDUFA III Decisions Goal Met	7	13	12	0	
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%	N/A	

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	1	
Number with MDUFA decision	7	13	12	0	
Number of Not Approvable	0	0	2	0	
Rate of Not Approvable	0%	0%	16.7%	N/A	

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	

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Section 4 Pre-Market Report Submissions

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

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Section 5 PMA Annual Metrics and Goals

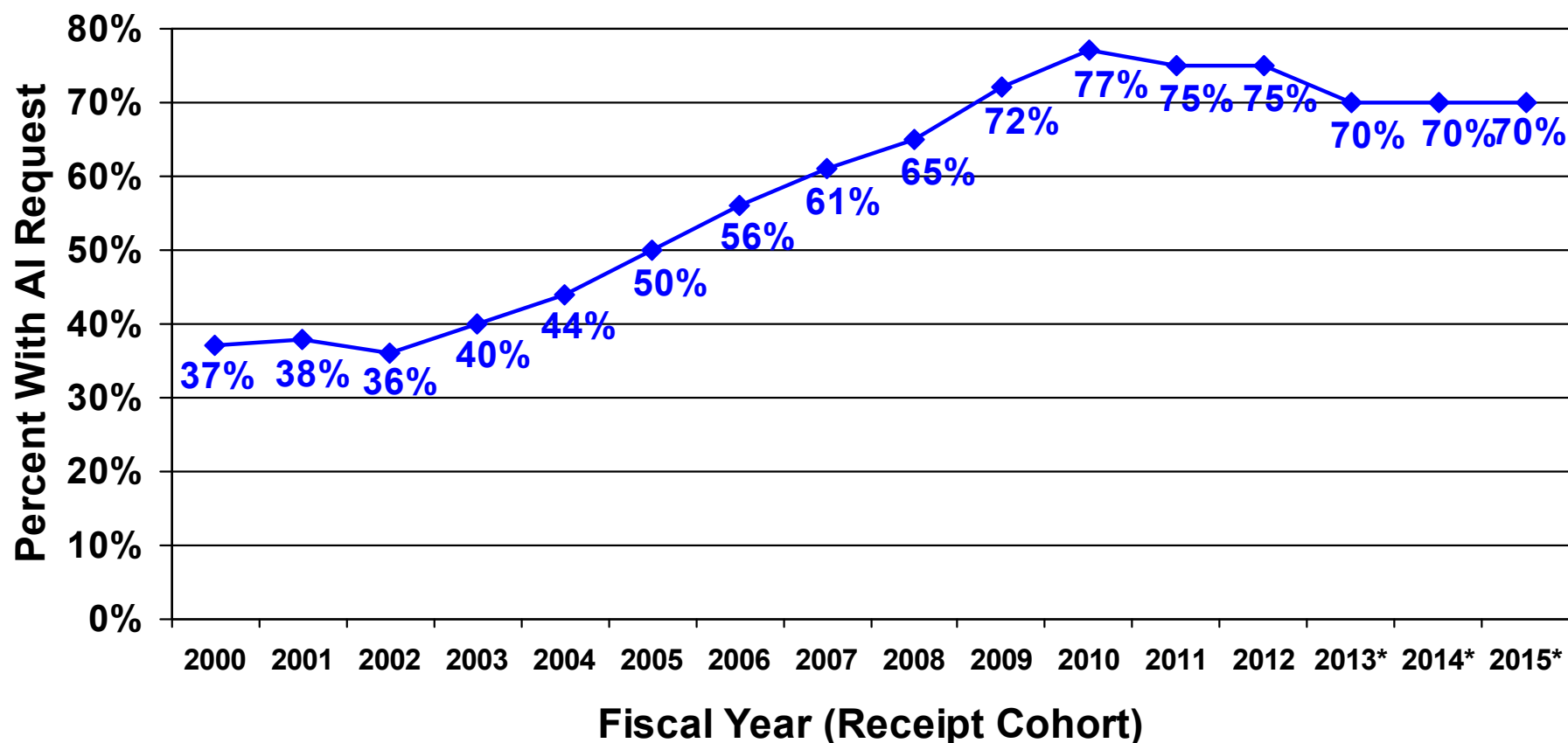
PMA Annual Metrics and Goals will be reported in the Annual Report.

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510(k)s

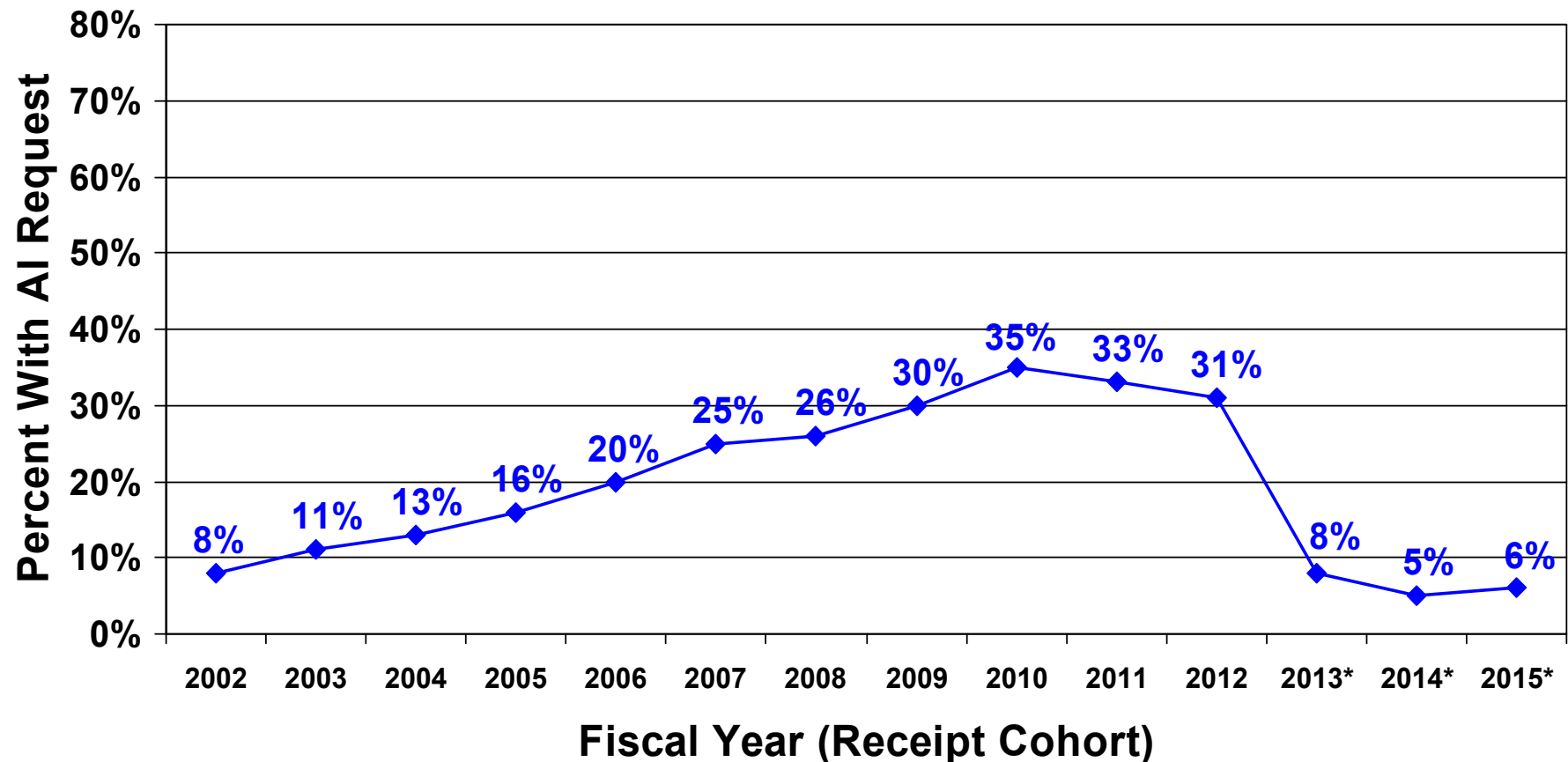
1st Q FY 2016

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



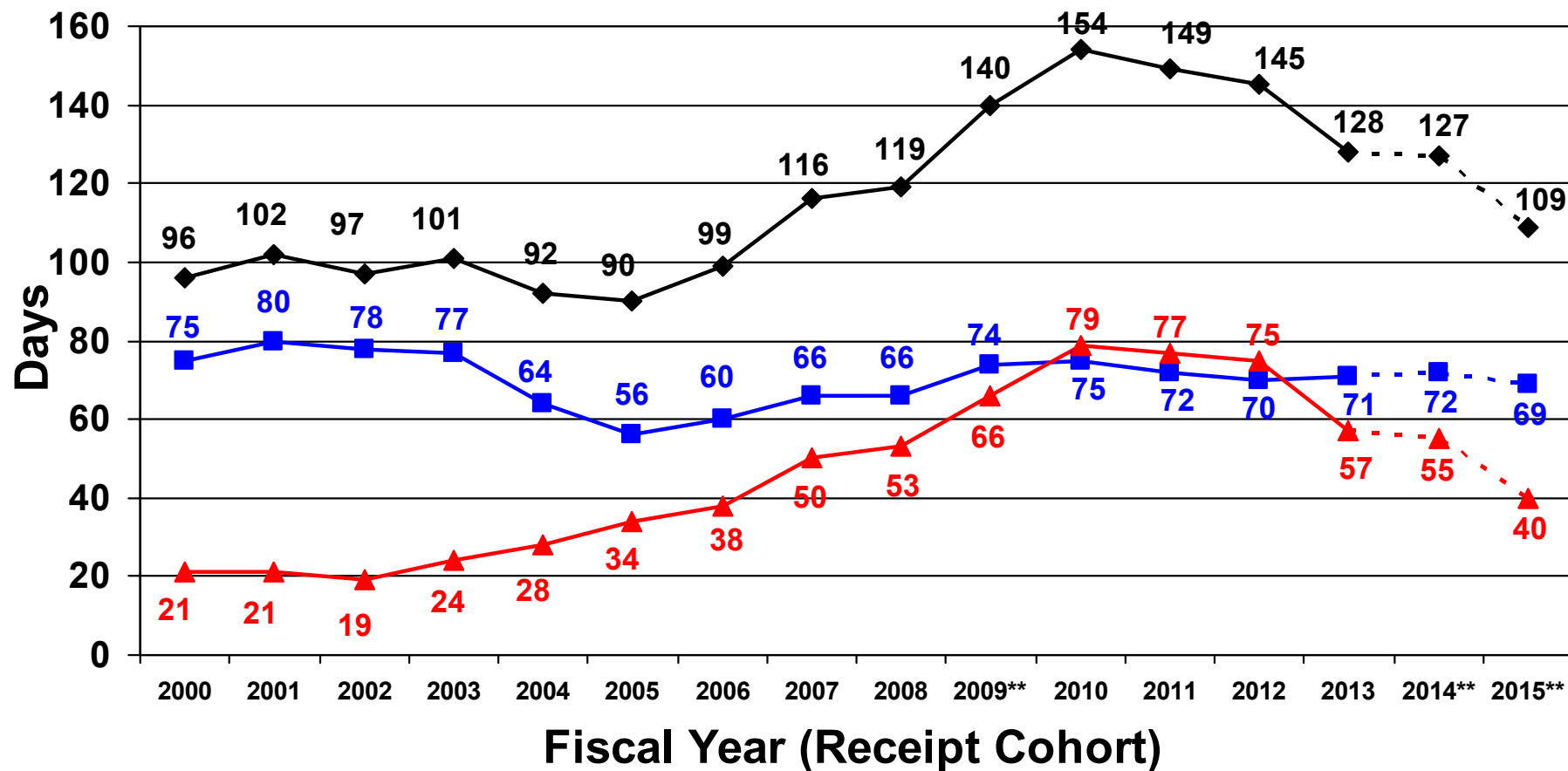
*FY 2013 - FY 2015 data are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for submissions accepted as of 9/30/2015; FY 2015 1st cycle cohort is still open as of 12/31/2015 and data may change

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 5/31/2015; FY 2014 and FY 2015 2nd cycle cohorts are still open as of 12/31/2015 and data may change

Average Time to Decision: 510(k)s* (Receipt Cohorts as of December 31, 2015)



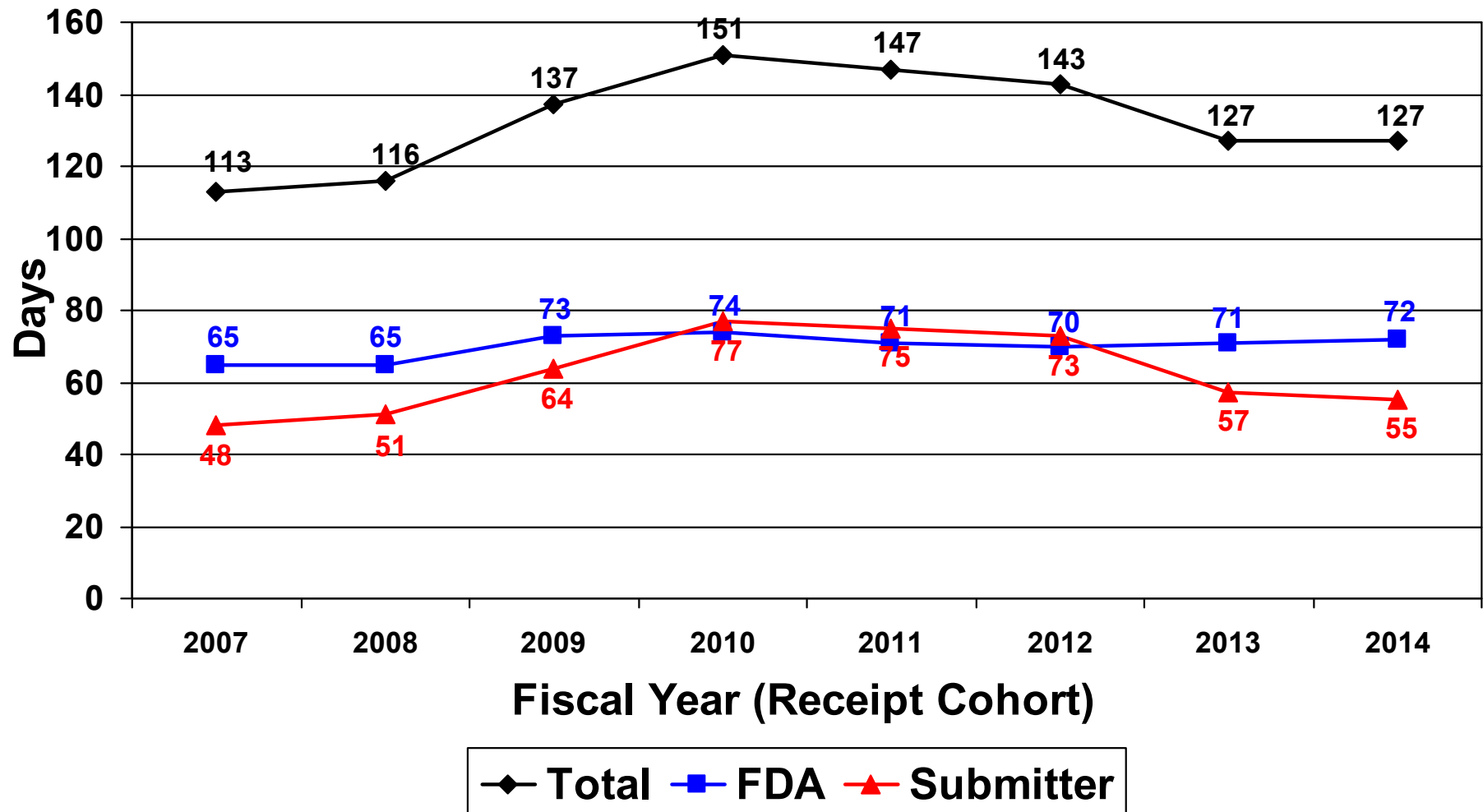
◆ Total ■ FDA ▲ Submitter

*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 = 99.4%, and FY 2015 = 74.2% —average times for FY 2014 and FY 2015 will increase

Average Time to Decision: 510(k)s*

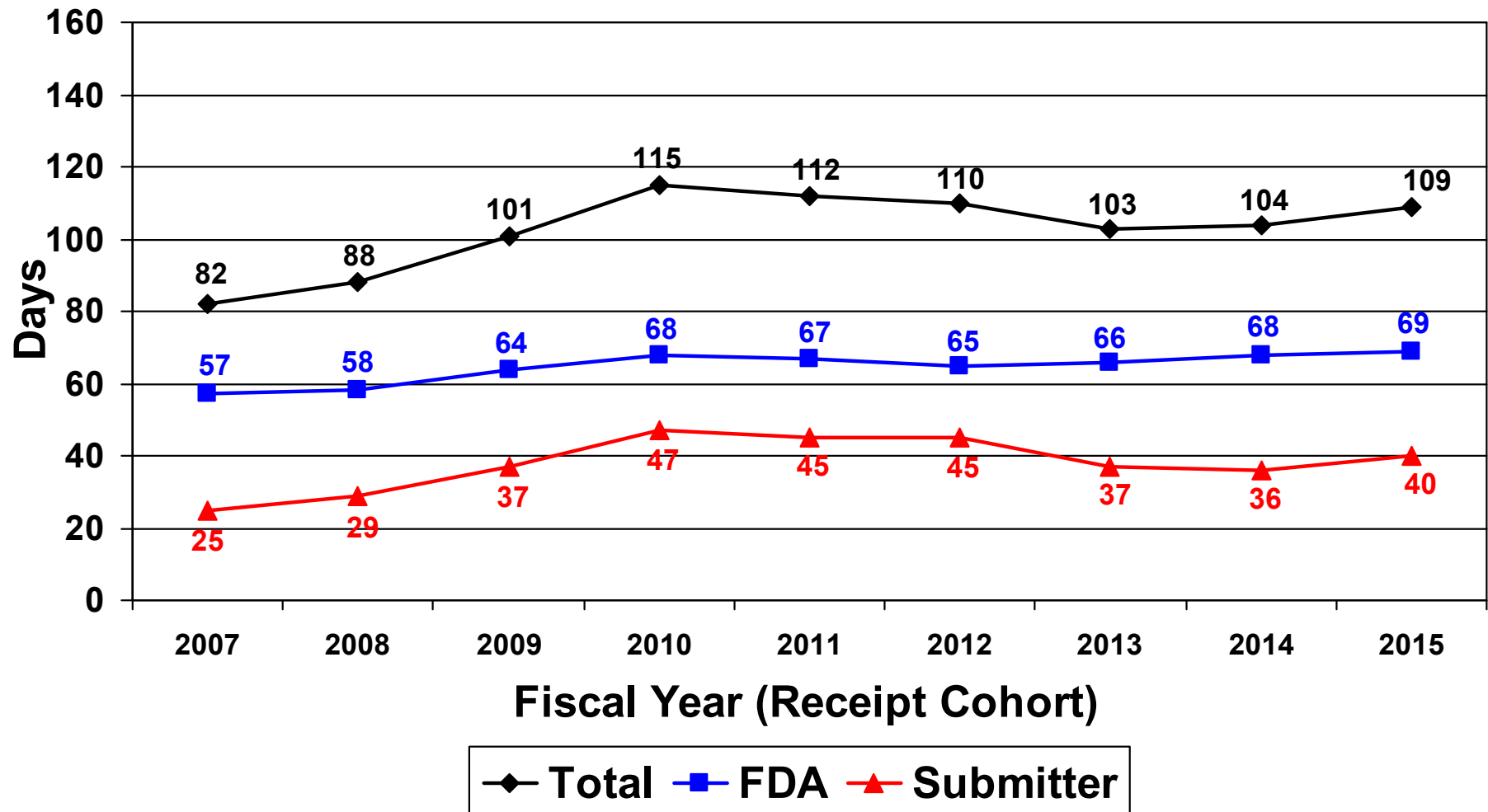
- Comparison of Receipt Cohorts When 99.4% Closed -



