

MDUFA III (FY 2013-2017) Performance Report
December 10, 2018, 1:00 – 2:30
WebEx

FDA MDUFA Performance — Actions through September 30, 2018

- Report on decision goals

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**Quarterly Update on
Medical Device Performance Goals
MDUFA III CDRH Performance Data**
Action through 30 September 2018

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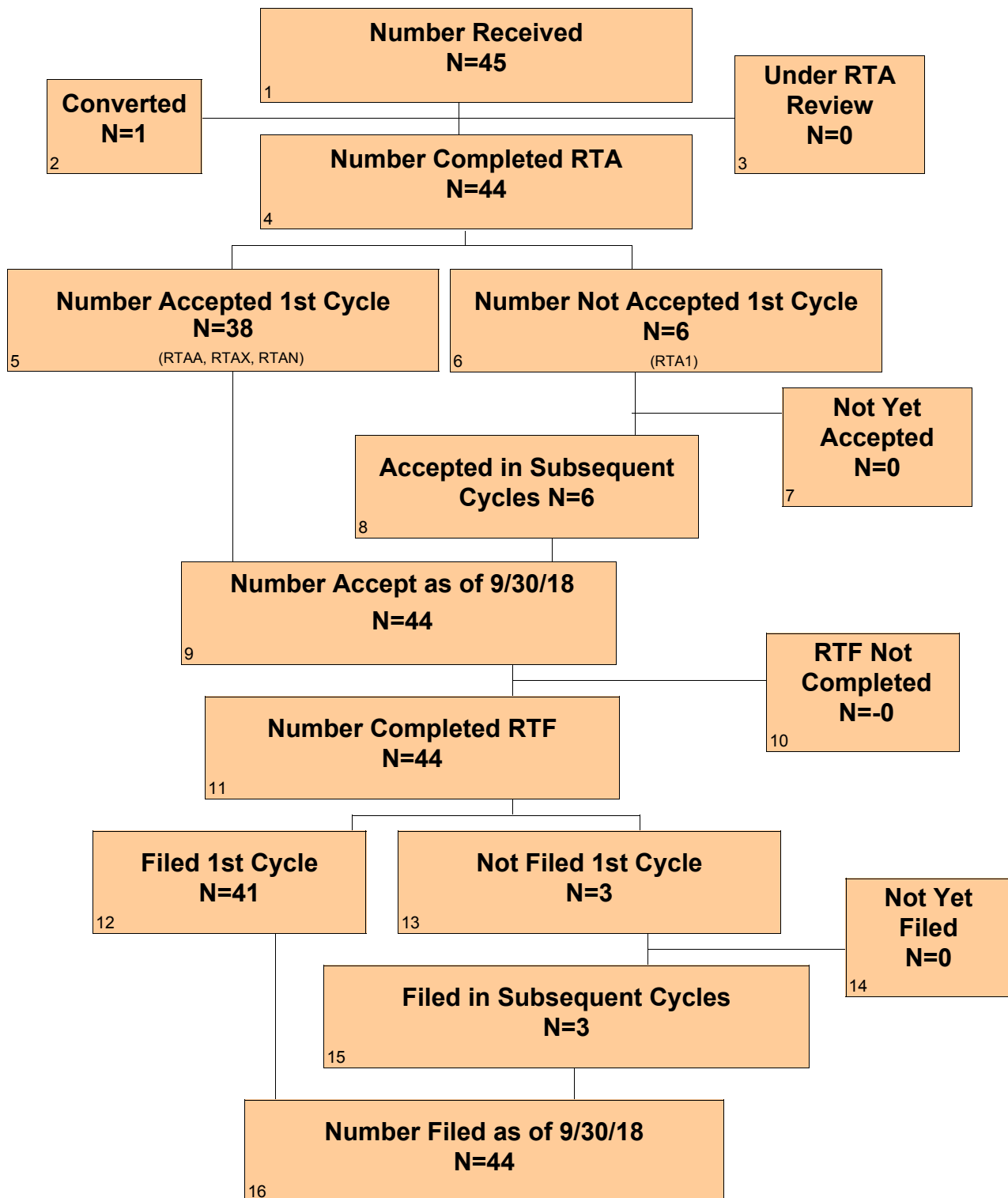
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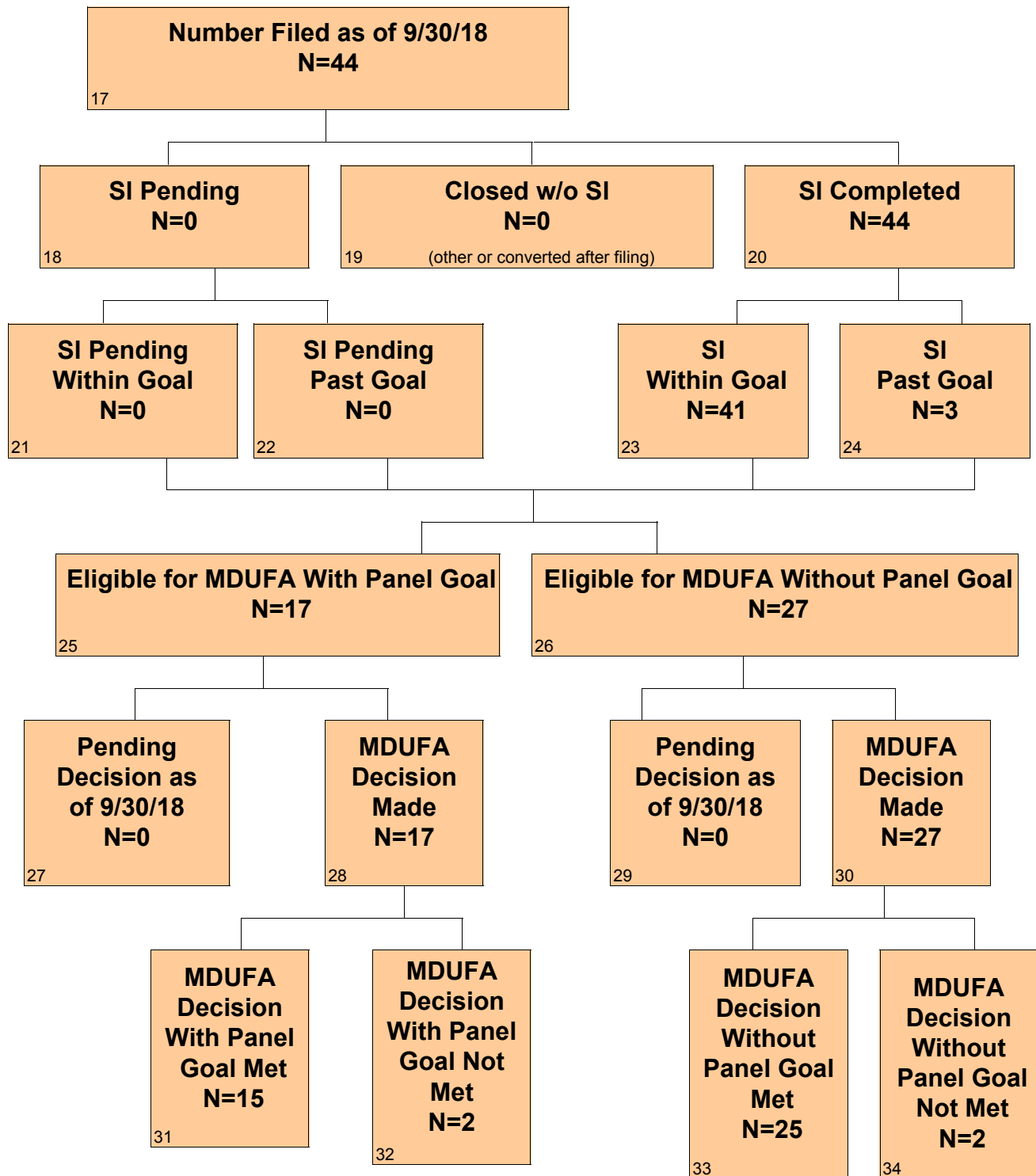
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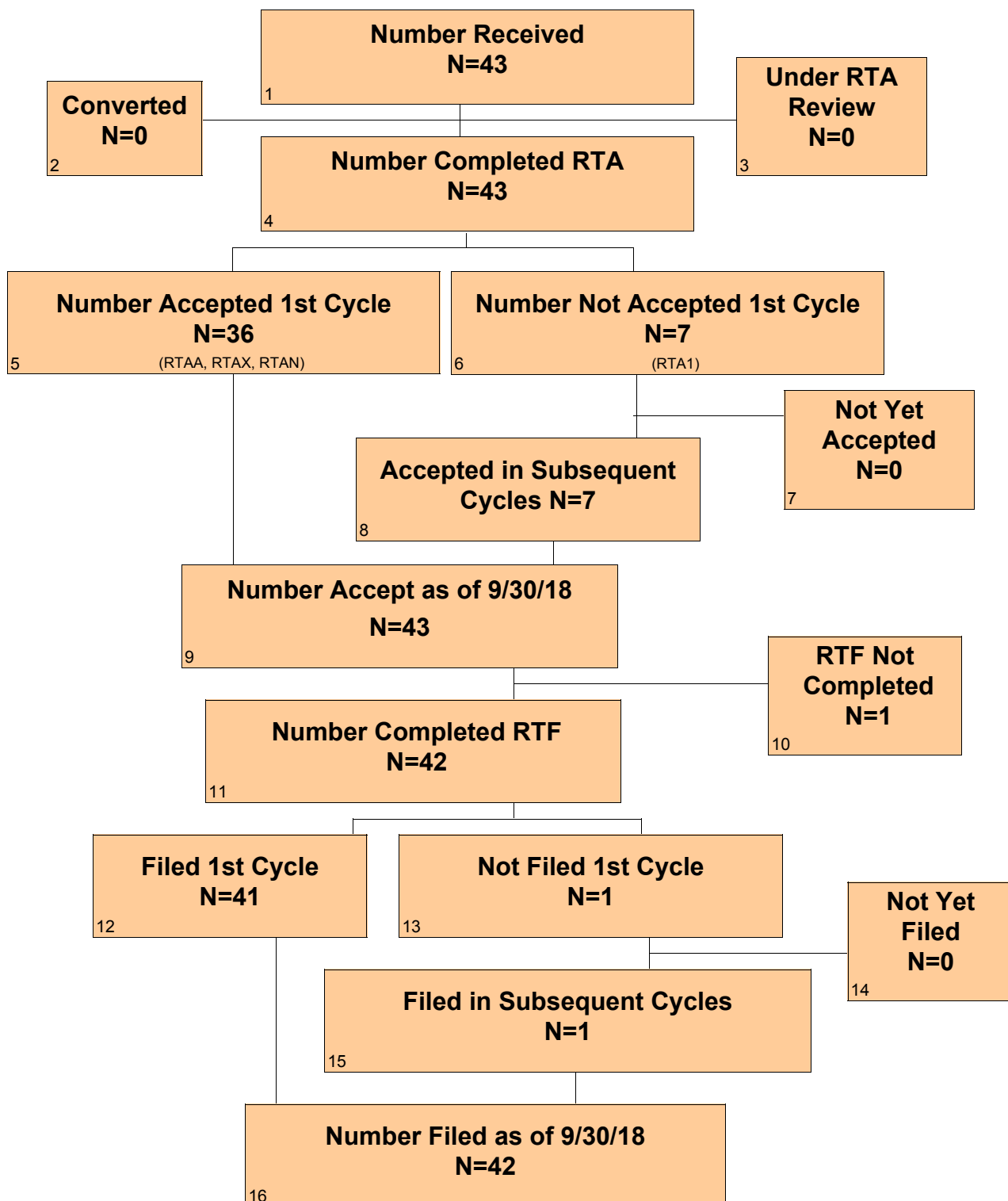
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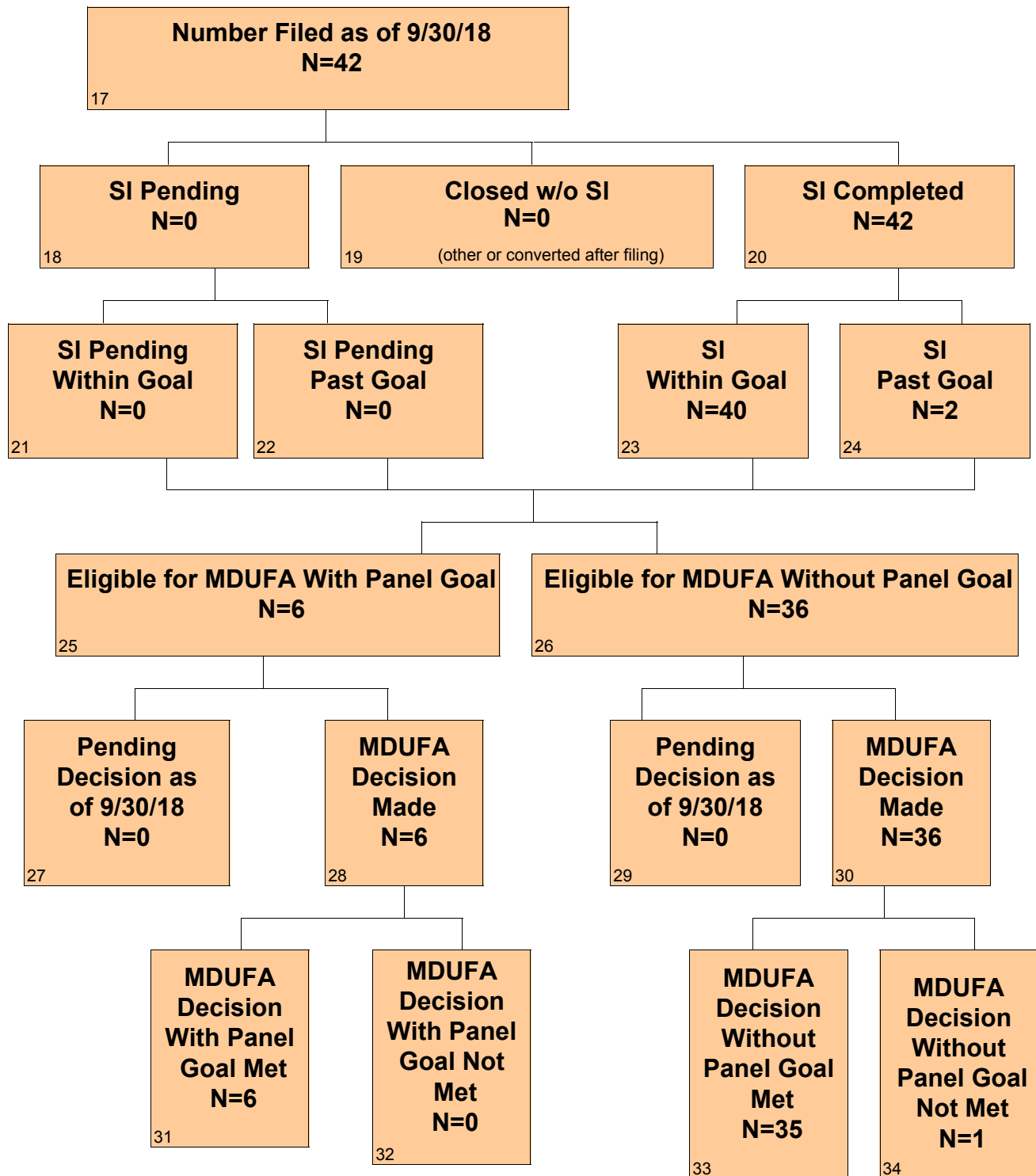