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

Average Time to Decision: 510(k)s*

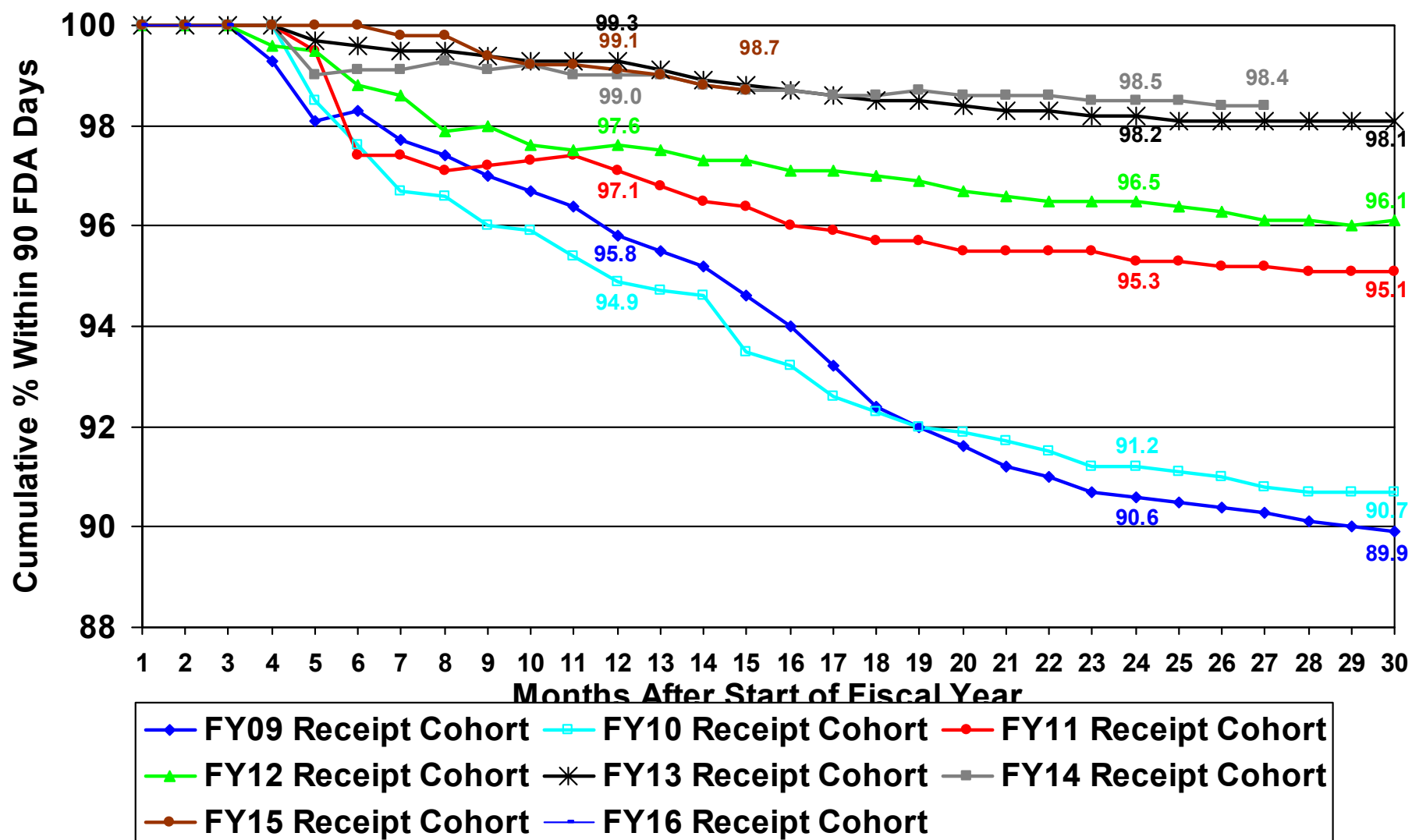
- Comparison of Receipt Cohorts When 74.2% Closed -



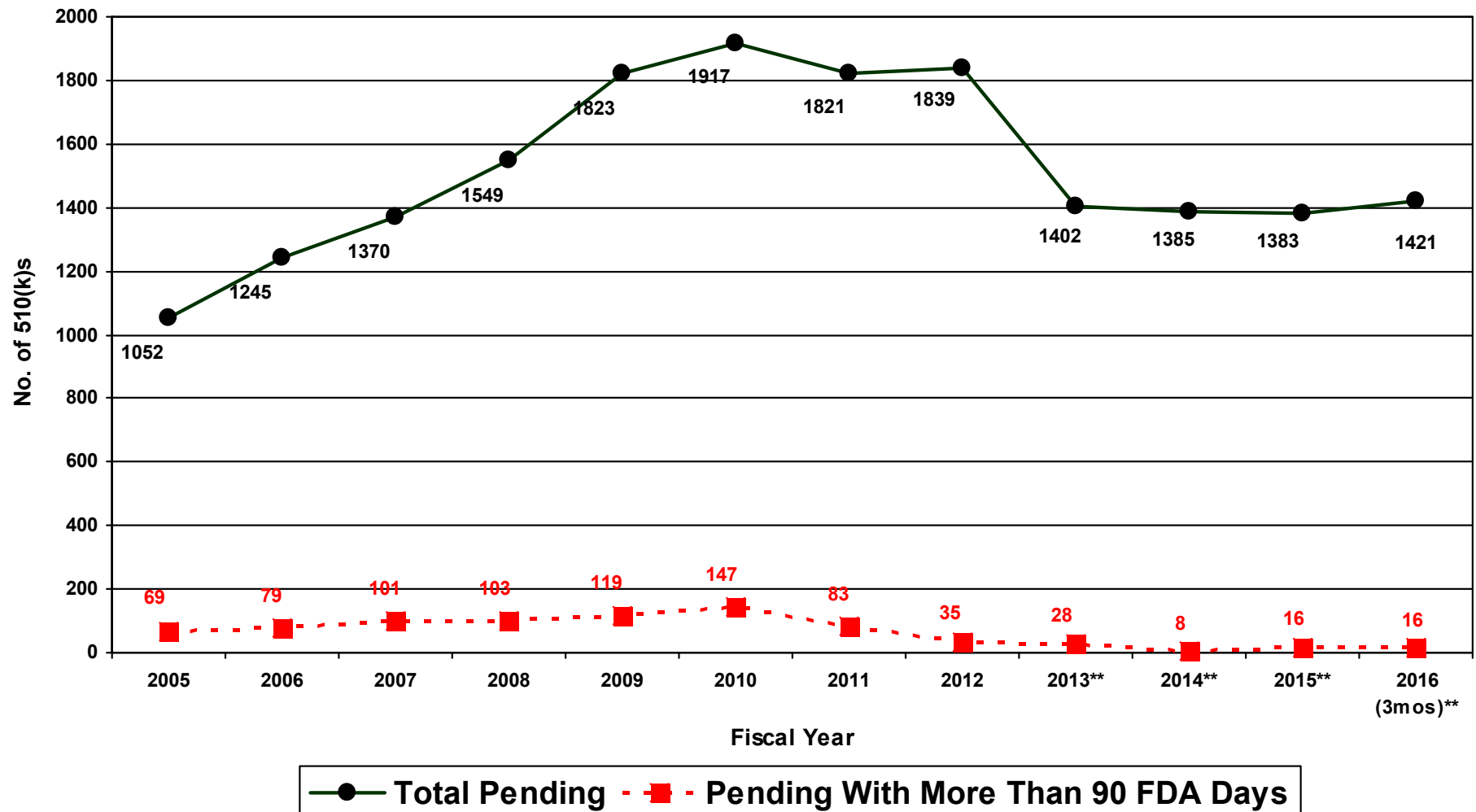
*SE and NSE decisions only; times may not add to total due to rounding

Trend in 510(k) MDUFA Decision Goal Performance

- Comparison of FY09 - FY15 Receipt Cohorts -



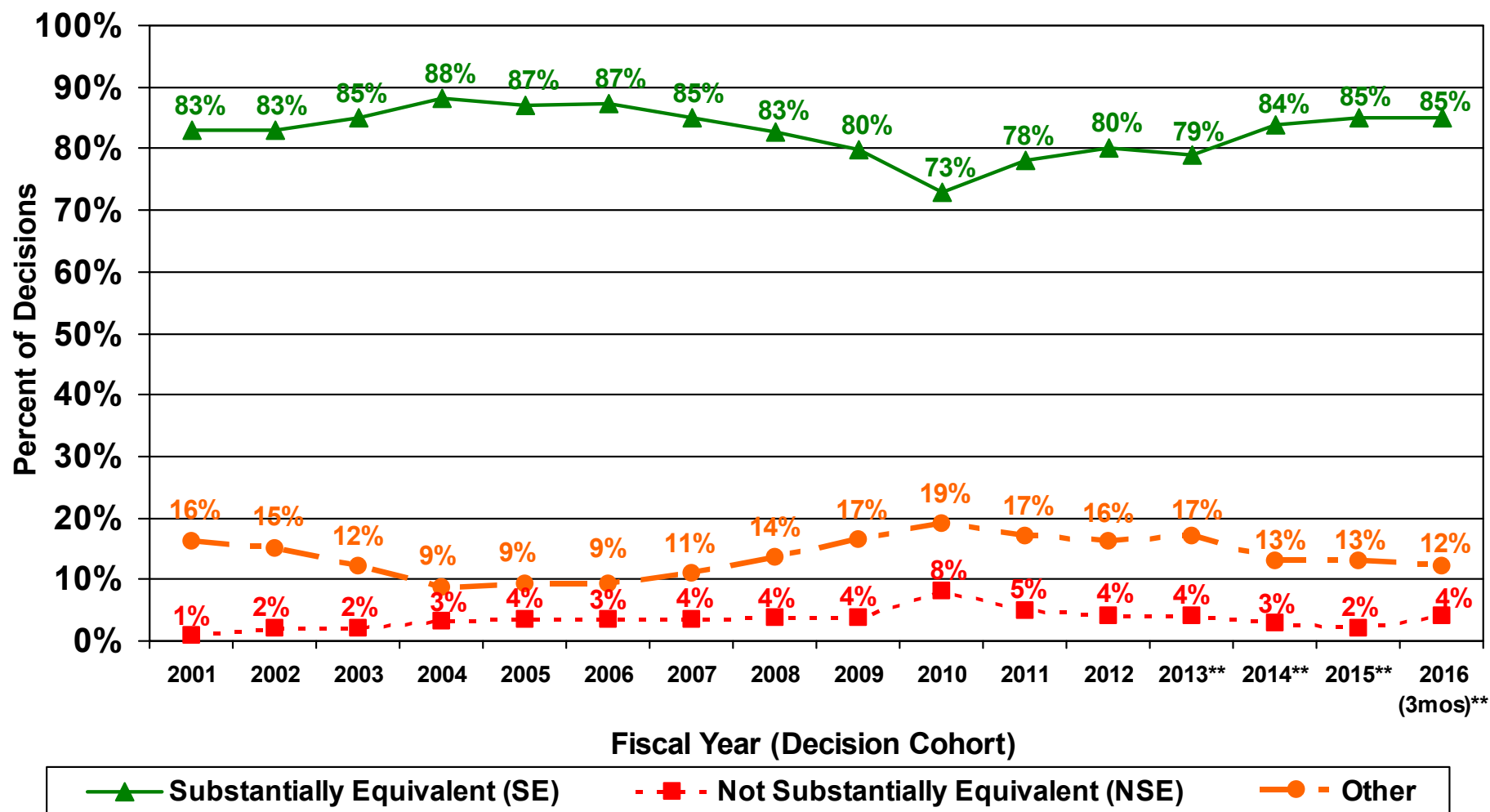
510(k)s Pending* at End of Year



*Under review or on hold

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

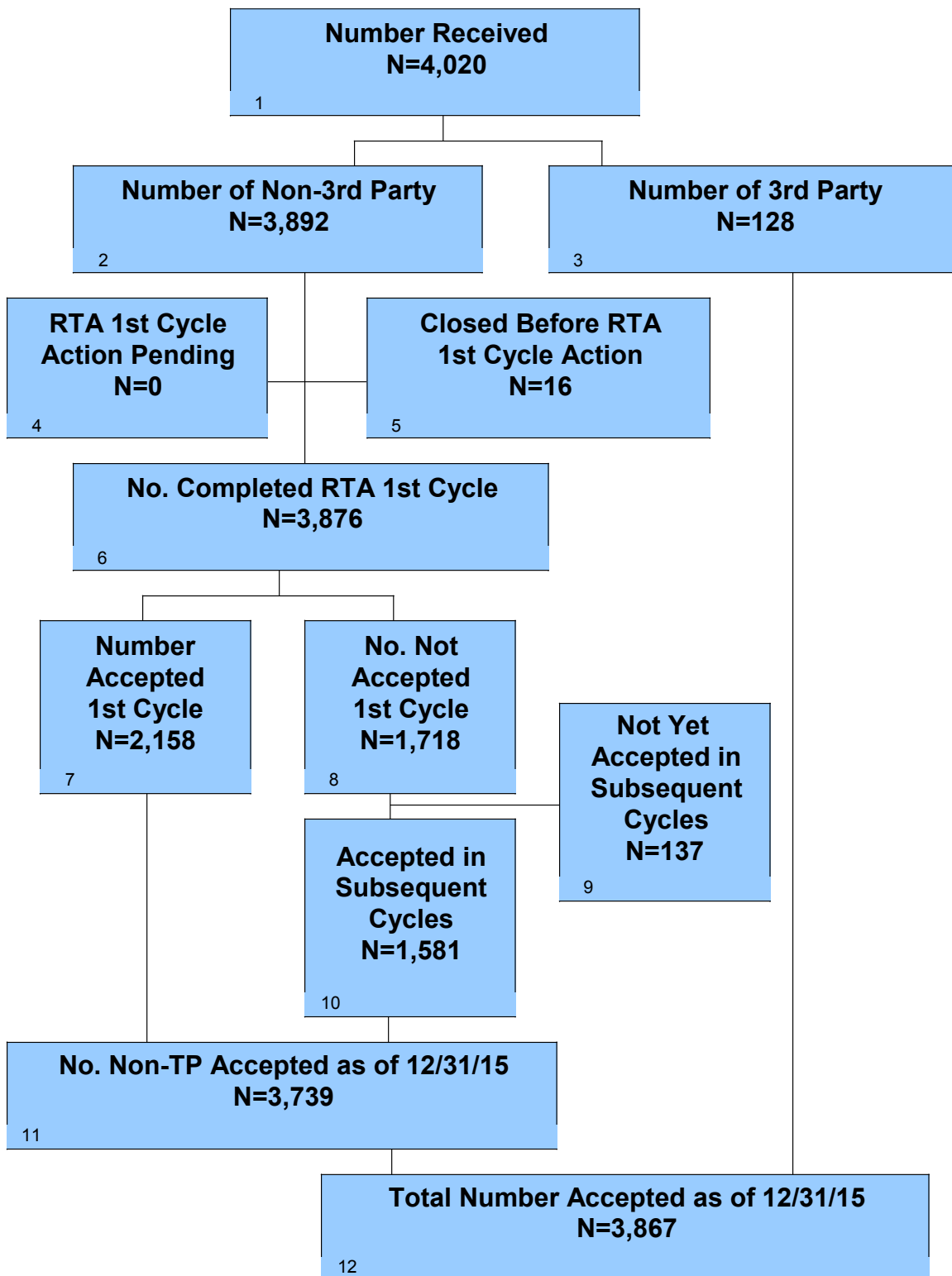
Percent of 510(k)s Determined to be Substantially Equivalent (SE)*

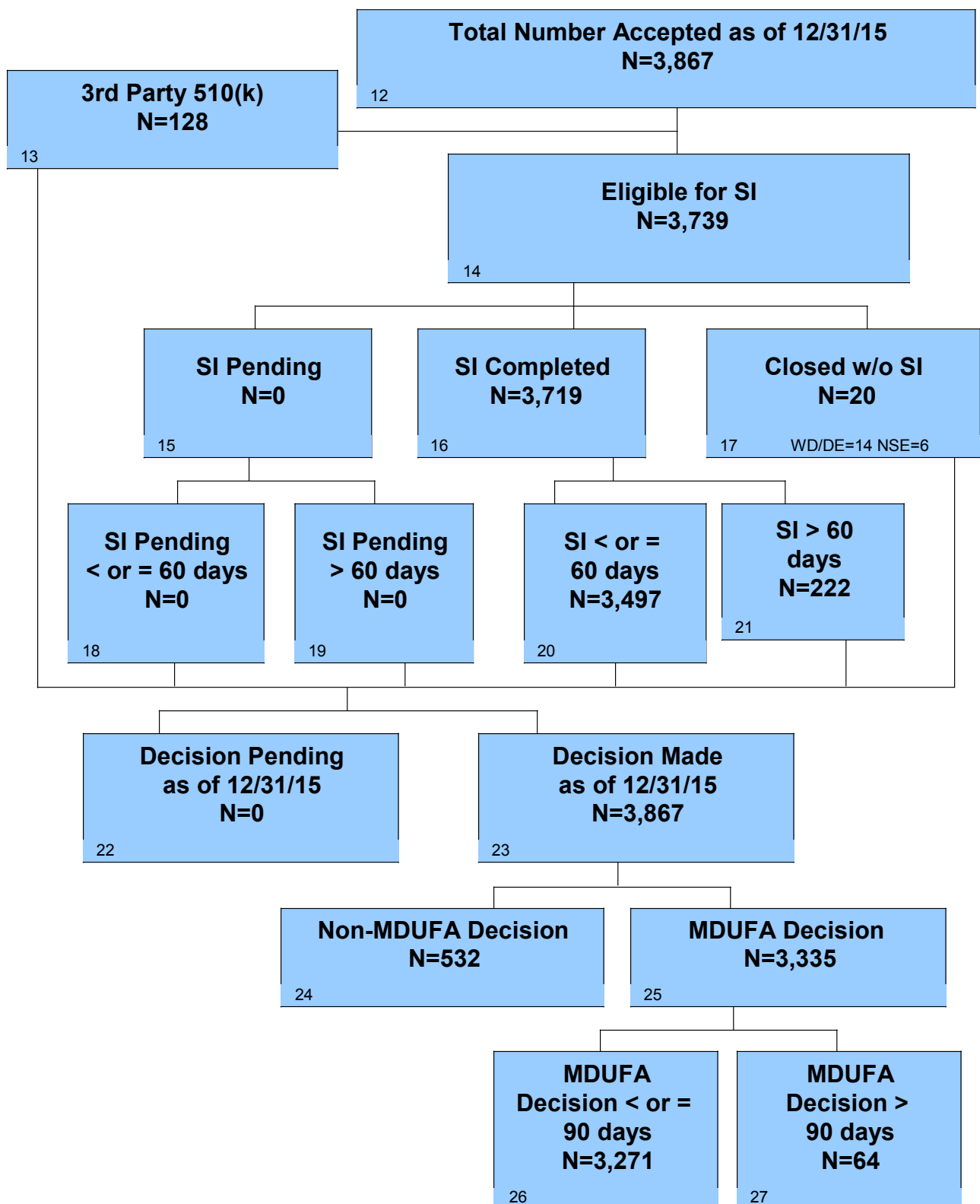


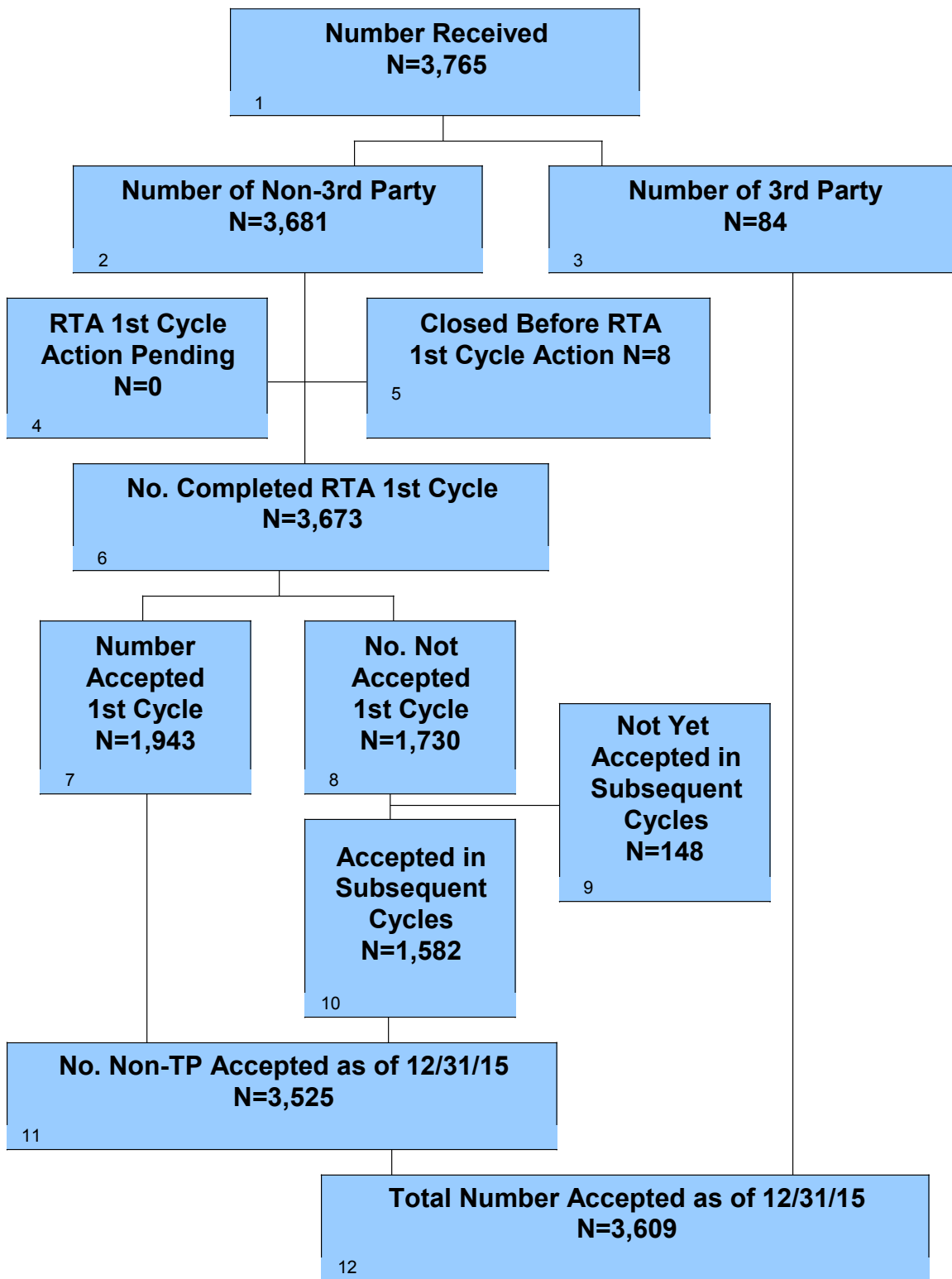
*Percentages may not add to 100% due to rounding

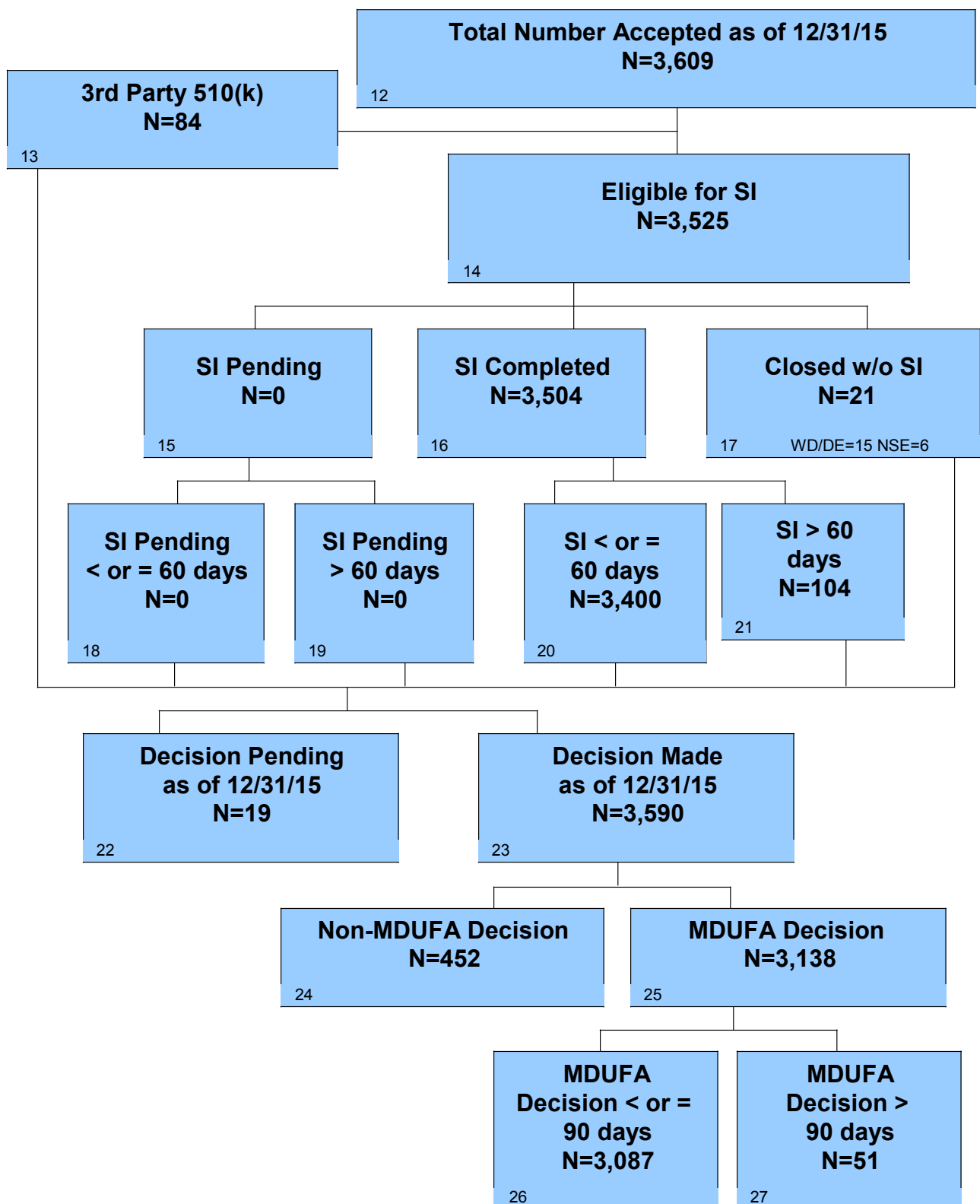
**Excludes final decisions made on FY 2013 - FY 2016 receipts that were not accepted for review as of 12/31/2015

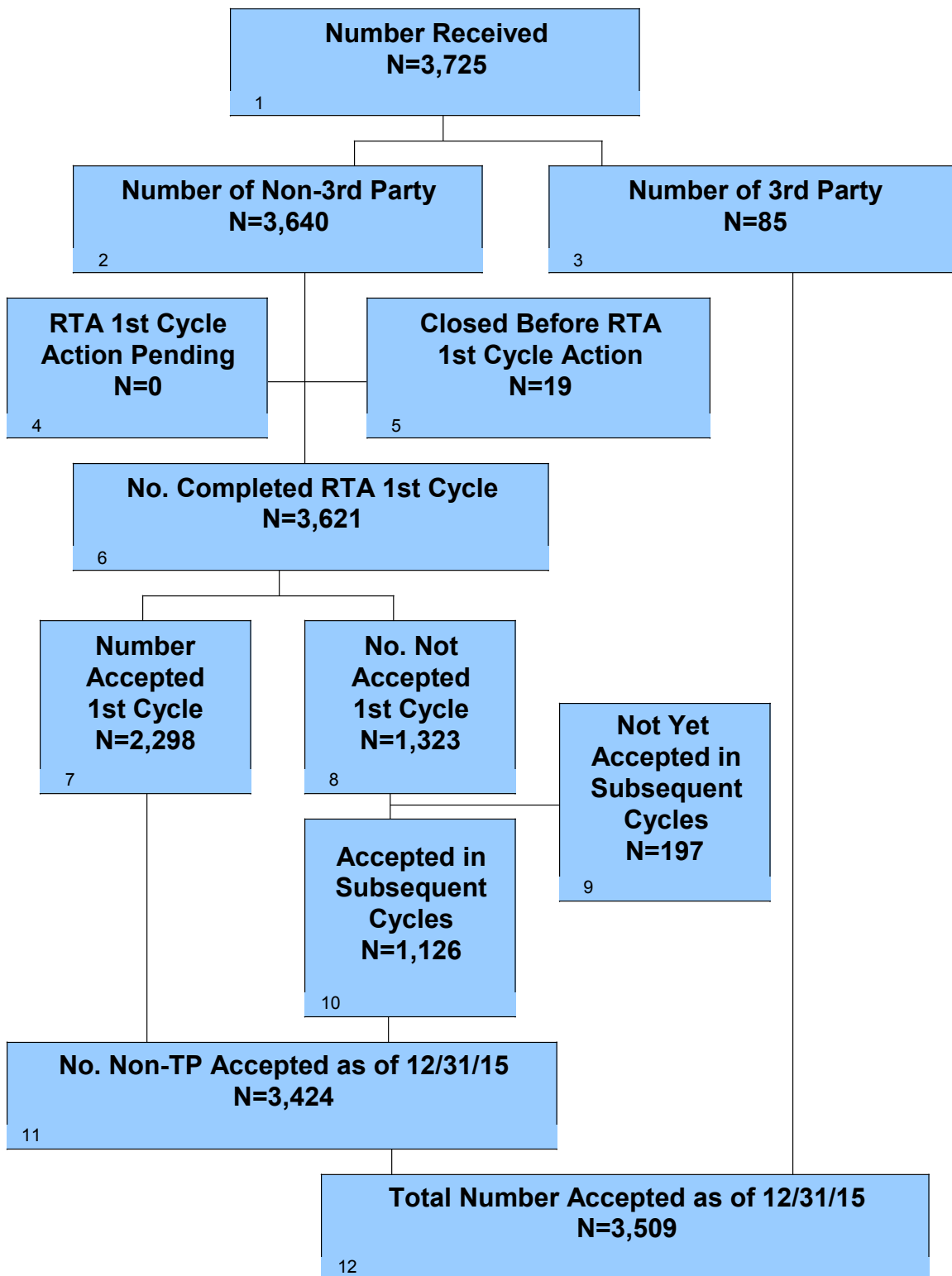
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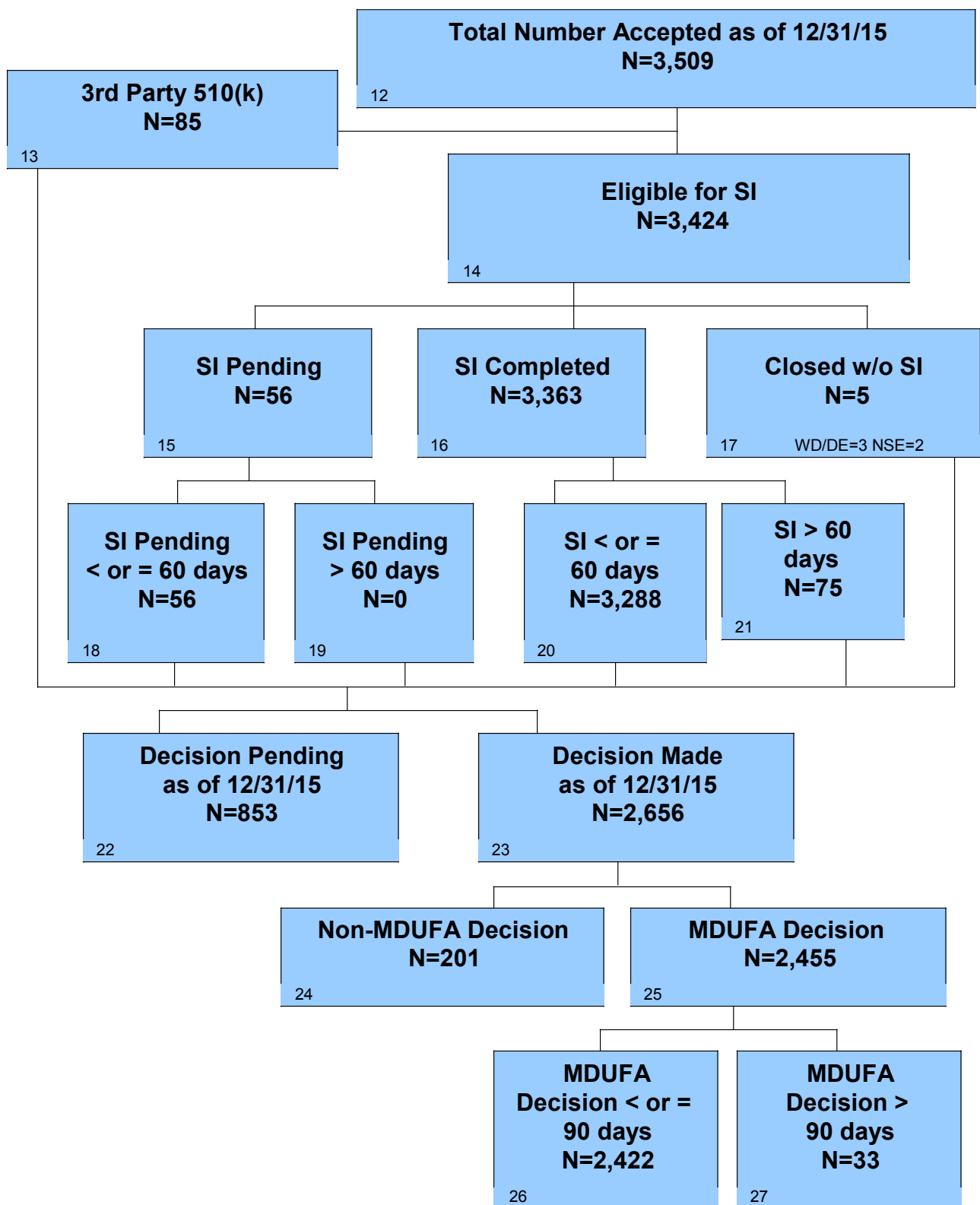


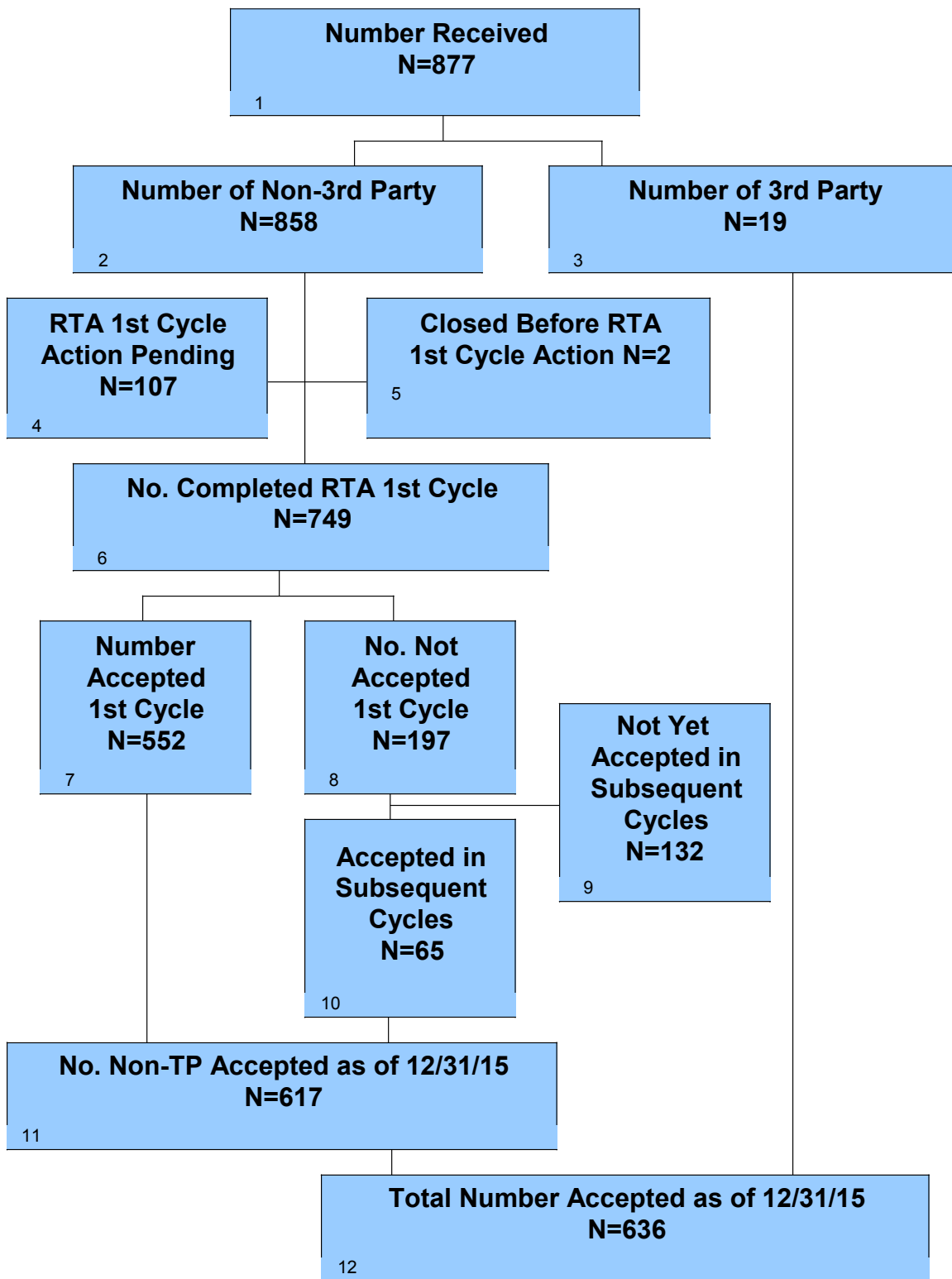


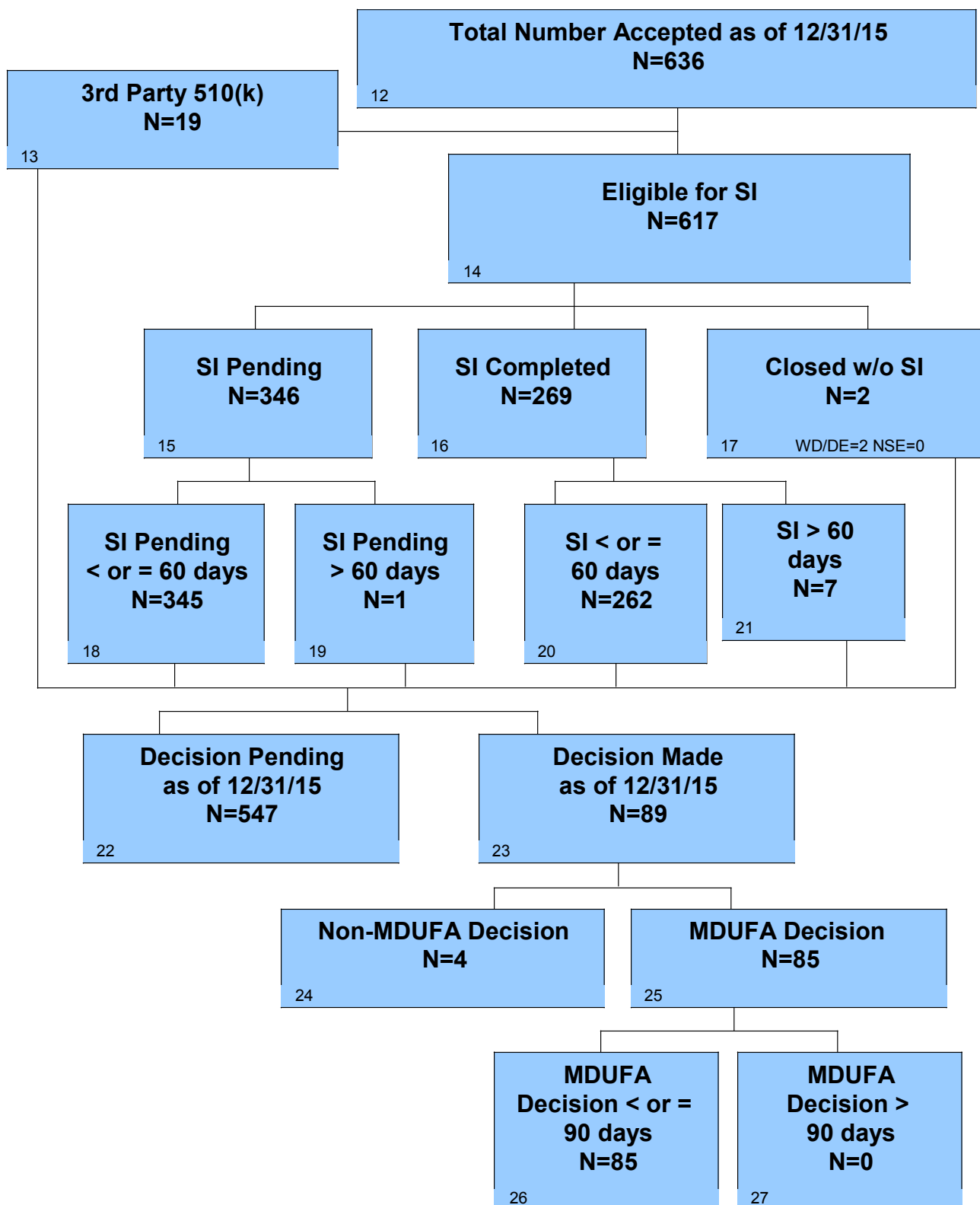












Section 6 510(k) Center Level Metrics

Table 6.1 CDRH – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,965	3,681	3,640	858	
Closed before RTA action	11	8	19	2	
Number Accepted	1,197	1,886	2,272	546	
Number without a RTA Review and > 15 Days since Date Received	42	57	26	6	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	107	
Number Not Accepted	1,715	1,730	1,323	197	
Rate of submissions not accepted for filing review	58.1%	47.1%	36.5%	26.3%	