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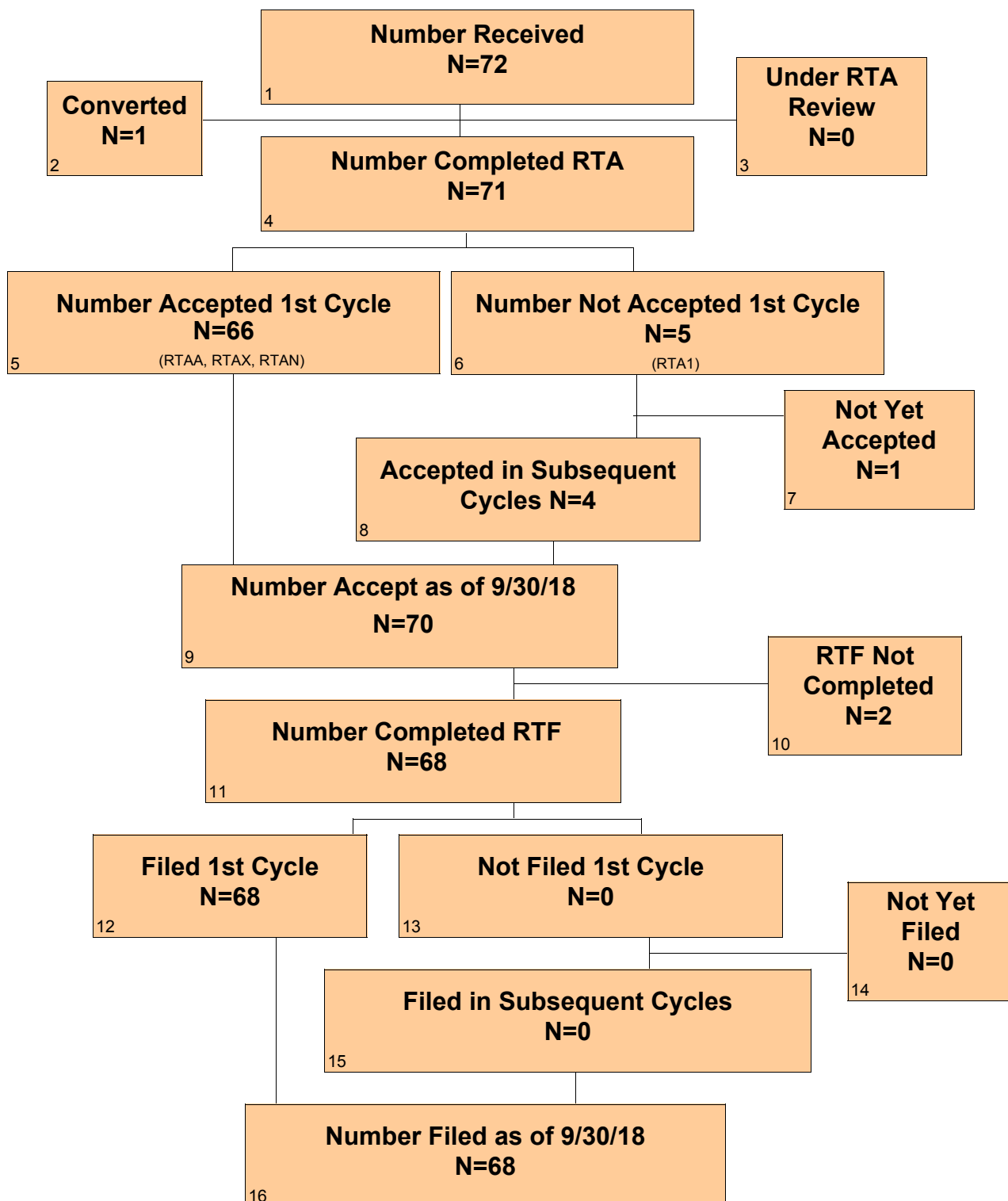
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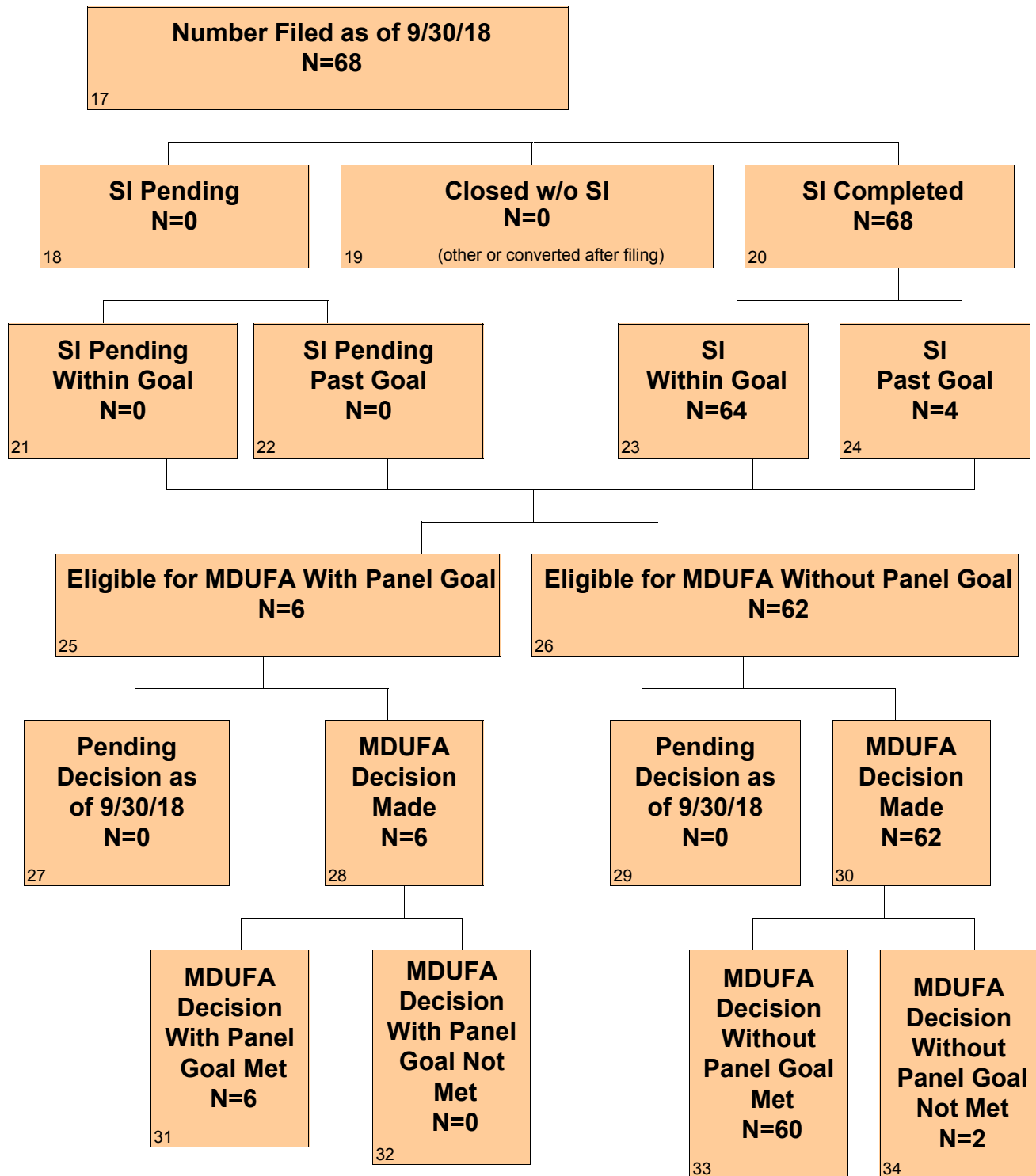
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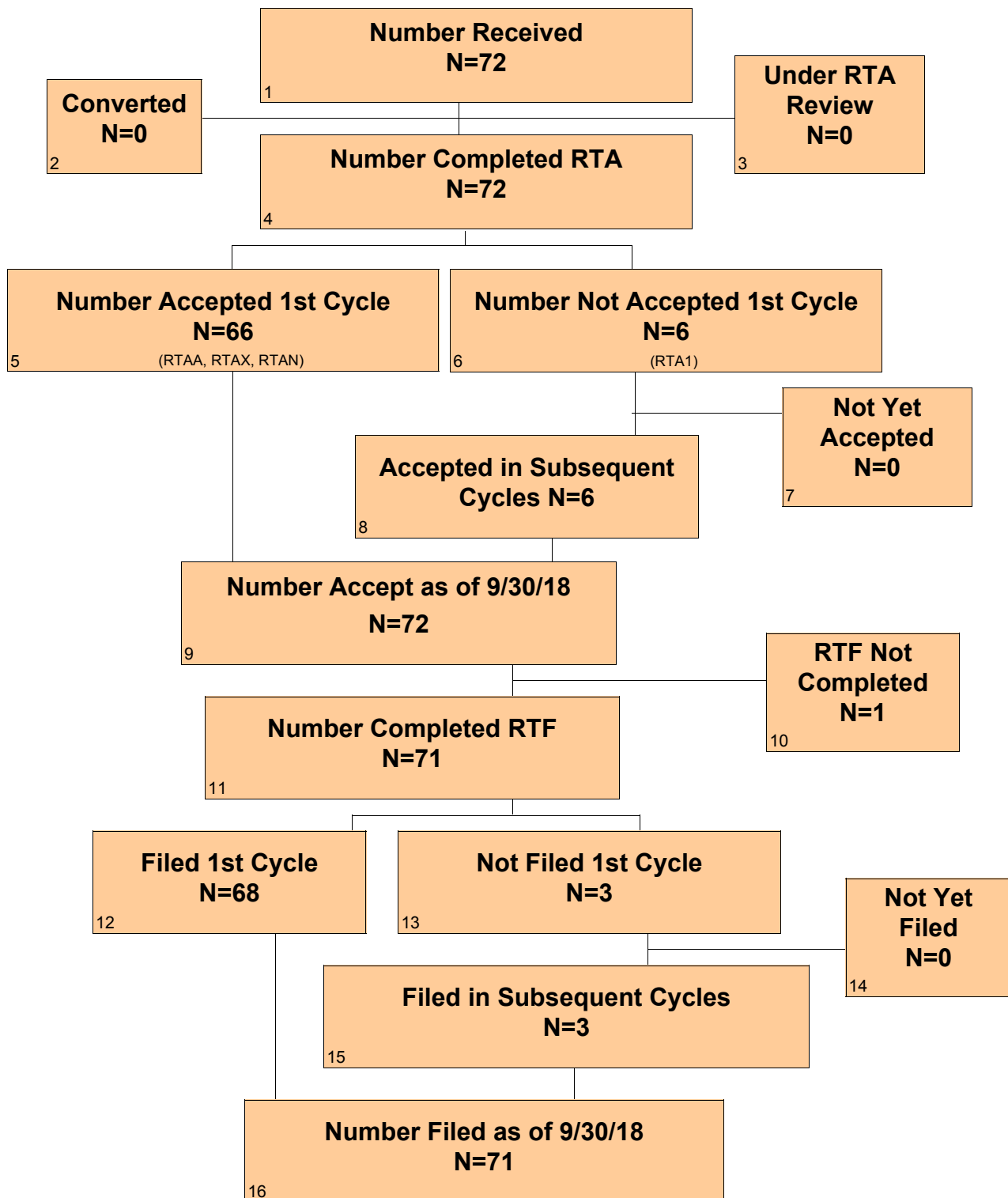
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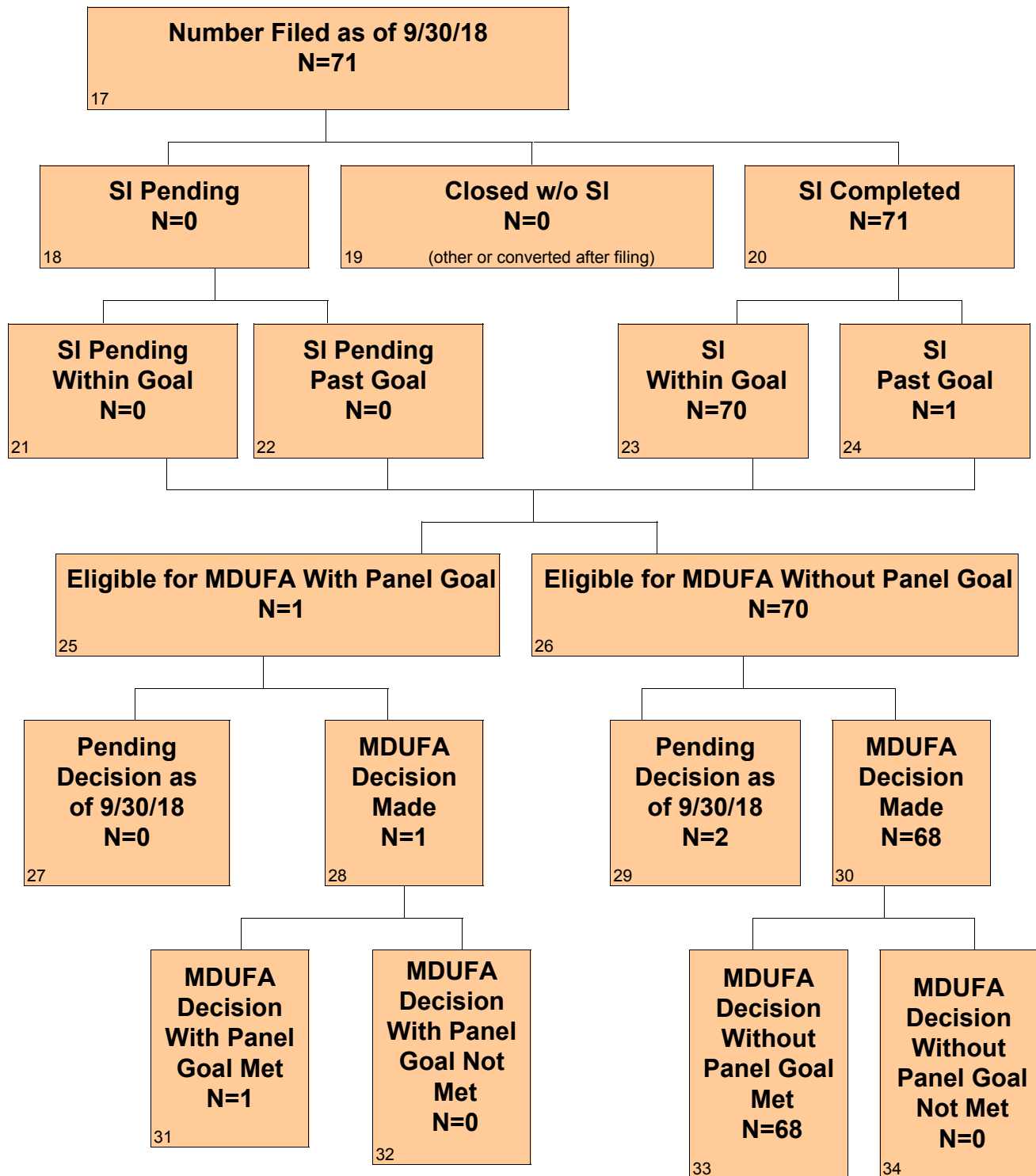