* 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 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	3,525	3,424	617	
Deleted or withdrawn prior to SI	14	15	3	2	
SI within 60 FDA days	3,497	3,400	3,288	262	
SI over 60 FDA days	222	104	75	7	
SI pending within 60 FDA days	0	0	56	345	
SI pending over 60 FDA days	0	0	0	1	
510(k)s NSE without SI	6	6	2	0	
Current SI Performance Percent within 60 FDA days	93.9%	96.9%	97.7%	97%	

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	3,363	269	
Average number of FDA days to Substantive Interaction	47.6	49.4	49.8	43.1	
20th Percentile FDA days to Substantive Interaction	30	33	37	28	
40th Percentile FDA days to Substantive Interaction	48	52	52	36	
60th Percentile FDA days to Substantive Interaction	56	57	57	53	
80th Percentile FDA days to Substantive Interaction	59	59	59	58	
Maximum FDA days to Substantive Interaction	98	188	140	86	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	3,867	3,609	3,509	636	
Non-MDUFA III Decisions	532	452	201	4	
MDUFA III Decisions (SE/NSE)	3,335	3,138	2,455	85	
MDUFA III Decisions within 90 FDA Days	3,271	3,087	2,422	85	
510(k)s pending MDUFA III Decision	0	19	853	547	
510(k) pending MDUFA III Decision over 90 FDA days	0	3	11	0	
Current Performance Percent within 90 FDA Days	98.1%	98.3%	98.2%	100%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.7	1.6	1.2	
Number with MDUFA III decision	3,335	3,138	2,455	85	
Average FDA days to MDUFA III decision	70.8	72.0	69.1	33.5	
20th Percentile FDA days to MDUFA III decision	48	51	45	22	
40th Percentile FDA days to MDUFA III decision	76	80	72	27	
60th Percentile FDA days to MDUFA III decision	86	87	86	29	
80th Percentile FDA days to MDUFA III decision	89	89	89	47	
Maximum FDA days to MDUFA III decision	342	245	160	86	
Average Industry days to MDUFA III decision	57.2	55.2	39.5	2.0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	14	14	0	0	
60th Percentile Industry days to MDUFA III decision	44	45	28	0	
80th Percentile Industry days to MDUFA III decision	116	115	76	0	
Maximum Industry days to MDUFA III decision	467	469	342	40	
Average Total days to MDUFA III decision	127.9	127.3	108.6	35.5	
20th Percentile Total days to MDUFA III decision	56	58	49	23	
40th Percentile Total days to MDUFA III decision	90	90	86	28	
60th Percentile Total days to MDUFA III decision	127	128	109	29	
80th Percentile Total days to MDUFA III decision	199	201	158	56	
Maximum Total days to MDUFA III decision	691	556	432	86	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,867	3,609	3,509	636	
Number with MDUFA decision	3,335	3,138	2,455	85	
Number of SE decisions	3,202	3,053	2,405	85	
Number of NSE decisions	133	85	50	0	
Number of Withdrawals	231	211	113	3	
Number deleted	279	208	77	0	
Rate of SE decisions	96%	97.3%	98%	100%	
Rate of NSE decisions	4%	2.7%	2%	0%	
Rate of Withdrawals	6%	5.8%	3.2%	0.5%	
Rate of Deleted	7.2%	5.8%	2.2%	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	51	33	0	
Mean FDA days for submissions that missed goal	119	105	100	0	
Mean industry days for submissions that missed goal	138	123	80	0	

Section 6 510(k) Office Level Metrics

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,389	2,955	2,986	708	
Closed before RTA action	9	6	17	2	
Number Accepted	821	1,339	1,730	437	
Number without a RTA Review and > 15 Days since Date Received	24	50	23	4	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	87	
Number Not Accepted	1,535	1,560	1,216	178	
Rate of submissions not accepted for filing review	64.5%	52.9%	41%	28.8%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	2,976	2,828	2,795	501	
Deleted or withdrawn prior to SI	13	15	2	0	
SI within 60 FDA days	2,778	2,718	2,667	205	
SI over 60 FDA days	179	89	71	7	
SI pending within 60 FDA days	0	0	53	288	
SI pending over 60 FDA days	0	0	0	1	
510(k)s NSE without SI	6	6	2	0	
Current SI Performance Percent within 60 FDA days	93.8%	96.6%	97.3%	96.2%	

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	2,738	212	
Average number of FDA days to Substantive Interaction	48.3	50.4	50.8	44.3	
20th Percentile FDA days to Substantive Interaction	30	38	43	28	
40th Percentile FDA days to Substantive Interaction	49	54	54	42	
60th Percentile FDA days to Substantive Interaction	57	58	58	55	
80th Percentile FDA days to Substantive Interaction	59	60	59	59	
Maximum FDA days to Substantive Interaction	98	188	140	86	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,050	2,875	2,848	507	
Non-MDUFA III Decisions	446	381	169	2	
MDUFA III Decisions (SE/NSE)	2,604	2,479	1,949	58	
MDUFA III Decisions within 90 FDA Days	2,547	2,443	1,916	58	
510(k)s pending MDUFA III Decision	0	15	730	447	
510(k) pending MDUFA III Decision over 90 FDA days	0	3	11	0	
Current Performance Percent within 90 FDA Days	97.8%	98.4%	98%	100%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.7	1.6	1.2	
Number with MDUFA III decision	2,604	2,479	1,949	58	
Average FDA days to MDUFA III decision	72.8	73.7	71.6	35.9	
20th Percentile FDA days to MDUFA III decision	53	55	51	24	
40th Percentile FDA days to MDUFA III decision	80	83	80	28	
60th Percentile FDA days to MDUFA III decision	87	87	87	30	
80th Percentile FDA days to MDUFA III decision	89	89	89	54	
Maximum FDA days to MDUFA III decision	342	245	160	86	
Average Industry days to MDUFA III decision	57.3	55.6	40.3	2.7	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	17	16	6	0	
60th Percentile Industry days to MDUFA III decision	46	47	29	0	
80th Percentile Industry days to MDUFA III decision	116	117	76	0	
Maximum Industry days to MDUFA III decision	438	408	342	40	
Average Total days to MDUFA III decision	130.1	129.3	111.9	38.7	
20th Percentile Total days to MDUFA III decision	59	61	55	24	
40th Percentile Total days to MDUFA III decision	94	94	89	28	
60th Percentile Total days to MDUFA III decision	129	131	112	31	
80th Percentile Total days to MDUFA III decision	200	203	160	58	
Maximum Total days to MDUFA III decision	691	512	432	86	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,050	2,875	2,848	507	
Number with MDUFA decision	2,604	2,479	1,949	58	
Number of SE decisions	2,493	2,413	1,915	58	
Number of NSE decisions	111	66	34	0	
Number of Withdrawals	189	175	94	1	
Number deleted	237	174	64	0	
Rate of SE decisions	95.7%	97.3%	98%	100%	
Rate of NSE decisions	4.3%	2.7%	1.7%	0%	
Rate of Withdrawals	6.2%	6.1%	3.3%	0.2%	
Rate of Deleted	7.8%	6.1%	2.2%	0%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	57	36	33	0	
Mean FDA days for submissions that missed goal	121	107	100	0	
Mean industry days for submissions that missed goal	137	146	80	0	

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	150	
Closed before RTA action	2	2	2	0	
Number Accepted	376	547	542	109	
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	20	
Number Not Accepted	180	170	107	19	
Rate of submissions not accepted for filing review	31.4%	23.5%	16.4%	14.6%	

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	763	697	629	116	
Deleted or withdrawn prior to SI	1	0	1	2	
SI within 60 FDA days	719	682	621	57	
SI over 60 FDA days	43	15	4	0	
SI pending within 60 FDA days	0	0	3	57	
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	625	57	
Average number of FDA days to Substantive Interaction	45.0	45.7	45.2	38.6	
20th Percentile FDA days to Substantive Interaction	29	30	29	23	
40th Percentile FDA days to Substantive Interaction	43	45	45	29	
60th Percentile FDA days to Substantive Interaction	51	53	53	46	
80th Percentile FDA days to Substantive Interaction	58	58	58	55	
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
510(k)s accepted	817	734	661	129	
Non-MDUFA III Decisions	86	71	32	2	
MDUFA III Decisions (SE/NSE)	731	659	506	27	
MDUFA III Decisions within 90 FDA Days	724	644	506	27	
510(k)s pending MDUFA III Decision	0	4	123	100	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	99%	97.7%	100%	100%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.7	1.5	1.1	
Number with MDUFA III decision	731	659	506	27	
Average FDA days to MDUFA III decision	63.5	65.6	59.3	28.1	
20th Percentile FDA days to MDUFA III decision	34	33	29	20	
40th Percentile FDA days to MDUFA III decision	58	60	55	24	
60th Percentile FDA days to MDUFA III decision	81	84	73	28	
80th Percentile FDA days to MDUFA III decision	88	88	86	29	
Maximum FDA days to MDUFA III decision	121	137	90	77	
Average Industry days to MDUFA III decision	56.7	53.9	36.7	0.6	
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	20	0	
80th Percentile Industry days to MDUFA III decision	112	105	76	0	
Maximum Industry days to MDUFA III decision	467	469	319	7	
Average Total days to MDUFA III decision	120.2	119.5	96.0	28.7	
20th Percentile Total days to MDUFA III decision	36	35	29	20	
40th Percentile Total days to MDUFA III decision	77	85	58	24	
60th Percentile Total days to MDUFA III decision	111	113	90	28	
80th Percentile Total days to MDUFA III decision	194	189	148	30	
Maximum Total days to MDUFA III decision	557	556	406	77	

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	661	129	
Number with MDUFA decision	731	659	506	27	
Number of SE decisions	709	640	490	27	
Number of NSE decisions	22	19	16	0	
Number of Withdrawals	42	36	19	2	
Number deleted	42	34	13	0	
Rate of SE decisions	97%	97.1%	96.8%	100%	
Rate of NSE decisions	3%	2.9%	3.2%	0%	
Rate of Withdrawals	5.1%	4.9%	2.9%	1.6%	
Rate of Deleted	5.1%	4.6%	2%	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	0	0	
Mean FDA days for submissions that missed goal	103	100	0	0	
Mean industry days for submissions that missed goal	143	67	0	0	

Section 6 510(k) Division Level Metrics

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	637	775	776	188	
Closed before RTA action	6	1	3	0	
Number Accepted	189	317	375	85	
Number without a RTA Review and > 15 Days since Date Received	5	14	6	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	29	
Number Not Accepted	437	443	392	74	
Rate of submissions not accepted for filing review	69.3%	57.2%	50.7%	46.5%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	782	724	688	109	
Deleted or withdrawn prior to SI	3	7	0	0	
SI within 60 FDA days	749	711	645	42	
SI over 60 FDA days	26	3	9	0	
SI pending within 60 FDA days	0	0	32	66	
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%	98.3%	97.7%	

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	714	654	42	
Average number of FDA days to Substantive Interaction	50.9	53.4	54.2	45.8	
20th Percentile FDA days to Substantive Interaction	43	50	52	28	
40th Percentile FDA days to Substantive Interaction	55	57	57	45	
60th Percentile FDA days to Substantive Interaction	58	59	58	56	
80th Percentile FDA days to Substantive Interaction	60	60	60	59	
Maximum FDA days to Substantive Interaction	90	188	79	60	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	797	738	704	112	
Non-MDUFA III Decisions	165	114	42	1	
MDUFA III Decisions (SE/NSE)	632	617	411	6	
MDUFA III Decisions within 90 FDA Days	613	601	389	6	
510(k)s pending MDUFA III Decision	0	7	251	105	
510(k) pending MDUFA III Decision over 90 FDA days	0	1	3	0	
Current Performance Percent within 90 FDA Days	97%	97.2%	94%	100%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.8	1.8	1.7	
Number with MDUFA III decision	632	617	411	6	
Average FDA days to MDUFA III decision	78.0	80.0	81.5	34.3	
20th Percentile FDA days to MDUFA III decision	63	78	83	27	
40th Percentile FDA days to MDUFA III decision	84	86	87	28	
60th Percentile FDA days to MDUFA III decision	88	88	88	29	
80th Percentile FDA days to MDUFA III decision	90	90	90	43	
Maximum FDA days to MDUFA III decision	280	107	100	54	
Average Industry days to MDUFA III decision	64.2	68.1	48.8	8.8	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	21	28	16	0	
60th Percentile Industry days to MDUFA III decision	54	69	42	2	
80th Percentile Industry days to MDUFA III decision	141	141	101	11	
Maximum Industry days to MDUFA III decision	420	357	230	40	
Average Total days to MDUFA III decision	142.2	148.1	130.2	43.2	
20th Percentile Total days to MDUFA III decision	78	87	87	28	
40th Percentile Total days to MDUFA III decision	102	114	102	29	
60th Percentile Total days to MDUFA III decision	140	156	128	36	
80th Percentile Total days to MDUFA III decision	220	230	190	56	
Maximum Total days to MDUFA III decision	610	446	317	83	

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	704	112	
Number with MDUFA decision	632	617	411	6	
Number of SE decisions	603	592	404	6	
Number of NSE decisions	29	25	7	0	
Number of Withdrawals	56	52	24	1	
Number deleted	104	51	13	0	
Rate of SE decisions	95.4%	95.9%	98.3%	100%	
Rate of NSE decisions	4.6%	4.1%	1.7%	0%	
Rate of Withdrawals	7%	7%	3.4%	0.9%	
Rate of Deleted	13%	6.9%	1.8%	0%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	19	16	22	0	
Mean FDA days for submissions that missed goal	125	98	95	0	
Mean industry days for submissions that missed goal	157	159	73	0	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	336	407	406	113	
Closed before RTA action	0	1	2	1	
Number Accepted	151	196	278	76	
Number without a RTA Review and > 15 Days since Date Received	10	9	5	2	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	12	
Number Not Accepted	175	201	121	22	
Rate of submissions not accepted for filing review	52.1%	49.5%	30%	22%	

* 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
Eligible for SI	432	400	394	87	
Deleted or withdrawn prior to SI	2	2	1	0	
SI within 60 FDA days	392	379	377	46	
SI over 60 FDA days	38	19	14	4	
SI pending within 60 FDA days	0	0	2	37	
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%	96.4%	92%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	430	398	391	50	
Average number of FDA days to Substantive Interaction	45.5	46.5	47.2	43.7	
20th Percentile FDA days to Substantive Interaction	29	29	29	27	
40th Percentile FDA days to Substantive Interaction	43	46	49	36	
60th Percentile FDA days to Substantive Interaction	50	55	56	51	
80th Percentile FDA days to Substantive Interaction	58	59	59	59	
Maximum FDA days to Substantive Interaction	98	90	140	78	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	456	414	406	87	
Non-MDUFA III Decisions	29	41	13	0	
MDUFA III Decisions (SE/NSE)	427	372	309	9	
MDUFA III Decisions within 90 FDA Days	412	367	303	9	
510(k)s pending MDUFA III Decision	0	1	84	78	
510(k) pending MDUFA III Decision over 90 FDA days	0	1	3	0	
Current Performance Percent within 90 FDA Days	96.5%	98.4%	97.1%	100%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.7	1.6	1.1	
Number with MDUFA III decision	427	372	309	9	
Average FDA days to MDUFA III decision	67.2	68.1	64.6	28.8	
20th Percentile FDA days to MDUFA III decision	36	40	30	22	
40th Percentile FDA days to MDUFA III decision	59	60	58	27	
60th Percentile FDA days to MDUFA III decision	86	87	84	28	
80th Percentile FDA days to MDUFA III decision	89	89	89	34	
Maximum FDA days to MDUFA III decision	237	140	160	46	
Average Industry days to MDUFA III decision	47.5	47.9	33.5	2.7	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	11	9	0	0	
60th Percentile Industry days to MDUFA III decision	38	34	23	0	
80th Percentile Industry days to MDUFA III decision	84	112	59	0	
Maximum Industry days to MDUFA III decision	358	226	178	24	
Average Total days to MDUFA III decision	114.8	116.0	98.1	31.4	
20th Percentile Total days to MDUFA III decision	41	45	30	22	
40th Percentile Total days to MDUFA III decision	85	87	63	27	
60th Percentile Total days to MDUFA III decision	119	119	108	28	
80th Percentile Total days to MDUFA III decision	171	194	147	36	
Maximum Total days to MDUFA III decision	451	315	267	66	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	456	414	406	87	
Number with MDUFA decision	427	372	309	9	
Number of SE decisions	418	369	303	9	
Number of NSE decisions	9	3	6	0	
Number of Withdrawals	14	21	7	0	
Number deleted	14	20	6	0	
Rate of SE decisions	97.9%	99.2%	98.1%	100%	
Rate of NSE decisions	2.1%	0.8%	1.9%	0%	
Rate of Withdrawals	3.1%	5.1%	1.7%	0%	
Rate of Deleted	3.1%	4.8%	1.5%	0%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	15	5	6	0	
Mean FDA days for submissions that missed goal	123	110	114	0	
Mean industry days for submissions that missed goal	114	104	61	0	

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	54	
Closed before RTA action	0	1	0	0	
Number Accepted	39	81	110	32	
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	10	
Number Not Accepted	150	120	117	11	
Rate of submissions not accepted for filing review	78.9%	58.5%	50.9%	25%	

* 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
Eligible for SI	230	188	210	36	
Deleted or withdrawn prior to SI	1	1	0	0	
SI within 60 FDA days	203	180	207	16	
SI over 60 FDA days	26	7	1	0	
SI pending within 60 FDA days	0	0	2	20	
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%	100%	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	187	208	16	
Average number of FDA days to Substantive Interaction	51.9	53.8	54.3	50.8	
20th Percentile FDA days to Substantive Interaction	43	53	52	30	
40th Percentile FDA days to Substantive Interaction	55	58	58	56	
60th Percentile FDA days to Substantive Interaction	58	59	59	58	
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
510(k)s accepted	236	191	218	37	
Non-MDUFA III Decisions	31	37	11	1	
MDUFA III Decisions (SE/NSE)	205	154	137	2	
MDUFA III Decisions within 90 FDA Days	199	148	137	2	
510(k)s pending MDUFA III Decision	0	0	70	34	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	97.1%	96.1%	100%	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	1.9	1.9	1.8	2.0	
Number with MDUFA III decision	205	154	137	2	
Average FDA days to MDUFA III decision	83.7	84.0	77.3	55.0	
20th Percentile FDA days to MDUFA III decision	86	86	58	54	
40th Percentile FDA days to MDUFA III decision	88	88	88	55	
60th Percentile FDA days to MDUFA III decision	89	89	89	55	
80th Percentile FDA days to MDUFA III decision	90	90	90	56	
Maximum FDA days to MDUFA III decision	148	245	90	56	
Average Industry days to MDUFA III decision	77.5	76.6	54.5	11.0	
20th Percentile Industry days to MDUFA III decision	8	7	0	8	
40th Percentile Industry days to MDUFA III decision	41	44	20	10	
60th Percentile Industry days to MDUFA III decision	84	82	50	12	
80th Percentile Industry days to MDUFA III decision	152	156	114	14	
Maximum Industry days to MDUFA III decision	345	291	202	16	
Average Total days to MDUFA III decision	161.2	160.5	131.8	66.0	
20th Percentile Total days to MDUFA III decision	90	90	70	64	
40th Percentile Total days to MDUFA III decision	128	131	108	65	
60th Percentile Total days to MDUFA III decision	174	170	137	67	
80th Percentile Total days to MDUFA III decision	240	249	204	68	
Maximum Total days to MDUFA III decision	435	385	291	70	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	236	191	218	37	
Number with MDUFA decision	205	154	137	2	
Number of SE decisions	187	145	135	2	
Number of NSE decisions	18	9	2	0	
Number of Withdrawals	13	18	4	0	
Number deleted	13	16	6	0	
Rate of SE decisions	91.2%	94.2%	99%	100%	
Rate of NSE decisions	8.8%	5.8%	1%	0%	
Rate of Withdrawals	5.5%	9.4%	1.8%	0%	
Rate of Deleted	5.5%	8.4%	2.8%	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	162	
Closed before RTA action	0	1	3	1	
Number Accepted	181	313	395	110	
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	15	
Number Not Accepted	342	348	271	36	
Rate of submissions not accepted for filing review	65.4%	52.4%	40.7%	24.7%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	655	654	654	124	
Deleted or withdrawn prior to SI	3	1	0	0	
SI within 60 FDA days	623	636	631	41	
SI over 60 FDA days	29	15	18	0	
SI pending within 60 FDA days	0	0	5	83	
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%	100%	

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	649	41	
Average number of FDA days to Substantive Interaction	47.9	48.8	48.8	42.0	
20th Percentile FDA days to Substantive Interaction	30	29	33	28	
40th Percentile FDA days to Substantive Interaction	48	52	51	30	
60th Percentile FDA days to Substantive Interaction	56	57	56	50	
80th Percentile FDA days to Substantive Interaction	59	59	58	55	
Maximum FDA days to Substantive Interaction	88	90	92	60	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	656	654	654	124	
Non-MDUFA III Decisions	73	48	35	0	
MDUFA III Decisions (SE/NSE)	583	604	516	18	
MDUFA III Decisions within 90 FDA Days	579	602	516	18	
510(k)s pending MDUFA III Decision	0	2	103	106	
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%	100%	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	1.6	1.6	1.5	1.1	
Number with MDUFA III decision	583	604	516	18	
Average FDA days to MDUFA III decision	69.9	69.0	67.8	38.2	
20th Percentile FDA days to MDUFA III decision	49	47	48	24	
40th Percentile FDA days to MDUFA III decision	74	73	67	29	
60th Percentile FDA days to MDUFA III decision	85	85	84	33	
80th Percentile FDA days to MDUFA III decision	88	88	87	55	
Maximum FDA days to MDUFA III decision	100	94	90	82	
Average Industry days to MDUFA III decision	40.5	38.4	27.8	0.4	
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	16	0	
80th Percentile Industry days to MDUFA III decision	75	78	49	0	
Maximum Industry days to MDUFA III decision	430	264	182	8	
Average Total days to MDUFA III decision	110.4	107.4	95.6	38.6	
20th Percentile Total days to MDUFA III decision	52	50	50	24	
40th Percentile Total days to MDUFA III decision	85	84	80	29	
60th Percentile Total days to MDUFA III decision	110	105	96	33	
80th Percentile Total days to MDUFA III decision	163	161	132	57	
Maximum Total days to MDUFA III decision	520	352	269	82	

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	654	124	
Number with MDUFA decision	583	604	516	18	
Number of SE decisions	564	596	510	18	
Number of NSE decisions	19	8	6	0	
Number of Withdrawals	37	26	22	0	
Number deleted	35	22	13	0	
Rate of SE decisions	96.7%	98.7%	99%	100%	
Rate of NSE decisions	3.3%	1.3%	1%	0%	
Rate of Withdrawals	5.6%	4%	3.4%	0%	
Rate of Deleted	5.3%	3.4%	2%	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	34	
Closed before RTA action	0	0	1	0	
Number Accepted	59	75	79	24	
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	5	
Number Not Accepted	54	65	60	4	
Rate of submissions not accepted for filing review	45.8%	45.8%	42.6%	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.DOED - ODE - 510(k) Substantive Interaction Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	139	137	137	26	
Deleted or withdrawn prior to SI	0	1	0	0	
SI within 60 FDA days	134	135	134	10	
SI over 60 FDA days	5	1	2	2	
SI pending within 60 FDA days	0	0	1	14	
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%	83.3%	

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	136	12	
Average number of FDA days to Substantive Interaction	48.7	51.3	52.5	50.4	
20th Percentile FDA days to Substantive Interaction	43	46	49	39	
40th Percentile FDA days to Substantive Interaction	49	53	56	51	
60th Percentile FDA days to Substantive Interaction	54	57	58	57	
80th Percentile FDA days to Substantive Interaction	57	59	60	60	
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
510(k)s accepted	146	139	140	26	
Non-MDUFA III Decisions	20	27	11	0	
MDUFA III Decisions (SE/NSE)	126	111	93	3	
MDUFA III Decisions within 90 FDA Days	123	111	93	3	
510(k)s pending MDUFA III Decision	0	1	36	23	
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	1.8	1.8	1.7	1.3	
Number with MDUFA III decision	126	111	93	3	
Average FDA days to MDUFA III decision	75.5	78.3	72.3	59.3	
20th Percentile FDA days to MDUFA III decision	56	60	54	57	
40th Percentile FDA days to MDUFA III decision	84	87	81	58	
60th Percentile FDA days to MDUFA III decision	88	89	88	59	
80th Percentile FDA days to MDUFA III decision	90	90	90	62	
Maximum FDA days to MDUFA III decision	91	90	90	64	
Average Industry days to MDUFA III decision	62.8	56.7	37	6	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	21	21	6	0	
60th Percentile Industry days to MDUFA III decision	60	42	26	3	
80th Percentile Industry days to MDUFA III decision	160	115	56	10	
Maximum Industry days to MDUFA III decision	250	333	180	17	
Average Total days to MDUFA III decision	138.3	135.0	109.4	65.0	
20th Percentile Total days to MDUFA III decision	70	79	58	60	
40th Percentile Total days to MDUFA III decision	105	105	85	63	
60th Percentile Total days to MDUFA III decision	135	132	109	66	
80th Percentile Total days to MDUFA III decision	230	203	143	69	
Maximum Total days to MDUFA III decision	332	423	268	73	

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	26	
Number with MDUFA decision	126	111	93	3	
Number of SE decisions	121	104	87	3	
Number of NSE decisions	5	7	6	0	
Number of Withdrawals	8	7	6	0	
Number deleted	11	17	4	0	
Rate of SE decisions	96%	93.7%	93.5%	100%	
Rate of NSE decisions	4%	6.3%	6.5%	0%	
Rate of Withdrawals	5.5%	5%	4.3%	0%	
Rate of Deleted	7.5%	12.2%	2.9%	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	51	
Closed before RTA action	0	2	7	0	
Number Accepted	66	145	185	42	
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	3	
Number Not Accepted	144	123	76	6	
Rate of submissions not accepted for filing review	68.6%	44.7%	28.9%	12.5%	

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	265	267	248	43	
Deleted or withdrawn prior to SI	1	3	1	0	
SI within 60 FDA days	253	256	241	24	
SI over 60 FDA days	9	7	2	0	
SI pending within 60 FDA days	0	0	4	19	
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	263	243	24	
Average number of FDA days to Substantive Interaction	48.2	48.9	48.3	39.2	
20th Percentile FDA days to Substantive Interaction	36	38	37	27	
40th Percentile FDA days to Substantive Interaction	50	50	47	28	
60th Percentile FDA days to Substantive Interaction	56	56	56	46	
80th Percentile FDA days to Substantive Interaction	58	59	59	56	
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
510(k)s accepted	278	274	252	44	
Non-MDUFA III Decisions	42	36	14	0	
MDUFA III Decisions (SE/NSE)	236	237	178	11	
MDUFA III Decisions within 90 FDA Days	236	237	177	11	
510(k)s pending MDUFA III Decision	0	1	60	33	
510(k) pending MDUFA III Decision over 90 FDA days	0	1	1	0	
Current Performance Percent within 90 FDA Days	100%	99.6%	98.9%	100%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.9	1.8	1.7	1.2	
Number with MDUFA III decision	236	237	178	11	
Average FDA days to MDUFA III decision	71.4	71.1	70.5	26.0	
20th Percentile FDA days to MDUFA III decision	54	52	48	18	
40th Percentile FDA days to MDUFA III decision	80	77	78	26	
60th Percentile FDA days to MDUFA III decision	86	86	85	28	
80th Percentile FDA days to MDUFA III decision	88	88	89	29	
Maximum FDA days to MDUFA III decision	90	90	108	46	
Average Industry days to MDUFA III decision	73.1	58.1	54.9	2.0	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	32	22	7	0	
60th Percentile Industry days to MDUFA III decision	74	55	48	0	
80th Percentile Industry days to MDUFA III decision	152	112	121	0	
Maximum Industry days to MDUFA III decision	416	236	240	16	
Average Total days to MDUFA III decision	144.6	129.1	125.4	28.0	
20th Percentile Total days to MDUFA III decision	59	60	51	22	
40th Percentile Total days to MDUFA III decision	112	103	90	26	
60th Percentile Total days to MDUFA III decision	154	135	127	28	
80th Percentile Total days to MDUFA III decision	239	199	208	29	
Maximum Total days to MDUFA III decision	506	316	329	56	

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	44	
Number with MDUFA decision	236	237	178	11	
Number of SE decisions	221	232	176	11	
Number of NSE decisions	15	5	2	0	
Number of Withdrawals	18	11	8	0	
Number deleted	22	21	5	0	
Rate of SE decisions	93.6%	97.9%	98.9%	100%	
Rate of NSE decisions	6.4%	2.1%	1.1%	0%	
Rate of Withdrawals	6.5%	4%	3.2%	0%	
Rate of Deleted	7.9%	7.7%	2%	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	1	0	
Mean FDA days for submissions that missed goal	0	0	108	0	
Mean industry days for submissions that missed goal	0	0	167	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	106	
Closed before RTA action	3	0	1	0	
Number Accepted	136	212	308	68	
Number without a RTA Review and > 15 Days since Date Received	3	11	5	0	
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	13	
Number Not Accepted	233	260	179	25	
Rate of submissions not accepted for filing review	62.6%	53.8%	36.4%	26.9%	

* 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.DSD - ODE - 510(k) Substantive Interaction Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	473	458	464	76	
Deleted or withdrawn prior to SI	3	0	0	0	
SI within 60 FDA days	424	421	432	26	
SI over 60 FDA days	46	37	25	1	
SI pending within 60 FDA days	0	0	7	49	
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	90.2%	91.9%	94.5%	96.3%	

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	457	27	
Average number of FDA days to Substantive Interaction	45.4	50.4	51.0	44.4	
20th Percentile FDA days to Substantive Interaction	28	36	41	28	
40th Percentile FDA days to Substantive Interaction	44	53	55	34	
60th Percentile FDA days to Substantive Interaction	56	57	58	55	
80th Percentile FDA days to Substantive Interaction	59	60	60	57	
Maximum FDA days to Substantive Interaction	90	90	93	86	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	481	465	474	77	
Non-MDUFA III Decisions	86	78	43	0	
MDUFA III Decisions (SE/NSE)	395	384	305	9	
MDUFA III Decisions within 90 FDA Days	385	377	301	9	
510(k)s pending MDUFA III Decision	0	3	126	68	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	3	0	
Current Performance Percent within 90 FDA Days	97.5%	98.2%	97.7%	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	1.8	1.7	1.6	1.1	
Number with MDUFA III decision	395	384	305	9	
Average FDA days to MDUFA III decision	69.0	72.7	69.9	39.9	
20th Percentile FDA days to MDUFA III decision	43	55	44	28	
40th Percentile FDA days to MDUFA III decision	70	79	78	29	
60th Percentile FDA days to MDUFA III decision	85	87	86	36	
80th Percentile FDA days to MDUFA III decision	89	89	89	53	
Maximum FDA days to MDUFA III decision	342	147	129	86	
Average Industry days to MDUFA III decision	60.0	59.7	42.8	1.3	
20th Percentile Industry days to MDUFA III decision	0	0	0	0	
40th Percentile Industry days to MDUFA III decision	20	17	5	0	
60th Percentile Industry days to MDUFA III decision	44	51	29	0	
80th Percentile Industry days to MDUFA III decision	125	122	78	0	
Maximum Industry days to MDUFA III decision	438	408	342	12	
Average Total days to MDUFA III decision	129.1	132.4	112.6	41.2	
20th Percentile Total days to MDUFA III decision	51	61	52	28	
40th Percentile Total days to MDUFA III decision	93	90	87	29	
60th Percentile Total days to MDUFA III decision	128	134	111	39	
80th Percentile Total days to MDUFA III decision	204	211	164	57	
Maximum Total days to MDUFA III decision	691	512	432	86	

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	474	77	
Number with MDUFA decision	395	384	305	9	
Number of SE decisions	379	375	300	9	
Number of NSE decisions	16	9	5	0	
Number of Withdrawals	43	40	23	0	
Number deleted	38	27	17	0	
Rate of SE decisions	95.9%	97.7%	98.4%	100%	
Rate of NSE decisions	4.1%	2.3%	1.6%	0%	
Rate of Withdrawals	8.9%	8.6%	4.9%	0%	
Rate of Deleted	7.9%	5.8%	3.6%	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	4	0	
Mean FDA days for submissions that missed goal	137	106	105	0	
Mean industry days for submissions that missed goal	160	171	120	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	47	
Closed before RTA action	1	1	1	0	
Number Accepted	118	127	154	27	
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	11	
Number Not Accepted	69	66	35	7	
Rate of submissions not accepted for filing review	36.9%	34%	18.4%	19.4%	

* 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.DCTD - OIR - 510(k) Substantive Interaction Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	247	184	177	29	
Deleted or withdrawn prior to SI	0	0	0	2	
SI within 60 FDA days	247	184	174	9	
SI over 60 FDA days	0	0	2	0	
SI pending within 60 FDA days	0	0	1	18	
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	176	9	
Average number of FDA days to Substantive Interaction	41.0	42.7	43.4	38.7	
20th Percentile FDA days to Substantive Interaction	29	30	29	27	
40th Percentile FDA days to Substantive Interaction	38	43	42	29	
60th Percentile FDA days to Substantive Interaction	45	47	49	42	
80th Percentile FDA days to Substantive Interaction	52	54	57	52	
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
510(k)s accepted	247	184	177	29	
Non-MDUFA III Decisions	34	33	16	2	
MDUFA III Decisions (SE/NSE)	213	148	117	2	
MDUFA III Decisions within 90 FDA Days	212	146	117	2	
510(k)s pending MDUFA III Decision	0	3	44	25	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	99.5%	98.6%	100%	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	1.9	1.9	1.6	1.0	
Number with MDUFA III decision	213	148	117	2	
Average FDA days to MDUFA III decision	64.9	67.1	62.5	25.5	
20th Percentile FDA days to MDUFA III decision	34	34	30	24	
40th Percentile FDA days to MDUFA III decision	58	59	58	25	
60th Percentile FDA days to MDUFA III decision	84	85	82	26	
80th Percentile FDA days to MDUFA III decision	88	88	88	27	
Maximum FDA days to MDUFA III decision	99	131	90	28	
Average Industry days to MDUFA III decision	83.4	84.4	48	0	
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	67	37	0	
80th Percentile Industry days to MDUFA III decision	166	175	107	0	
Maximum Industry days to MDUFA III decision	467	469	275	0	
Average Total days to MDUFA III decision	148.4	151.5	110.9	25.5	
20th Percentile Total days to MDUFA III decision	35	34	30	24	
40th Percentile Total days to MDUFA III decision	87	83	69	25	
60th Percentile Total days to MDUFA III decision	148	152	108	26	
80th Percentile Total days to MDUFA III decision	245	262	193	27	
Maximum Total days to MDUFA III decision	557	556	356	28	

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	177	29	
Number with MDUFA decision	213	148	117	2	
Number of SE decisions	207	147	113	2	
Number of NSE decisions	6	1	4	0	
Number of Withdrawals	17	20	8	2	
Number deleted	17	13	8	0	
Rate of SE decisions	97.2%	99.3%	97%	100%	
Rate of NSE decisions	2.8%	0.7%	3%	0%	
Rate of Withdrawals	6.9%	10.9%	4.5%	6.9%	
Rate of Deleted	6.9%	7.1%	4.5%	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	13	
Closed before RTA action	1	1	0	0	
Number Accepted	38	57	50	9	
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	2	
Rate of submissions not accepted for filing review	25.5%	20.8%	15%	18.2%	