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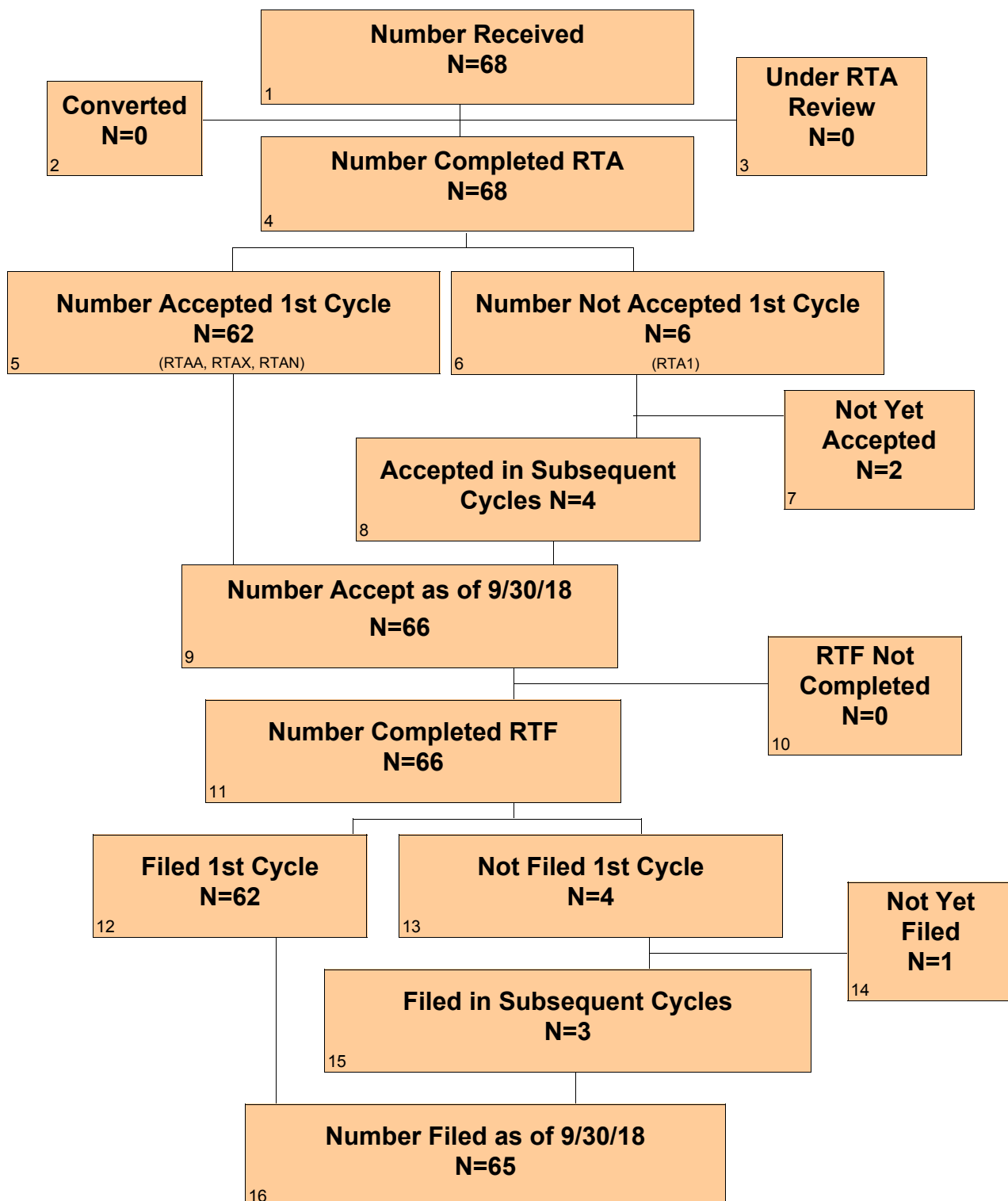
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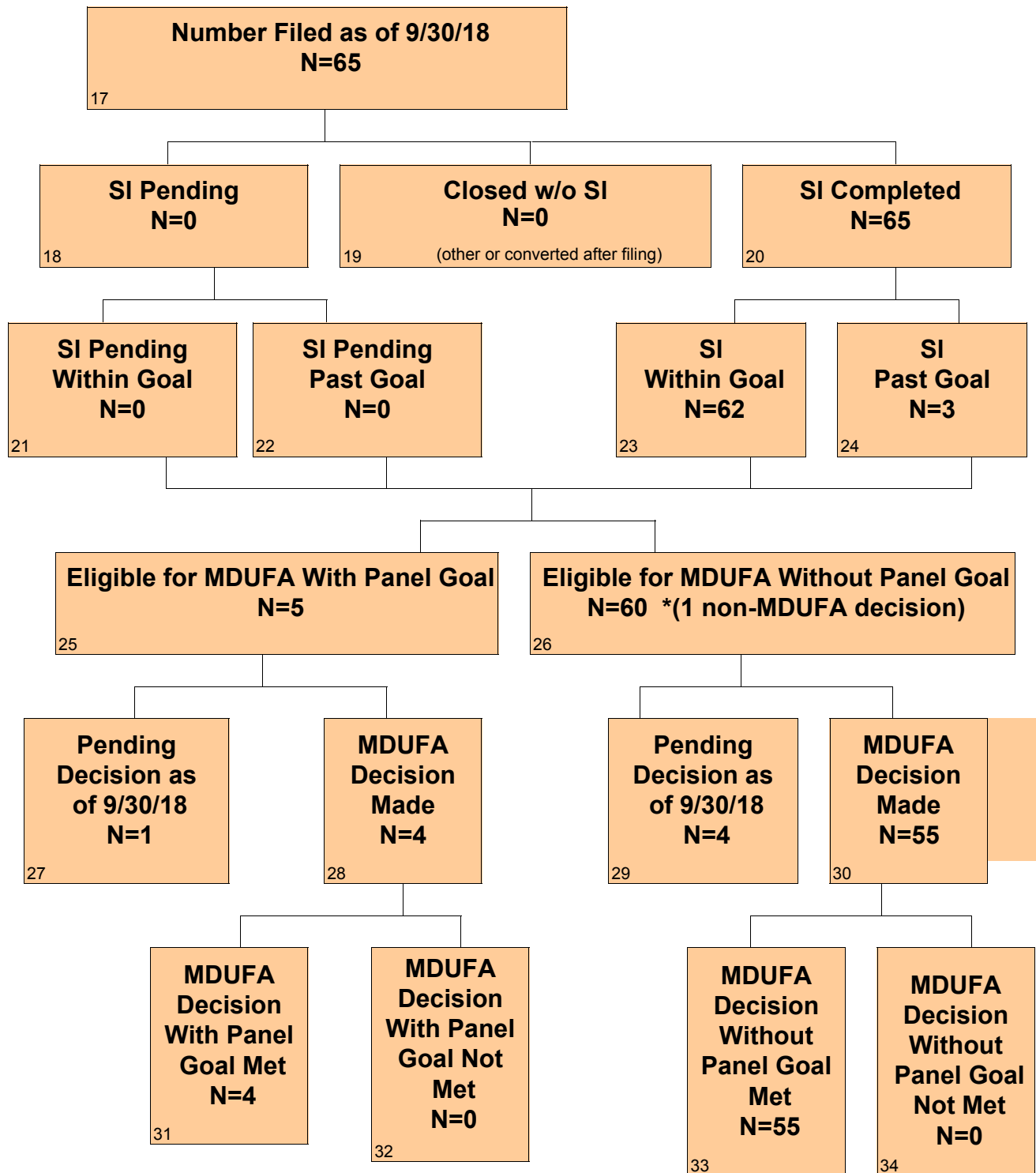
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CDRH PMA Original and Panel Track Supplements - FY 2017 As of 9/30/18