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

Table 6.2.DIHD - OIR - 510(k) Substantive Interaction Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	69	65	57	9	
Deleted or withdrawn prior to SI	0	0	1	0	
SI within 60 FDA days	68	65	56	4	
SI over 60 FDA days	1	0	0	0	
SI pending within 60 FDA days	0	0	0	5	
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	4	
Average number of FDA days to Substantive Interaction	47.6	51.0	52.4	50.3	
20th Percentile FDA days to Substantive Interaction	41	46	49	44	
40th Percentile FDA days to Substantive Interaction	50	52	57	59	
60th Percentile FDA days to Substantive Interaction	54	57	59	60	
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
510(k)s accepted	69	65	57	9	
Non-MDUFA III Decisions	22	20	7	0	
MDUFA III Decisions (SE/NSE)	47	44	28	2	
MDUFA III Decisions within 90 FDA Days	47	43	28	2	
510(k)s pending MDUFA III Decision	0	1	22	7	
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	2.0	1.9	1.8	1.0	
Number with MDUFA III decision	47	44	28	2	
Average FDA days to MDUFA III decision	71.6	79.5	69.0	49.5	
20th Percentile FDA days to MDUFA III decision	50	70	30	33	
40th Percentile FDA days to MDUFA III decision	77	88	87	44	
60th Percentile FDA days to MDUFA III decision	86	89	89	55	
80th Percentile FDA days to MDUFA III decision	88	90	90	66	
Maximum FDA days to MDUFA III decision	90	91	90	77	
Average Industry days to MDUFA III decision	115.4	106.4	81	0	
20th Percentile Industry days to MDUFA III decision	29	45	0	0	
40th Percentile Industry days to MDUFA III decision	89	63	22	0	
60th Percentile Industry days to MDUFA III decision	157	154	106	0	
80th Percentile Industry days to MDUFA III decision	177	176	170	0	
Maximum Industry days to MDUFA III decision	329	325	209	0	
Average Total days to MDUFA III decision	187.0	185.8	149.9	49.5	
20th Percentile Total days to MDUFA III decision	91	118	30	33	
40th Percentile Total days to MDUFA III decision	151	140	111	44	
60th Percentile Total days to MDUFA III decision	236	237	194	55	
80th Percentile Total days to MDUFA III decision	264	265	259	66	
Maximum Total days to MDUFA III decision	417	414	299	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	9	
Number with MDUFA decision	47	44	28	2	
Number of SE decisions	43	37	28	2	
Number of NSE decisions	4	7	0	0	
Number of Withdrawals	6	7	5	0	
Number deleted	14	13	2	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%	3.5%	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	14	
Closed before RTA action	0	0	1	0	
Number Accepted	55	80	66	12	
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	2	
Number Not Accepted	4	3	2	0	
Rate of submissions not accepted for filing review	6.8%	3.6%	2.9%	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.DMD - OIR - 510(k) Substantive Interaction Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	80	83	67	12	
Deleted or withdrawn prior to SI	0	0	0	0	
SI within 60 FDA days	79	82	67	9	
SI over 60 FDA days	1	1	0	0	
SI pending within 60 FDA days	0	0	0	3	
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	9	
Average number of FDA days to Substantive Interaction	43.1	47.6	48.3	43.8	
20th Percentile FDA days to Substantive Interaction	28	29	31	29	
40th Percentile FDA days to Substantive Interaction	39	51	55	47	
60th Percentile FDA days to Substantive Interaction	53	56	57	54	
80th Percentile FDA days to Substantive Interaction	57	59	59	54	
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
510(k)s accepted	80	83	67	12	
Non-MDUFA III Decisions	9	7	3	0	
MDUFA III Decisions (SE/NSE)	71	76	49	3	
MDUFA III Decisions within 90 FDA Days	71	76	49	3	
510(k)s pending MDUFA III Decision	0	0	15	9	
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	1.3	1.5	1.4	1.0	
Number with MDUFA III decision	71	76	49	3	
Average FDA days to MDUFA III decision	58.5	65.8	64.1	24.0	
20th Percentile FDA days to MDUFA III decision	29	36	29	20	
40th Percentile FDA days to MDUFA III decision	55	72	57	25	
60th Percentile FDA days to MDUFA III decision	78	81	84	28	
80th Percentile FDA days to MDUFA III decision	81	86	87	29	
Maximum FDA days to MDUFA III decision	89	90	90	29	
Average Industry days to MDUFA III decision	31.5	51.9	34	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	24	0	0	
80th Percentile Industry days to MDUFA III decision	65	126	67	0	
Maximum Industry days to MDUFA III decision	180	349	179	0	
Average Total days to MDUFA III decision	90.0	117.7	98.4	24.0	
20th Percentile Total days to MDUFA III decision	29	36	29	20	
40th Percentile Total days to MDUFA III decision	58	85	83	25	
60th Percentile Total days to MDUFA III decision	81	97	90	28	
80th Percentile Total days to MDUFA III decision	133	213	136	29	
Maximum Total days to MDUFA III decision	267	434	266	29	

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	12	
Number with MDUFA decision	71	76	49	3	
Number of SE decisions	71	73	47	3	
Number of NSE decisions	0	3	2	0	
Number of Withdrawals	6	5	3	0	
Number deleted	3	2	0	0	
Rate of SE decisions	100%	96.1%	95.9%	100%	
Rate of NSE decisions	0%	3.9%	4.1%	0%	
Rate of Withdrawals	7.5%	6%	4%	0%	
Rate of Deleted	3.8%	2.4%	0%	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	2	
Closed before RTA action	0	0	0	0	
Number Accepted	14	9	4	2	
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
Eligible for SI	18	9	5	2	
Deleted or withdrawn prior to SI	0	0	0	0	
SI within 60 FDA days	18	9	5	2	
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	2	
Average number of FDA days to Substantive Interaction	51.7	45.8	44.6	42.5	
20th Percentile FDA days to Substantive Interaction	44	29	30	39	
40th Percentile FDA days to Substantive Interaction	55	47	41	41	
60th Percentile FDA days to Substantive Interaction	58	56	52	44	
80th Percentile FDA days to Substantive Interaction	59	58	57	46	
Maximum FDA days to Substantive Interaction	60	60	58	49	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	18	9	5	2	
Non-MDUFA III Decisions	4	2	1	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	3	2	
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	
Current Performance Percent within 90 FDA Days	100%	100%	100%	N/A	

Table 6.5.DMGP - OIR - 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	2.4	1.6	3.0	0	
Number with MDUFA III decision	14	7	1	0	
Average FDA days to MDUFA III decision	83.7	78.1	90.0	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	151.9	81.7	164.0	0.00	
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	235.6	159.9	254.0	0.00	
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	2	
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	1	0	
Number deleted	1	0	0	0	
Rate of SE decisions	78.6%	85.7%	100%	N/A	
Rate of NSE decisions	21.4%	14.3%	0%	N/A	
Rate of Withdrawals	16.7%	22.2%	20%	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	74	
Closed before RTA action	0	0	0	0	
Number Accepted	151	274	268	59	
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	5	
Number Not Accepted	90	86	60	10	
Rate of submissions not accepted for filing review	35.2%	23.6%	18.2%	14.5%	

* 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.DRH - OIR - 510(k) Substantive Interaction Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	349	356	323	64	
Deleted or withdrawn prior to SI	1	0	0	0	
SI within 60 FDA days	307	342	319	33	
SI over 60 FDA days	41	14	2	0	
SI pending within 60 FDA days	0	0	2	31	
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	88.22%	96.07%	99.38%	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	321	33	
Average number of FDA days to Substantive Interaction	47.4	45.8	44.3	35.5	
20th Percentile FDA days to Substantive Interaction	31	30	29	20	
40th Percentile FDA days to Substantive Interaction	44	44	44	27	
60th Percentile FDA days to Substantive Interaction	56	54	50	44	
80th Percentile FDA days to Substantive Interaction	59	59	57	51	
Maximum FDA days to Substantive Interaction	91	93	70	59	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	403	393	355	77	
Non-MDUFA III Decisions	17	9	5	0	
MDUFA III Decisions (SE/NSE)	386	384	311	20	
MDUFA III Decisions within 90 FDA Days	380	372	311	20	
510(k)s pending MDUFA III Decision	0	0	39	57	
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%	100%	100%	

Table 6.5.DRH - OIR - 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.6	1.7	1.5	1.2	
Number with MDUFA III decision	386	384	311	20	
Average FDA days to MDUFA III decision	61.9	63.2	56.4	26.9	
20th Percentile FDA days to MDUFA III decision	35	31	28	20	
40th Percentile FDA days to MDUFA III decision	56	58	54	25	
60th Percentile FDA days to MDUFA III decision	77	79	69	27	
80th Percentile FDA days to MDUFA III decision	87	88	80	29	
Maximum FDA days to MDUFA III decision	121	137	90	58	
Average Industry days to MDUFA III decision	35.9	36.0	28.3	0.8	
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	17	0	
80th Percentile Industry days to MDUFA III decision	60	64	46	0	
Maximum Industry days to MDUFA III decision	358	346	319	7	
Average Total days to MDUFA III decision	97.8	99.2	84.7	27.7	
20th Percentile Total days to MDUFA III decision	37	32	29	20	
40th Percentile Total days to MDUFA III decision	71	77	57	25	
60th Percentile Total days to MDUFA III decision	90	102	85	28	
80th Percentile Total days to MDUFA III decision	137	141	128	30	
Maximum Total days to MDUFA III decision	466	428	406	58	

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	355	77	
Number with MDUFA decision	386	384	311	20	
Number of SE decisions	377	377	301	20	
Number of NSE decisions	9	7	10	0	
Number of Withdrawals	10	2	2	0	
Number deleted	7	6	3	0	
Rate of SE decisions	97.7%	98.2%	96.8%	100%	
Rate of NSE decisions	2.3%	1.8%	3.2%	0%	
Rate of Withdrawals	2.5%	0.5%	1%	0%	
Rate of Deleted	1.7%	1.5%	0.8%	0%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	6	12	0	0	
Mean FDA days for submissions that missed goal	104	98	0	0	
Mean industry days for submissions that missed goal	135	37	0	0	

Section 7 510(k) Annual General Metrics

510(k) Annual Metrics and Goals will be reported in the Annual Report.

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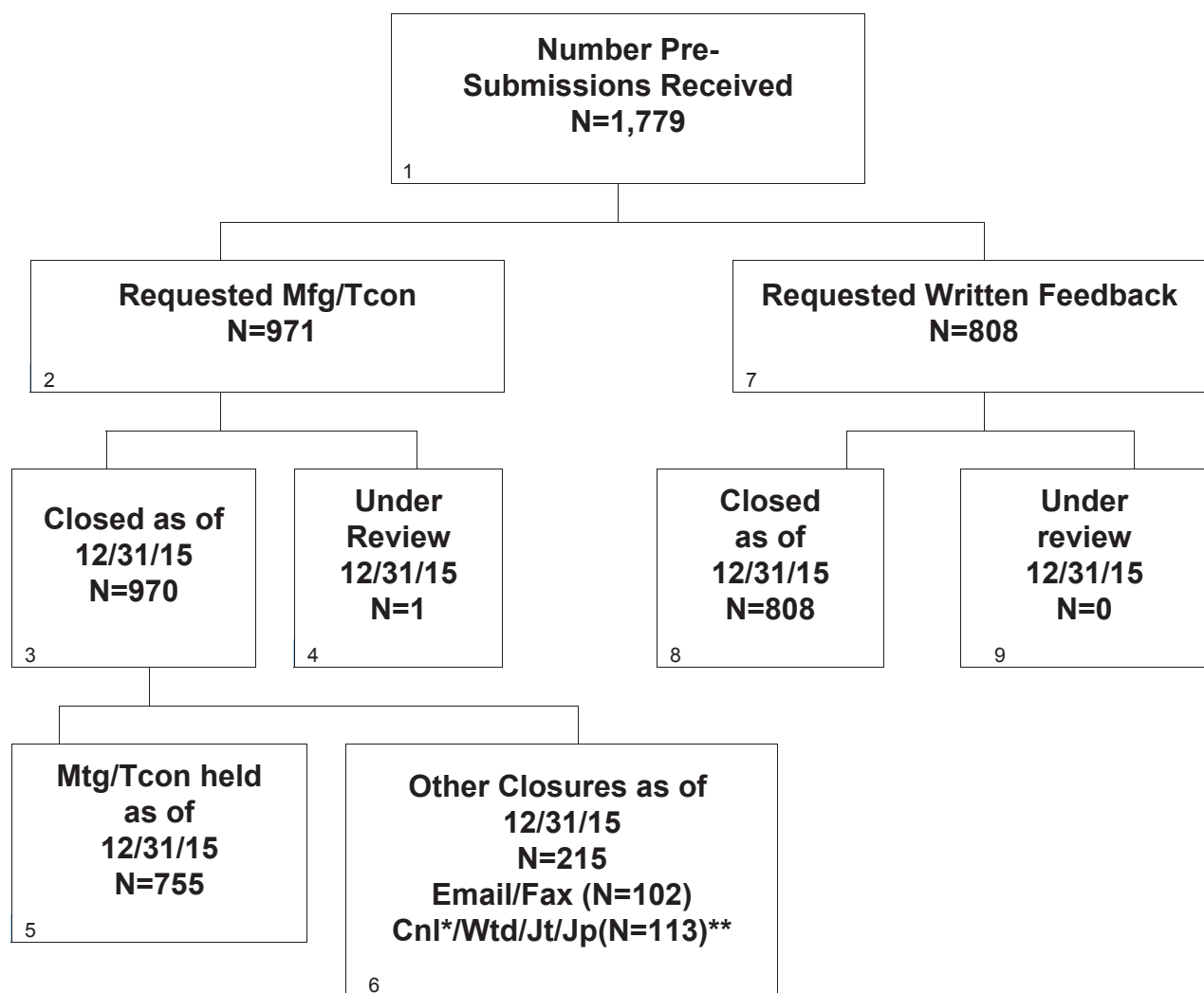
Section 8 Annual Metrics for De Novo Requests

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

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CDRH Pre-Submissions - FY 2013

As of 12/31/15

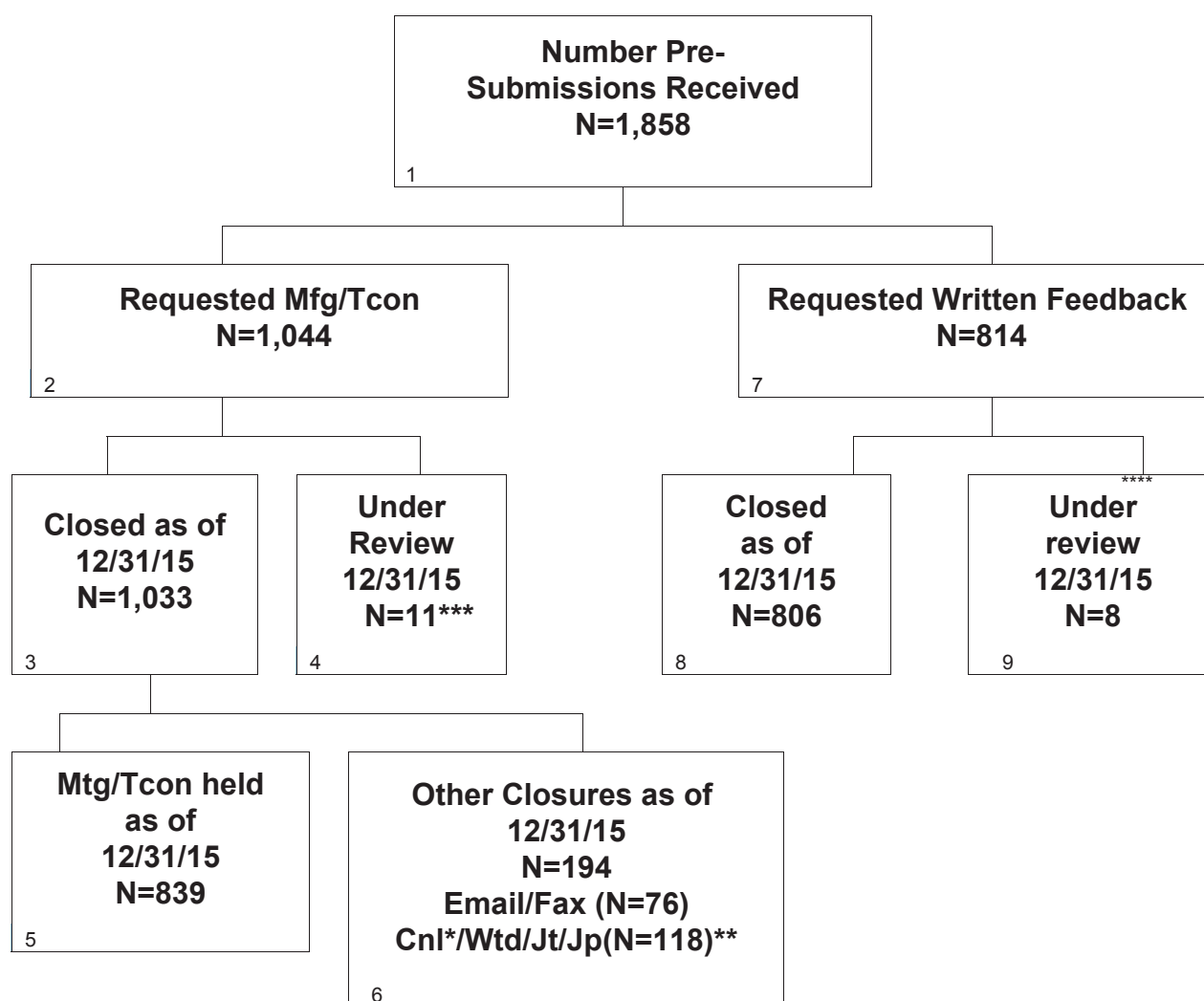


*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

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

CDRH Pre-Submissions - FY 2014

As of 12/31/15



*** Includes 10 Pre-Submissions on RTA Hold as of 12/31/2015

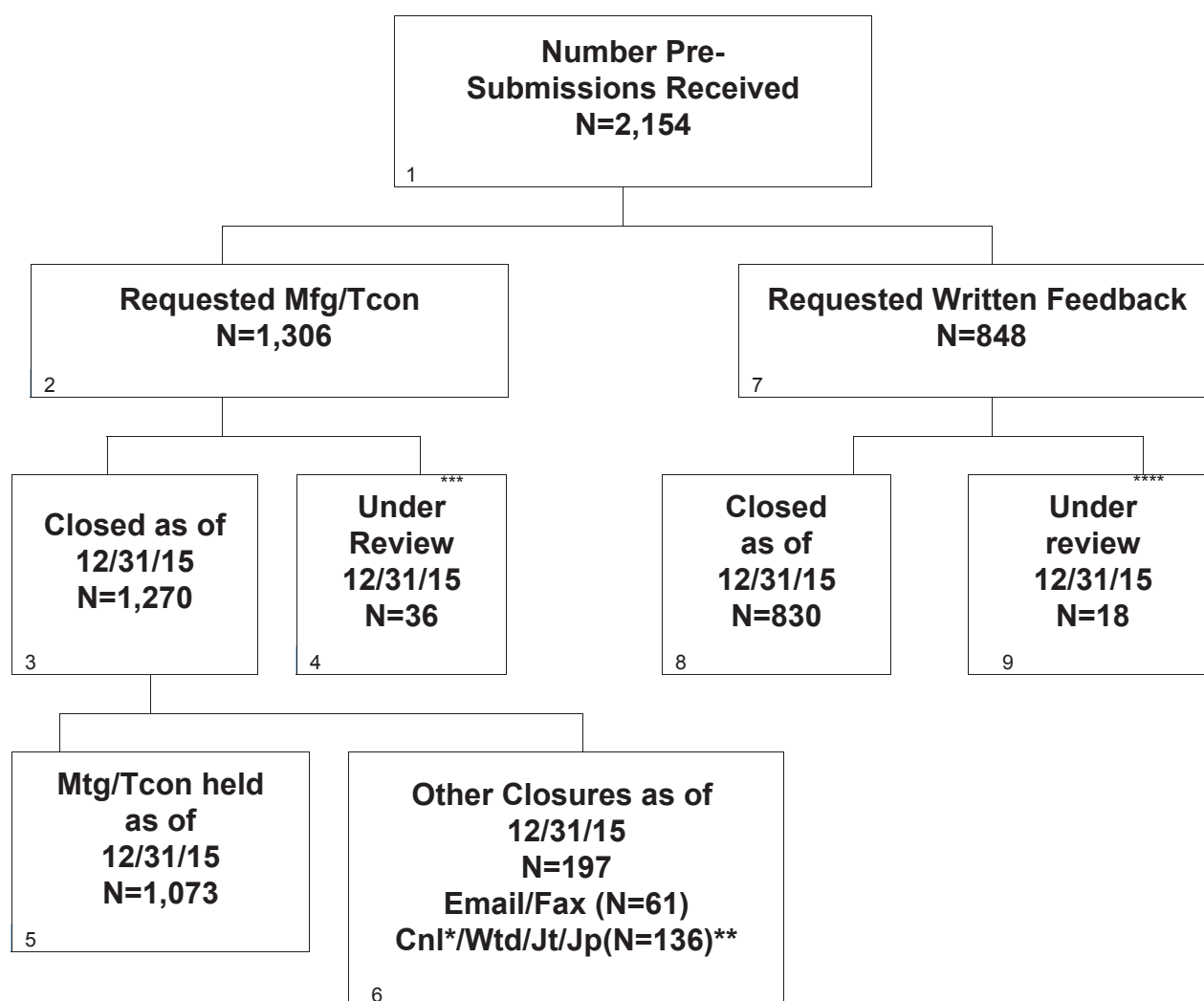
**** Includes 7 Pre-Submissions on RTA Hold as of 12/31/2015

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

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

CDRH Pre-Submissions - FY 2015

As of 12/31/15



*** Includes 21 Pre-Submissions on RTA Hold as of 12/31/2015

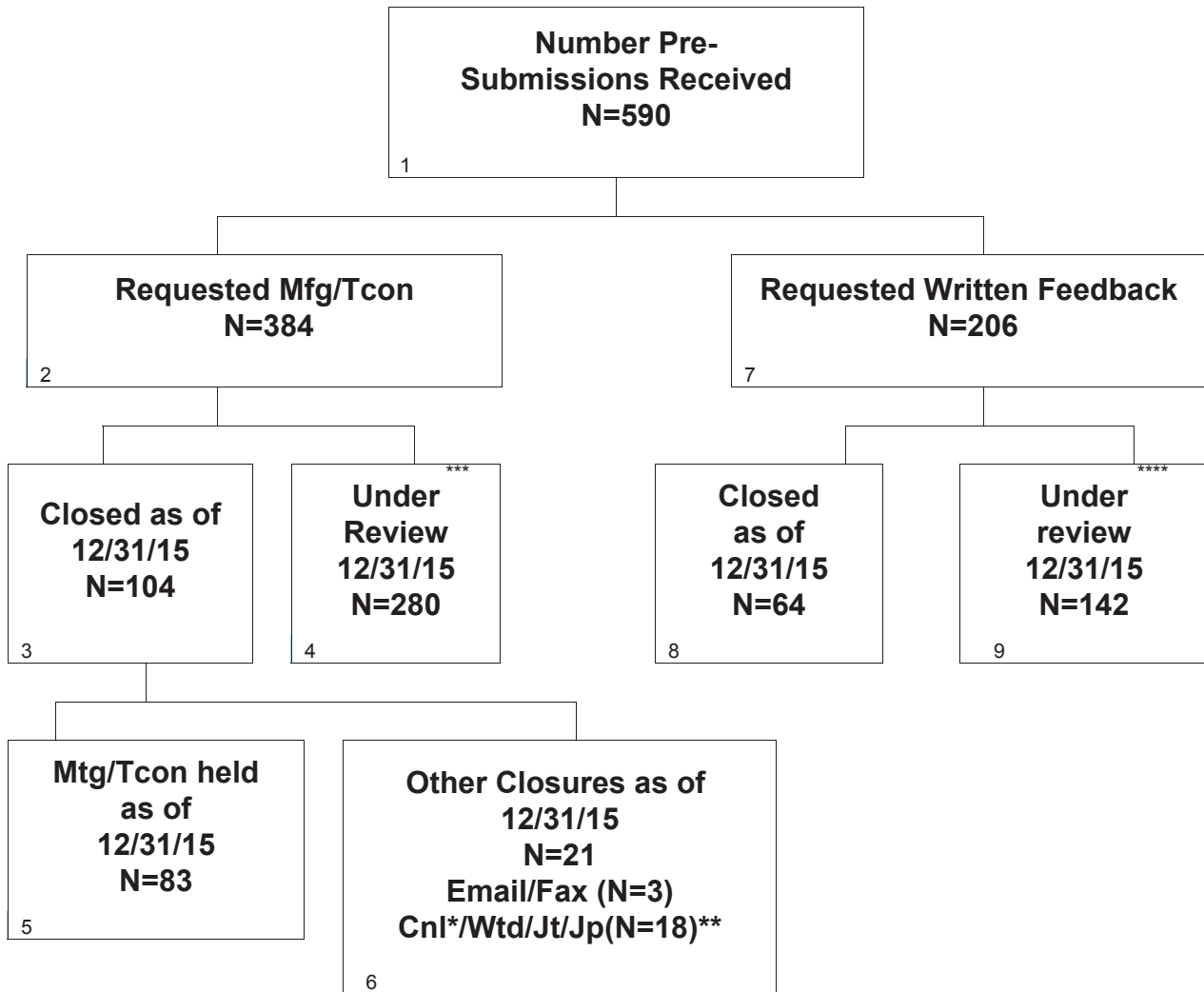
**** Includes 11 Pre-Submissions on RTA Hold as of 12/31/2015

*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 2016

As of 12/31/15



*** Includes 5 Pre-Submissions on RTA Hold as of 12/31/2015

**** Includes 4 Pre-Submissions on RTA Hold as of 12/31/2015

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

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

Section 9 Pre-Submissions

Table 9.1 CDRH – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	1,779	1,858	2,154	590	
Number requesting a meeting or teleconference	971	1,044	1,306	384	
Number with meetings or teleconferences held	755	839	1,073	83	
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	356	
Number requesting a meeting or teleconference	611	698	860	250	
Number with meetings or teleconferences held	455	555	688	47	
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	234	
Number requesting a meeting or teleconference	360	346	446	134	
Number with meetings or teleconferences held	300	284	385	36	
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	75	
Number requesting a meeting or teleconference	82	110	137	50	
Number with meetings or teleconferences held	58	82	104	8	
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	106	
Number requesting a meeting or teleconference	214	236	264	78	
Number with meetings or teleconferences held	173	200	223	18	
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	35	
Number requesting a meeting or teleconference	50	72	108	30	
Number with meetings or teleconferences held	32	49	90	7	
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	25	
Number requesting a meeting or teleconference	61	71	83	22	
Number with meetings or teleconferences held	39	62	66	6	
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	30	
Number requesting a meeting or teleconference	49	46	75	17	
Number with meetings or teleconferences held	35	34	55	0	
Average days to meeting	66.4	75.4	74.1	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	47	
Number requesting a meeting or teleconference	76	83	90	25	
Number with meetings or teleconferences held	60	66	71	4	
Average days to meeting	60.0	59.8	69.9	52.0	
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	38	
Number requesting a meeting or teleconference	79	80	103	28	
Number with meetings or teleconferences held	58	62	79	4	
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	65	
Number requesting a meeting or teleconference	107	99	151	36	
Number with meetings or teleconferences held	91	88	137	8	
Average days to meeting	51.3	57.0	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	37	
Number requesting a meeting or teleconference	66	72	65	22	
Number with meetings or teleconferences held	54	67	65	5	
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	55	
Number requesting a meeting or teleconference	59	48	63	22	
Number with meetings or teleconferences held	49	28	44	7	
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	51	
Number requesting a meeting or teleconference	83	90	118	33	
Number with meetings or teleconferences held	70	69	102	8	
Average days to meeting	63.0	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	26	
Number requesting a meeting or teleconference	45	37	49	21	
Number with meetings or teleconferences held	36	32	37	8	
Average days to meeting	46.7	57.5	61.0	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	

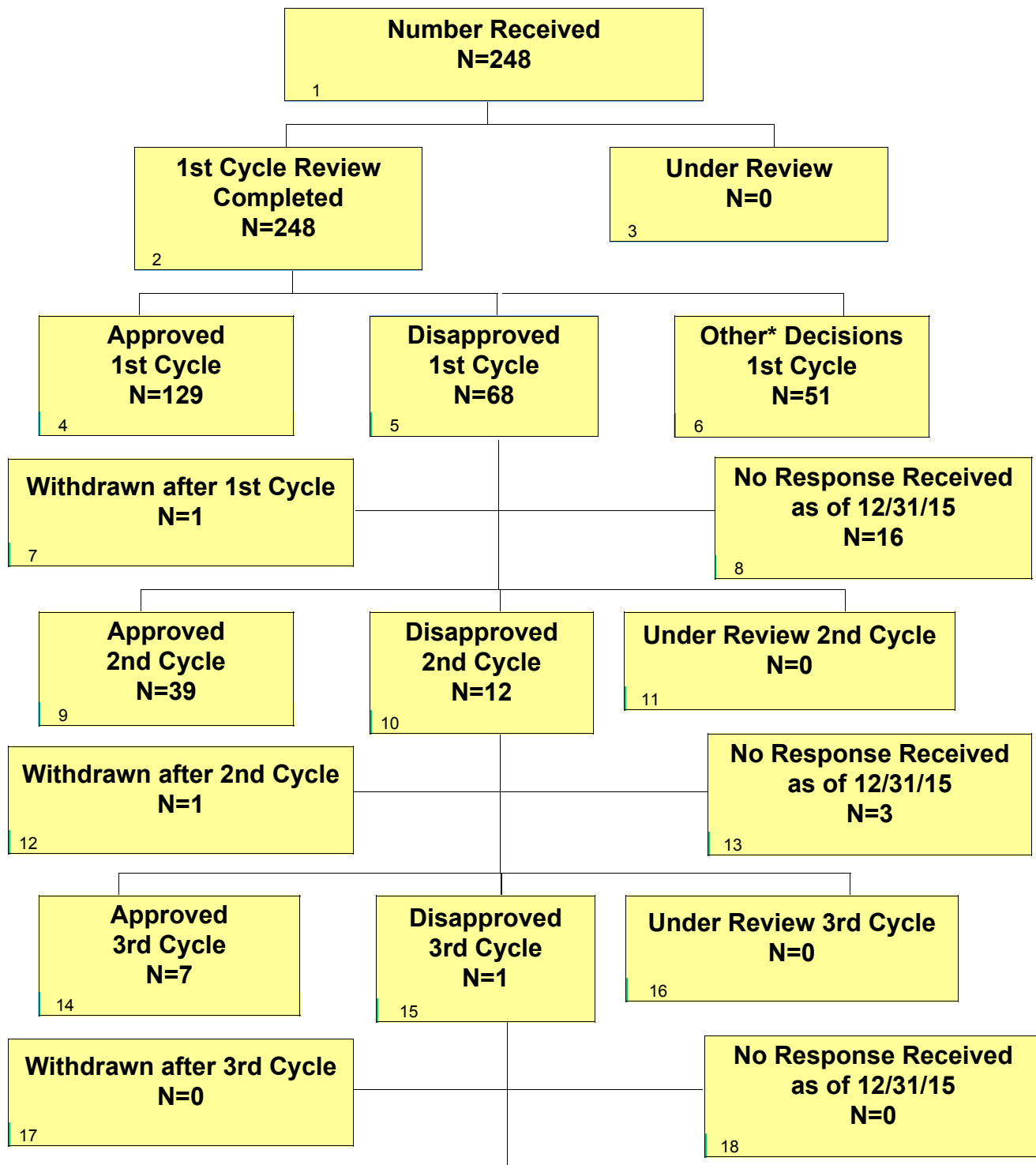
Section 10 CLIA Waiver Annual Metrics

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

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CDRH IDEs - FY 2014

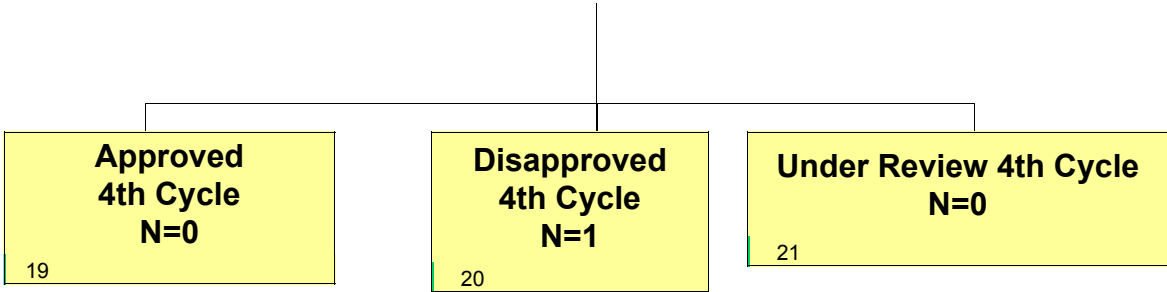
As of 12/31/15



* 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).

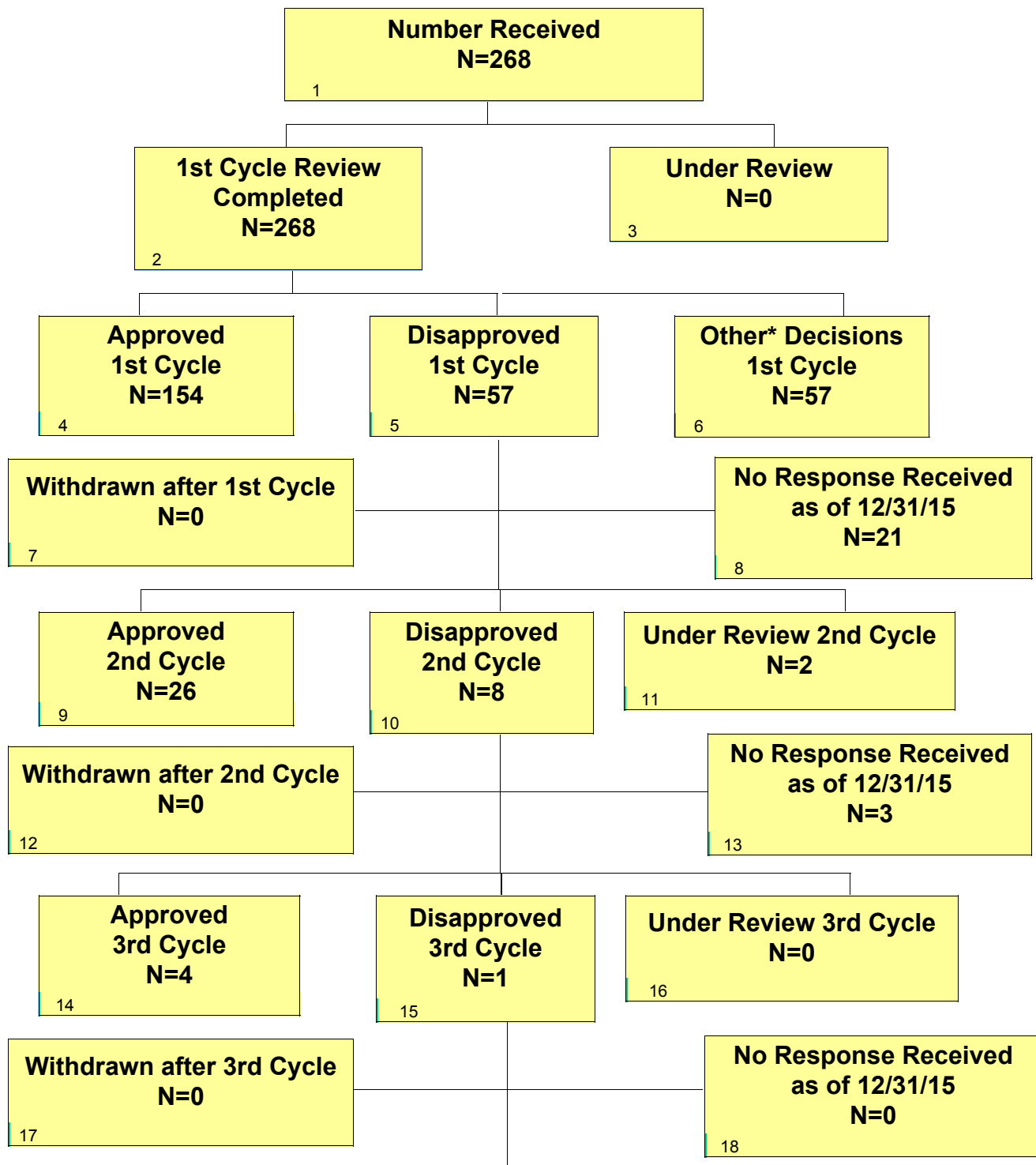
CDRH IDEs - FY 2014

As of 12/31/15 Continued



CDRH IDEs - FY 2015

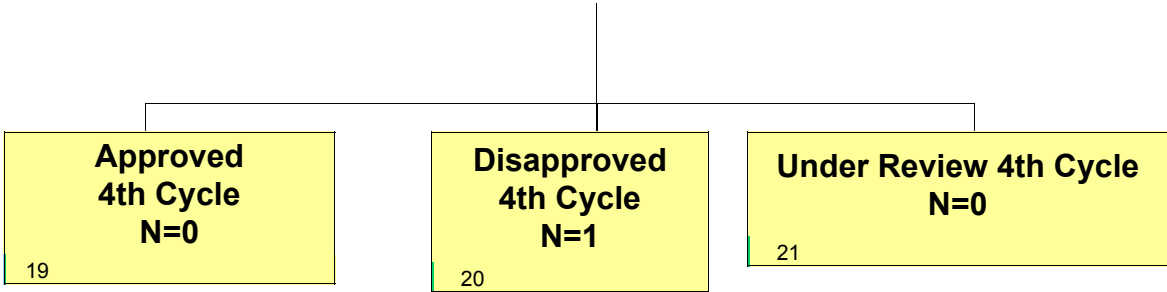
As of 12/31/15



* 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).

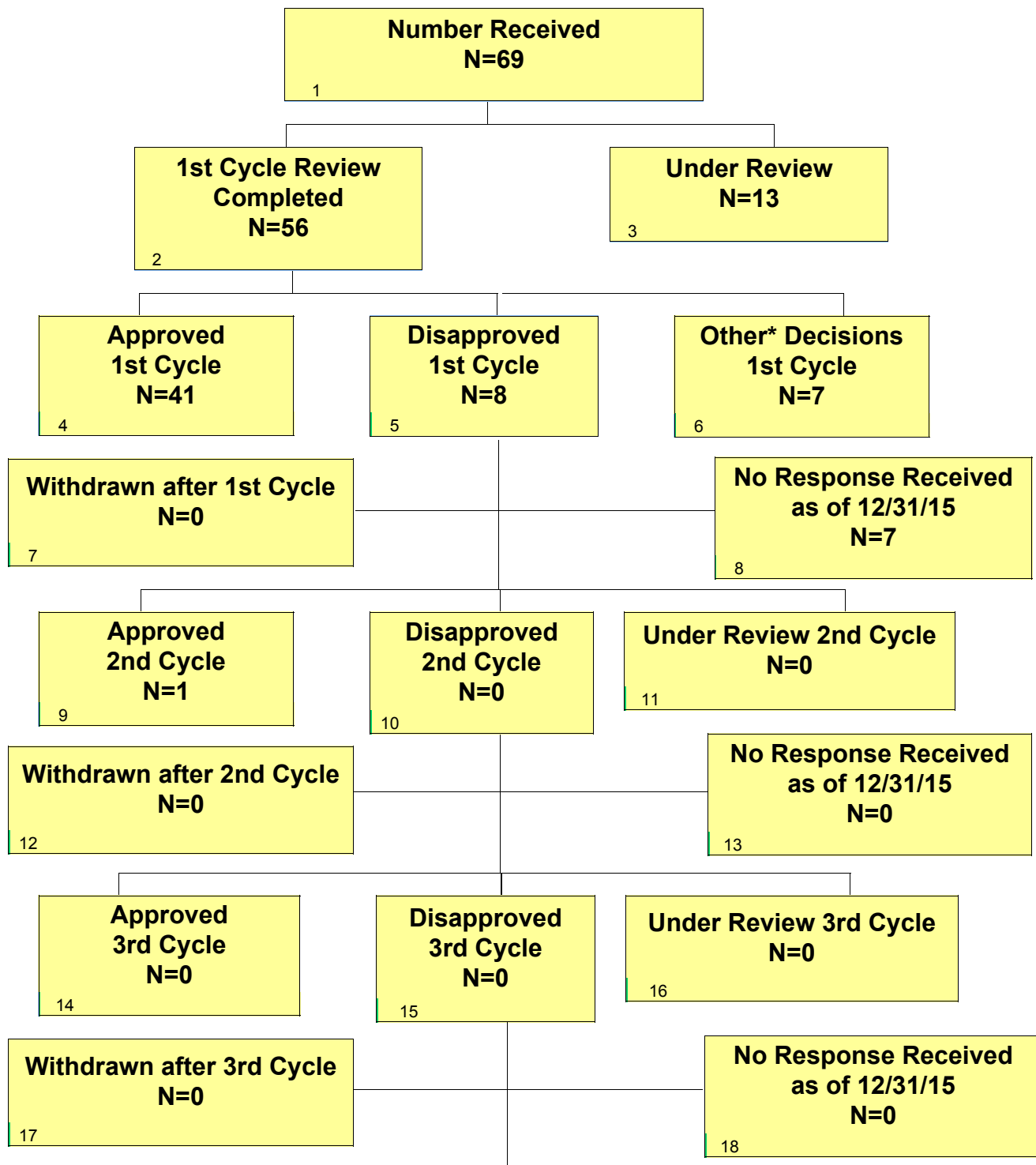
CDRH IDEs - FY 2015

As of 12/31/15 Continued



CDRH IDEs - FY 2016

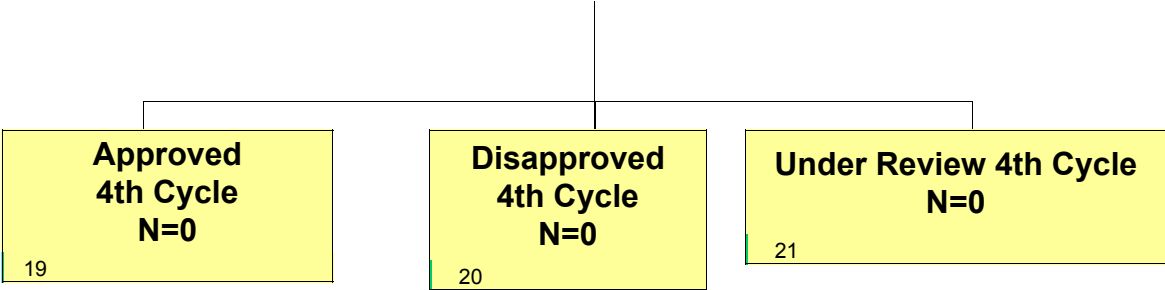
As of 12/31/15



* Other decisions include withdrawn (N=4), RTA (N=0), nonsignificant risk device (N=0), exempt (N=1), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1).