CDRH PMA Original and Panel Track Supplements - FY 2017 As of 9/30/18 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	72	68
Closed before RTA action	1	0	1	0	0
Number with accepted RTA review	27	35	64	66	61
Number without a RTA Review and > 15 Days since Date Received	1	1	2	0	1
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	6	7	5	6	6
Rate of submissions not accepted for filing review	17.65%	16.28%	7.04%	8.33%	8.82%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	72	68
Number Accepted	38	36	66	66	62
Completed RTF	44	42	68	71	66
Number Not Filed	3	1	0	3	4
Rate of submissions Not Filed	6.82%	2.38%	0%	4.23%	6.06%

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	71	65
SI Goal Met	41	40	64	70	62
SI Goal Not Met	3	2	4	1	3
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	93.18%	95.24%	94.12%	98.59%	95.38%

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	71	65
Average number of FDA days to Substantive Interaction	109.73	90.02	91.74	87.52	88.08
20th Percentile FDA days to Substantive Interaction	86	87	85	85	87
40th Percentile FDA days to Substantive Interaction	88	88	88	88	88
60th Percentile FDA days to Substantive Interaction	90	89	90	90	90
80th Percentile FDA days to Substantive Interaction	90	90	90	90	90
Maximum FDA days to Substantive Interaction	1,031	136	168	163	155

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of PMAs filed	27	36	62	70	60
Non-MDUFA III Decisions	0	0	0	0	1
MDUFA III Decisions	27	36	62	68	55
MDUFA III Decisions Goal Met	25	35	60	68	55
PMAs pending MDUFA III Decision	0	0	0	2	4
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	92.59%	97.22%	96.77%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of PMAs filed	17	6	6	1	5
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	17	6	6	1	4
MDUFA III Decisions Goal Met	15	6	6	1	4
PMAs pending MDUFA III Decision	0	0	0	0	1
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	88.24%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	27	36	62	68	55
Average FDA days to MDUFA III decision	208.81	175.81	177.84	163.99	174.44
20th Percentile FDA days to MDUFA III decision	175	176	174	145	169.8
40th Percentile FDA days to MDUFA III decision	178	179	178	177	178
60th Percentile FDA days to MDUFA III decision	180	179	180	179	179
80th Percentile FDA days to MDUFA III decision	180	180	180	180	180
Maximum FDA days to MDUFA III decision	1,031	359	256	256	281
Average Industry days to MDUFA III decision	163.81	54.08	96.87	128.56	63.22
20th Percentile Industry days to MDUFA III decision	0	0	0	6	0
40th Percentile Industry days to MDUFA III decision	80	0	44	48	21
60th Percentile Industry days to MDUFA III decision	116	48	84	105	59
80th Percentile Industry days to MDUFA III decision	337	106	178	256	114
Maximum Industry days to MDUFA III decision	563	238	361	566	360
Average Total days to MDUFA III decision	372.63	229.89	274.71	292.54	237.65
20th Percentile Total days to MDUFA III decision	181	179	178	177	179
40th Percentile Total days to MDUFA III decision	253	180	225	216	191
60th Percentile Total days to MDUFA III decision	345	244	268	274	243
80th Percentile Total days to MDUFA III decision	538	283	361	396	274
Maximum Total days to MDUFA III decision	1,031	418	607	746	517

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	17	6	6	1	4
Average FDA days to MDUFA III decision	380.18	344.33	276.67	300.00	310.25
20th Percentile FDA days to MDUFA III decision	291	318	206	300	304
40th Percentile FDA days to MDUFA III decision	315	320	299	300	320
60th Percentile FDA days to MDUFA III decision	318	359	317	300	320
80th Percentile FDA days to MDUFA III decision	510	376	319	300	320
Maximum FDA days to MDUFA III decision	700	379	339	300	320
Average Industry days to MDUFA III decision	162.82	169.33	86.00	110.00	200.50
20th Percentile Industry days to MDUFA III decision	0	20	31	110	129
40th Percentile Industry days to MDUFA III decision	44	101	103	110	165.6
60th Percentile Industry days to MDUFA III decision	163	178	110	110	215
80th Percentile Industry days to MDUFA III decision	272	358	119	110	268
Maximum Industry days to MDUFA III decision	728	359	153	110	322
Average Total days to MDUFA III decision	543.00	513.67	362.67	410.00	510.75
20th Percentile Total days to MDUFA III decision	316	399	325	410	449
40th Percentile Total days to MDUFA III decision	371	415	370	410	485.6
60th Percentile Total days to MDUFA III decision	498	498	422	410	535
80th Percentile Total days to MDUFA III decision	656	717	427	410	572
Maximum Total days to MDUFA III decision	1,428	735	452	410	603