CDRH IDEs - FY 2016

As of 12/31/15 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	69	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.2	1.0	
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	58	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.4	1.2	1.0	
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	11	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.1	1.0	1.0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.1	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	7	
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	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	18	
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	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	19	
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	0	

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	1	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.2	0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0	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	3	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.1	1.0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0	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	7	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.5	1.3	1.0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.5	0	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	3	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.1	1.0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0	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	8	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.0	1.1	1.0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0	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	1.0	1.0	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	2	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.0	1.0	1.0	
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	1	
Average number of cycles to approval or conditional approval of the IDE	N/A	1.6	1.0	0	
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.6	0	0	

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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.

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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 (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 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 December 2015**

Section 1 PMA Original and Panel Track Supplements - Center Level

Table 1.1 CBER – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	6	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	1	
SI over 90 FDA days	0	0	0	0	
SI pending within 90 FDA days	0	0	1	1	
SI pending over 90 FDA days	0	0	1	0	
Closed without SI	1	0	0	0	
Current SI Performance Percent within 90 FDA days	100%	100%	75%	100%	

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	0	0	
MDUFA III Decisions within 180 FDA Days	2	1	0	0	
Supplements pending MDUFA III Decision	0	0	5	2	
Supplements pending MDUFA III Decision over 180 FDA days	0	0	0	0	
Current Performance Percent within 180 FDA Days	100%	100%	0%	0%	

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	1	5	2	
Number with MDUFA decision	2	1	0	0	
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	1	
MDUFA III Decisions within 90 FDA Days	3	2	5	1	
Supplements pending MDUFA III Decision	0	0	0	2	
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	1	
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	11	
Closed before RTA action	1	4	4	1	
Number Accepted	40	50	51	9	
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	7	5	2	
Rate of submissions not accepted for review	32.2%	12.3%	8.9%	18.2%	

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	50	51	9	
SI within 60 FDA days	41	49	47	4	
SI over 60 FDA days	6	1	1	0	
SI pending within 60 FDA days	0	0	1	5	
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%	98%	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	50	47	4	
Average number of FDA days to Substantive Interaction	49	49	48	39	
20th Percentile FDA days to Substantive Interaction	30	34	30	24	
40th Percentile FDA days to Substantive Interaction	46	54	50	30	
60th Percentile FDA days to Substantive Interaction	58	56	58	41	
80th Percentile FDA days to Substantive Interaction	59	59	59	60	
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	50	51	9	
Non-MDUFA III Decisions	8	4	6	0	
MDUFA III Decisions (SE/NSE)	39	41	34	3	
MDUFA III Decisions within 90 FDA Days	37	41	34	3	
510(k)s pending MDUFA III Decision	0	5	11	6	
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	1.38	1	
Number with MDUFA III decision	39	41	34	3	
Average FDA days to MDUFA III decision	71	68	65	42	
20th Percentile FDA days to MDUFA III decision	30	31	29	24	
40th Percentile FDA days to MDUFA III decision	81	63	74	30	
60th Percentile FDA days to MDUFA III decision	87	85	80	30	
80th Percentile FDA days to MDUFA III decision	89	88	87	72	
Maximum FDA days to MDUFA III decision	94	162	90	72	
Average Industry days to MDUFA III decision	76	57	26	0	
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	0	0	
80th Percentile Industry days to MDUFA III decision	150	112	47	0	
Maximum Industry days to MDUFA III decision	370	317	154	0	
Average Total days to MDUFA III decision	147	125	91	42	
20th Percentile Total days to MDUFA III decision	30	37	30	24	
40th Percentile Total days to MDUFA III decision	108	79	76	30	
60th Percentile Total days to MDUFA III decision	171	107	86	30	
80th Percentile Total days to MDUFA III decision	244	191	128	72	
Maximum Total days to MDUFA III decision	460	479	241	72	

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	50	51	9	
Number with MDUFA decision	39	41	34	3	
Number of SE decisions	36	38	31	3	
Number of NSE decisions	3	3	3	0	
Number of Withdrawals	8	4	6	0	
Number deleted	0	0	0	0	
Rate of SE decisions	92.3%	92.7%	91.2%	100%	
Rate of NSE decisions	7.7%	7.3%	8.8%	0%	
Rate of Withdrawals	17%	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-Submissions

Section 9 Pre-Submission Center Level Metrics

Table 9.1 CBER – Pre-Submission Center Level Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	44	57	60	21	
Number requesting a meeting or teleconference	34	46	48	17	
Number with meetings or teleconferences granted	29	41	45	16	
Number with meeting granted and industry cancelled	13	7	12	0	
Number with meeting granted and FDA cancelled	0	1	0	0	
Number with meeting granted and pending within timeframe	0	0	0	16	
Number with meeting granted and pending outside timeframe	0	0	1	0	
Number with meetings or teleconferences held	15	33	32	2	
Average days to meeting	65	68	68	37	
20th Percentile days to meeting	55	44	58	11	
40th Percentile days to meeting	58	62	68	11	
60th Percentile days to meeting	61	78	76	62	
80th Percentile days to meeting	70	92	83	62	
Maximum days to meeting	122	132	101	62	

CBER – Annual General Metric Report for BLAs **BLA Annual Metrics and Goals will be reported in the Annual Report**

BLA Efficacy Supplements

CBER – Annual General Metric Report for BLA Efficacy Supplements **BLA Efficacy Supplements Annual Metrics and Goals will be reported in the Annual Report**

IDEs

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

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**FY 2016 Medical Device User Fee Collections
as of September 31st, 2015
Excludes Unearned Fees**

	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	77,603,867	40,855	77,563,012		
Application Fees	9,027,334	5,438	9,021,896		
Total	86,631,201	46,293	86,584,908	137,677,000	62.89%

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

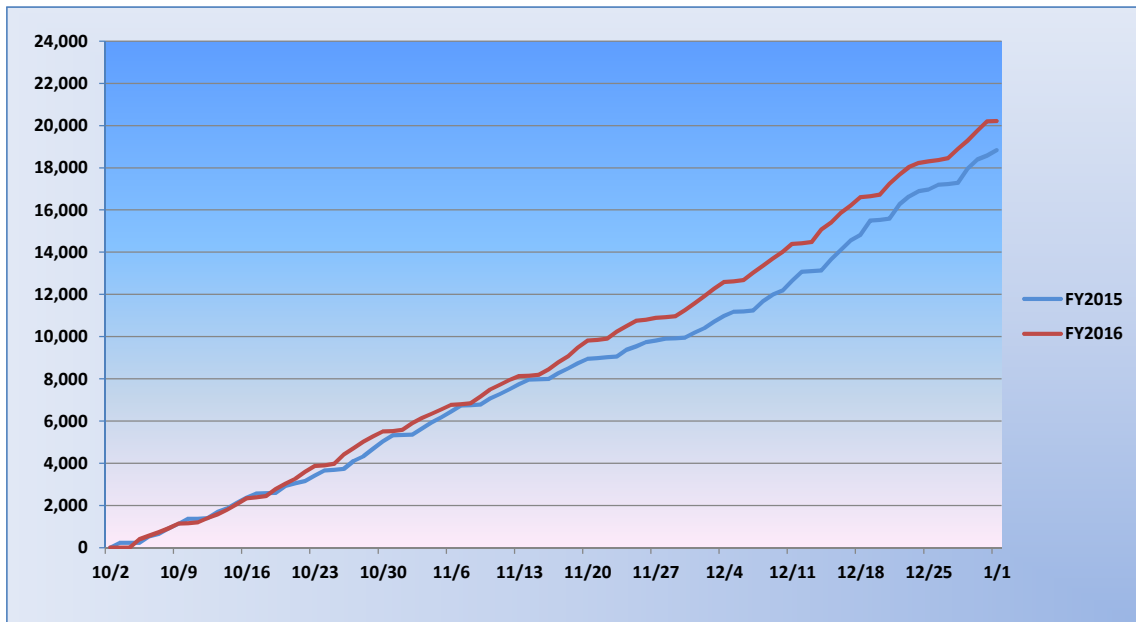
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
MD I	\$21,620,549	\$26,281,779	\$31,676,833	\$34,469,732	\$27,798,431
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
MD II	\$47,710,791	\$56,944,245	\$63,415,722	\$69,555,647	\$65,163,988
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
MD III	\$99,980,173	\$120,348,597	\$134,485,402	\$86,584,908	

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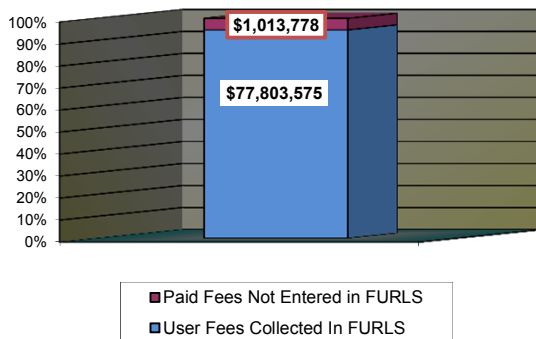
MDUFA III, Registrations, First Quarter Summary FY2016

Registrations by Type	FY16 End of 1st Quarter Active			FY15 Year End Active Totals			Progress by Est Type
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,029	7,428	12,457	5,943	8,872	14,815	84.08%
Contract Manufacturer	798	1,037	1,835	965	1,194	2,159	84.99%
Contract Sterilizer	72	116	188	78	124	202	93.07%
Specification Developer	1,310	366	1,676	1,657	428	2,085	80.38%
Reprocessor of Single Use Devices	16	0	16	25	1	26	61.54%
U.S. Manufacturer of Export Only Devices	101	0	101	131	0	131	77.10%
Repackager/Relabeler	888	123	1,011	1,143	176	1,319	76.65%
Remanufacturer	15	9	24	21	13	34	70.59%
Foreign Exporter/Private Label Distributor	0	516	516	0	630	630	81.90%
Initial Importer	2,388	0	2,388	3,323	0	3,323	71.86%
Unknown	7	1	8	8	6	14	57.14%
Total:	10,624	9,596	20,220	13,294	11,444	24,738	81.74%

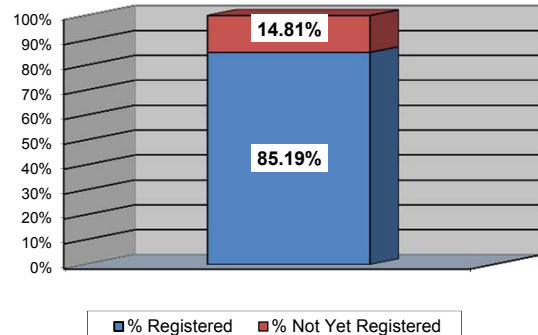
Registration Progress - FY2015 Versus FY2016



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



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MDUFA III Quarterly Performance Update

Independent Assessment of Medical Device Review Process

1st Quarter FY 2016 Status – February 9, 2016

Objectives

Pursuant to the Performance Goals and Procedures adopted under the 2012 Medical Device User Fee Amendments (MDUFA III), FDA agreed to participate with the device industry in a comprehensive assessment of the process for the review of device applications.

This requirement is to conduct a comprehensive assessment of FDA premarket review processes for medical devices and to identify opportunities for improvement that will significantly impact the review of device premarket applications. Primary objectives include:

Phase 1:

- Identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards
- In-depth analyses of the elements of the review process in order to identify best practices and opportunities for improvement, including root cause analyses of selected significant factors
- Assessment of resource allocation to premarket device reviews across FDA
- Development of implementation plans for selected recommendations
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results

Phase 2:

- Evaluation of the implementation of selected recommendations

Timeline

Milestone	Planned	Status
FY 2013		
Publish Federal Register notice	December 2012	Completed December 2012
Award contract	May 2013	Completed June 2013
Contract kickoff meeting between FDA and contractor	June 2013	Completed July 2013
Final workplan for Phase 1	July 2013	Completed August 2013
FY 2014		
Report on preliminary findings and high-priority recommendations	December 2013	Completed December 2013
Implementation plan for high-priority recommendations	June 2014	Completed June 2014
Final report on complete findings and recommendations	June 2014	Completed June 2014

Milestone	Planned	Status
FY 2015		
Phase 2 kickoff meeting between FDA and contractor	October 2014	Completed October 2014
Final workplan for Phase 2	November 2014	Completed November 2014
Implementation plan for final recommendations	December 2014	Completed December 2014
FY 2016		
Final evaluation report	February 1, 2016	Completed February 2016

Progress to-date:

- Established Project Advisory Group (PAG) – Kickoff Meeting held July 12, 2012
- Established Technical Advisory Group (TAG) – 1st Meeting held September 12, 2012
- Drafted Assessment Statement of Work for FDA clearance – October 11, 2012
- Published SOW for industry and public comment – December 18, 2012
- Spoke with industry representatives regarding SOW feedback – January 29, 2013
- Received comments from Federal Register notice – February 4, 2013
- Finalized SOW based on feedback from Federal Register notice – March 25, 2013
- Issued request for proposal – April 19, 2013
- Awarded task order to Booz Allen Hamilton (BAH) – June 11, 2013
- Held kick-off meeting – July 1, 2013
- Received draft workplan – July 19, 2013
- Final workplan – August 2, 2013
- Focus group with Medical Device Industry representatives – August 17, 2013
- Report on preliminary findings and high-priority recommendations – December 11, 2013
- BAH meeting with Medical Device Industry representatives – January 17, 2014
- BAH benchmarking discussions with U.S. Patent and Trademark Office – February 2014
- Final report on complete findings and recommendations – June 11, 2014
- Implementation plan for high-priority recommendations – June 11, 2014
- Award of Phase 2 of contract – July 25, 2014
- Kick off Meeting for Phase 2 – October 2, 2014
- Final workplan for Phase 2 of assessment – November 14, 2014
- FDA implementation plan for final recommendations – December 11, 2014
- Phase 2 kickoff meeting with Industry – January 2015
- FDA TAG meeting – January 2015
- BAH Presented Phase 1 assessment findings at the 2 day MDMA-FDA Forum – March 2015
- FDA demo to BAH CDRH’s “SMART Review Template,” a tool for guiding 510(k) reviews. – June 2015
- BAH Finalized SMART analysis on FDA’s Plan of Action – July 2015
- FDA completed implementation of all Plan of Action “Stage 1” actions, thus addressing all BAH recommendations. – December 2015
- BAH completed evaluation of FDA’s actions (implementation of FDA Plan of Action) in response to BAH’s report of findings and recommendations – December 2015

Progress from 1st Quarter FY 2016:

- FDA TAG meeting – January 2016
- BAH provided Industry briefing – January 2016
- FDA published the Federal Notice – February 2016
- BAH delivered the Final Implementation Evaluation Report – January 2016
- FDA posted the [Final Implementation Evaluation Report](#) – February 1, 2016

Planned Progress in 2nd Quarter FY 2016:

- No plans - Contractual obligations expire at the end of February

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Center for Devices and Radiological Health Internal Training Summary Report

Q1 FY16

October 2015 – December 2015

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

As of: 2/2/2015

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 December 31, 2015. DETD offered 176 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and program activities.

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

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA III	6	47	111
	ELP	9	108	1088
	Other LAW	53	515	1441
<i>LAW Subtotal:</i>		<i>68</i>	<i>670</i>	<i>2640</i>
Leadership Development Training (LED)	LEAD: Leadership for Managers	31	309	1338
	Leadership for Non-Managers	0	0	0
<i>LED Subtotal:</i>		<i>31</i>	<i>309</i>	<i>1338</i>
Professional Development (PRO) Training	New Employee Orientation (NEO)	1	41	287
	Other PRO	21	285	2187
<i>PRO Subtotal:</i>		<i>22</i>	<i>326</i>	<i>2474</i>
Science (SCI) Training	All SCI	43	1034	4725
Center-Specific Information Technology (CIT) Training	All CIT	12	451	252
Grand Total:		176	2790	11429

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 – December 31, 2015*

Category	Total Learning Events	Total Participants	Total Completions	Total Training Hours	Examples of Training Conducted
RCP	35	32	413	2373	<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 (Cont.)

RCP Training by Cohort: *September 2015* – December 2015*

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
Total:	13	24	-	32	459	2673

*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 – December 31, 2015*

Office	# of Site Visits	# of Attendees	Total Training Hours	Focus Area
ODE	6	67	704	<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	3	41	384	<ul style="list-style-type: none">• TPLC of auto antibody assays, including ELISA• Next Generation Sequencing (NGS) on tumor specimen
Total:	9	108	1088	

Booz Allen Hamilton (BAH) Independent Assessment

Training Recommendation Update

Evaluation of IT Infrastructure and Workload Tools

The Office of Communication and Education (OCE) collaborated with the Office of Device Evaluation (ODE) and Office of In Vitro Diagnostics and Radiological Health (OIR) to develop training for CDRH's three primary premarket IT systems: CTS, DocMan and Image2000+. The training is delivered in an online format and is being evaluated using Kirkpatrick's Level 1 and 2 evaluations. The training, which launched in July, is mandatory for staff involved in premarket review. To date, over 93% of ODE and OIR staff have completed the training. Additionally, OCE worked with OSEL and OSB to develop a premarket IT systems training module to specifically address the training needs of consulting reviewers. The consulting reviewer training launched in November 2015.

Evaluation of Training Programs

OCE continues to incorporate Kirkpatrick's evaluation Levels 1-4 into the CDRH training program. Specifically, OCE has implemented a revised Level 1 evaluation and updated the Level 2 evaluation data collection process for the Reviewer Certification Program. Additionally, OCE developed a standardized process for conducting an annual needs assessment and marketed Standard Operating Procedures (SOPs) for evaluation using Kirkpatrick's Levels 1-4 to the Center.

Promotion of Informal Training

OCE worked with a senior ODE reviewer to document all internal training (training that is not conducted by OCE and is not reflected on a reviewer's official transcript). OCE also piloted a standardized process and form to collect informal training data. Following completion of the pilot, OCE developed and marketed an Informal Training SOP to the Center.

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 – December 31, 2015*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	31	309	1338	<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 – December 31, 2015*

Office	Total # of Managers/Supervisors	# of Training Participants	Training Hours Completed	Training Hours Required*	% of Required Training Hours Completed
ODE	75	38	369	1200	31%
OIR	39	16	106	624	17%
Total:	114	54	475	1824	24%

*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.
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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.