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	62	70	60
Number with MDUFA decision	27	36	62	68	55
Number of Withdrawals	1	1	0	4	4
Number of Not Approvable	4	2	10	4	6
Rate of Withdrawals	3.70%	2.78%	0%	5.88%	7.27%
Rate of Not Approvable	14.81%	5.56%	16.13%	5.88%	10.91%

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	6	1	5
Number with MDUFA decision	17	6	6	1	4
Number of Withdrawals	1	1	1	0	0
Number of Not Approvable	3	1	2	0	2
Rate of Withdrawals	5.88%	16.67%	16.67%	0%	0%
Rate of Not Approvable	17.65%	16.67%	33.33%	0%	50.00%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	1	2	0	0
Mean FDA days for submissions that missed goal	661	201	189	0	0
Mean industry days for submissions that missed goal	57	43	44	0	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0	0	0
Mean FDA days for submissions that missed goal	684	0	0	0	0
Mean industry days for submissions that missed goal	364	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	46	43
Closed before RTA action	1	0	1	0	0
Number with accepted RTA review	20	30	47	41	39
Number without a RTA Review and > 15 Days since Date Received	1	1	2	0	1
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	6	6	5	5	3
Rate of submissions not accepted for filing review	22.22%	16.22%	9.26%	10.87%	6.98%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	46	43
Number Accepted	28	31	49	41	40
Completed RTF	34	36	51	46	43
Number Not Filed	3	1	0	3	2
Rate of submissions Not Filed	8.82%	2.78%	0%	6.52%	4.65%

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	34	36	51	46	43
SI Goal Met	31	34	48	46	41
SI Goal Not Met	3	2	3	0	2
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	91.18%	94.44%	94.12%	100%	95.35%

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	46	43
Average number of FDA days to Substantive Interaction	115.88	90.64	94.29	90.30	87.40
20th Percentile FDA days to Substantive Interaction	86	87	86	88	86
40th Percentile FDA days to Substantive Interaction	88	88	88	88	88
60th Percentile FDA days to Substantive Interaction	89	89	89	90	90
80th Percentile FDA days to Substantive Interaction	90	90	90	90	90
Maximum FDA days to Substantive Interaction	1,031	136	168	163	126

**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	46	45	39
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	21	30	46	43	37
MDUFA III Decisions Goal Met	19	29	44	43	37
PMAs pending MDUFA III Decision	0	0	0	2	2
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	90.48%	96.67%	95.65%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	13	6	5	1	4
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	13	6	5	1	3
MDUFA III Decisions Goal Met	11	6	5	1	3
PMAs pending MDUFA III Decision	0	0	0	0	1
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	84.62%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	21	30	46	43	37
Average FDA days to MDUFA III decision	225.05	178.30	185.11	172.40	178.11
20th Percentile FDA days to MDUFA III decision	177	175	178	177	177
40th Percentile FDA days to MDUFA III decision	180	179	179	179	178
60th Percentile FDA days to MDUFA III decision	180	179	180	180	179
80th Percentile FDA days to MDUFA III decision	180	180	180	180	180
Maximum FDA days to MDUFA III decision	1,031	359	256	256	258
Average Industry days to MDUFA III decision	167.29	49.43	108.72	142.26	71.00
20th Percentile Industry days to MDUFA III decision	0	0	0	6	0
40th Percentile Industry days to MDUFA III decision	68	11	49	48	33
60th Percentile Industry days to MDUFA III decision	113	46	99	90	67
80th Percentile Industry days to MDUFA III decision	356	82	182	358	126
Maximum Industry days to MDUFA III decision	563	193	361	566	360
Average Total days to MDUFA III decision	392.33	227.73	293.83	314.65	249.11
20th Percentile Total days to MDUFA III decision	180	179	180	185	179
40th Percentile Total days to MDUFA III decision	260	190	238	232	216
60th Percentile Total days to MDUFA III decision	397	238	286	283	254
80th Percentile Total days to MDUFA III decision	540	267	387	472	305
Maximum Total days to MDUFA III decision	1,031	392	607	746	517

**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	13	6	5	1	3
Average FDA days to MDUFA III decision	409.23	344.33	272.20	300.00	320.00
20th Percentile FDA days to MDUFA III decision	299	318	201	300	320
40th Percentile FDA days to MDUFA III decision	316	320	273	300	320
60th Percentile FDA days to MDUFA III decision	356	359	318	300	320
80th Percentile FDA days to MDUFA III decision	606	376	323	300	320
Maximum FDA days to MDUFA III decision	700	379	339	300	320
Average Industry days to MDUFA III decision	190.31	169.33	72.60	110.00	160.00
20th Percentile Industry days to MDUFA III decision	0	20	25	110	119
40th Percentile Industry days to MDUFA III decision	60	101	74	110	139
60th Percentile Industry days to MDUFA III decision	180	178	106	110	166
80th Percentile Industry days to MDUFA III decision	294	358	112	110	199
Maximum Industry days to MDUFA III decision	728	359	119	110	232
Average Total days to MDUFA III decision	599.54	513.67	344.80	410.00	480.00
20th Percentile Total days to MDUFA III decision	319	399	296	410	439
40th Percentile Total days to MDUFA III decision	394	415	352	410	459
60th Percentile Total days to MDUFA III decision	577	498	391	410	486
80th Percentile Total days to MDUFA III decision	750	717	423	410	519
Maximum Total days to MDUFA III decision	1,428	735	427	410	552

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	46	45	39
Number with MDUFA decision	21	30	46	43	37
Number of Withdrawals	1	1	0	3	0
Number of Not Approvable	3	2	9	1	6
Rate of Withdrawals	4.76%	3.33%	0%	6.98%	0%
Rate of Not Approvable	14.29%	6.67%	19.57%	2.33%	16.22%

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	5	1	4
Number with MDUFA decision	13	6	5	1	3
Number of Withdrawals	1	1	1	0	0
Number of Not Approvable	2	1	2	0	2
Rate of Withdrawals	7.69%	16.67%	20.00%	0%	0%
Rate of Not Approvable	15.38%	16.67%	40.00%	0%	66.67%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	1	2	0	0
Mean FDA days for submissions that missed goal	661	201	189	0	0
Mean industry days for submissions that missed goal	57	43	44	0	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0	0	0
Mean FDA days for submissions that missed goal	684	0	0	0	0
Mean industry days for submissions that missed goal	364	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	26	25
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	7	5	17	25	22
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	1	0	1	3
Rate of submissions not accepted for filing review	0%	16.67%	0%	3.85%	12.00%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	26	25
Number Accepted	10	5	17	25	22
Completed RTF	10	6	17	25	23
Number Not Filed	0	0	0	0	2
Rate of submissions Not Filed	0%	0%	0%	0%	8.70%

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	10	6	17	25	22
SI Goal Met	10	6	16	24	21
SI Goal Not Met	0	0	1	1	1
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	90.00%	100%	94.12%	96.00%	95.45%

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	25	22
Average number of FDA days to Substantive Interaction	88.80	86.33	84.06	82.40	89.41
20th Percentile FDA days to Substantive Interaction	86	85	84	82	87
40th Percentile FDA days to Substantive Interaction	90	86	87	85	88
60th Percentile FDA days to Substantive Interaction	90	87	90	87	90
80th Percentile FDA days to Substantive Interaction	90	88	90	88	90
Maximum FDA days to Substantive Interaction	112	89	91	94	155

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	16	25	21
Non-MDUFA III Decisions	0	0	0	0	1
MDUFA III Decisions	6	6	16	25	18
MDUFA III Decisions Goal Met	6	6	16	25	18
PMAs pending MDUFA III Decision	0	0	0	0	2
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

**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	16	25	18
Average FDA days to MDUFA III decision	152.00	163.33	156.94	149.52	166.89
20th Percentile FDA days to MDUFA III decision	116	177	133	117	147
40th Percentile FDA days to MDUFA III decision	167	179	170	147	168
60th Percentile FDA days to MDUFA III decision	174	179	175	173	177
80th Percentile FDA days to MDUFA III decision	177	179	177	177	180
Maximum FDA days to MDUFA III decision	179	180	180	180	281
Average Industry days to MDUFA III decision	151.67	77.33	62.81	105.00	47.22
20th Percentile Industry days to MDUFA III decision	81	0	0	22	0
40th Percentile Industry days to MDUFA III decision	107	0	21	49	0
60th Percentile Industry days to MDUFA III decision	118	106	63	127	37
80th Percentile Industry days to MDUFA III decision	133	120	105	178	80
Maximum Industry days to MDUFA III decision	400	238	283	357	215
Average Total days to MDUFA III decision	303.67	240.67	219.75	254.52	214.11
20th Percentile Total days to MDUFA III decision	217	179	172	174	177
40th Percentile Total days to MDUFA III decision	248	179	179	204	180
60th Percentile Total days to MDUFA III decision	284	283	197	261	199
80th Percentile Total days to MDUFA III decision	307	299	284	318	254
Maximum Total days to MDUFA III decision	579	418	459	537	496

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	1	0	1
Average FDA days to MDUFA III decision	285.75	0	299.00	0	281.00
20th Percentile FDA days to MDUFA III decision	261	0	299	0	281
40th Percentile FDA days to MDUFA III decision	301	0	299	0	281
60th Percentile FDA days to MDUFA III decision	311	0	299	0	281
80th Percentile FDA days to MDUFA III decision	319	0	299	0	281
Maximum FDA days to MDUFA III decision	325	0	299	0	281
Average Industry days to MDUFA III decision	73.50	0	153.00	0	322.00
20th Percentile Industry days to MDUFA III decision	0	0	153	0	322
40th Percentile Industry days to MDUFA III decision	21	0	153	0	322
60th Percentile Industry days to MDUFA III decision	84	0	153	0	322
80th Percentile Industry days to MDUFA III decision	139	0	153	0	322
Maximum Industry days to MDUFA III decision	189	0	153	0	322
Average Total days to MDUFA III decision	359.25	0	452.00	0	603.00
20th Percentile Total days to MDUFA III decision	261	0	452	0	603
40th Percentile Total days to MDUFA III decision	324	0	452	0	603
60th Percentile Total days to MDUFA III decision	403	0	452	0	603
80th Percentile Total days to MDUFA III decision	460	0	452	0	603
Maximum Total days to MDUFA III decision	504	0	452	0	603

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	16	25	21
Number with MDUFA decision	6	6	16	25	18
Number of Withdrawals	0	0	0	1	4
Number of Not Approvable	1	0	1	3	0
Rate of Withdrawals	0%	0%	0%	4.00%	22.22%
Rate of Not Approvable	16.67%	0%	6.25%	12.00%	0%

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	1	0	1
Number with MDUFA decision	4	0	1	0	1
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	1	0	0	0	0
Rate of Withdrawals	0%	N/A	0%	N/A	0%
Rate of Not Approvable	25.00%	N/A	0%	N/A	0%

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

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

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

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

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	1	1
Number Accepted	1	1	2	1	1
Completed RTF	2	1	2	1	1
Number Not Filed	0	0	0	0	0
Rate of submissions Not Filed	0%	0%	0%	0%	0%

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	1	1
SI Goal Met	2	1	2	1	1
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	100%	100%	100%

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	1	1
Average number of FDA days to Substantive Interaction	85.00	87.00	128.00	90.00	90.00
20th Percentile FDA days to Substantive Interaction	84	87	104	90	90
40th Percentile FDA days to Substantive Interaction	85	87	120	90	90
60th Percentile FDA days to Substantive Interaction	85	87	136	90	90
80th Percentile FDA days to Substantive Interaction	86	87	152	90	90
Maximum FDA days to Substantive Interaction	87	87	168	90	90

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

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

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

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	2	1	0
Average FDA days to MDUFA III decision	180.00	179.00	218.00	180.00	0
20th Percentile FDA days to MDUFA III decision	180	179	195	180	0
40th Percentile FDA days to MDUFA III decision	180	179	210	180	0
60th Percentile FDA days to MDUFA III decision	180	179	226	180	0
80th Percentile FDA days to MDUFA III decision	180	179	241	180	0
Maximum FDA days to MDUFA III decision	180	179	256	180	0
Average Industry days to MDUFA III decision	360.00	0	271.50	17.00	0
20th Percentile Industry days to MDUFA III decision	360	0	218	17	0
40th Percentile Industry days to MDUFA III decision	360	0	254	17	0
60th Percentile Industry days to MDUFA III decision	360	0	289	17	0
80th Percentile Industry days to MDUFA III decision	360	0	325	17	0
Maximum Industry days to MDUFA III decision	360	0	361	17	0
Average Total days to MDUFA III decision	540.00	179.00	489.50	197.00	0
20th Percentile Total days to MDUFA III decision	540	179	459	197	0
40th Percentile Total days to MDUFA III decision	540	179	479	197	0
60th Percentile Total days to MDUFA III decision	540	179	500	197	0
80th Percentile Total days to MDUFA III decision	540	179	520	197	0
Maximum Total days to MDUFA III decision	540	179	541	197	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	1
Average FDA days to MDUFA III decision	320.00	0	0	0	320.00
20th Percentile FDA days to MDUFA III decision	320	0	0	0	320
40th Percentile FDA days to MDUFA III decision	320	0	0	0	320
60th Percentile FDA days to MDUFA III decision	320	0	0	0	320
80th Percentile FDA days to MDUFA III decision	320	0	0	0	320
Maximum FDA days to MDUFA III decision	320	0	0	0	320
Average Industry days to MDUFA III decision	28.00	0	0	0	232.00
20th Percentile Industry days to MDUFA III decision	28	0	0	0	232
40th Percentile Industry days to MDUFA III decision	28	0	0	0	232
60th Percentile Industry days to MDUFA III decision	28	0	0	0	232
80th Percentile Industry days to MDUFA III decision	28	0	0	0	232
Maximum Industry days to MDUFA III decision	28	0	0	0	232
Average Total days to MDUFA III decision	348.00	0	0	0	552.00
20th Percentile Total days to MDUFA III decision	348	0	0	0	552
40th Percentile Total days to MDUFA III decision	348	0	0	0	552
60th Percentile Total days to MDUFA III decision	348	0	0	0	552
80th Percentile Total days to MDUFA III decision	348	0	0	0	552
Maximum Total days to MDUFA III decision	348	0	0	0	552

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	1	0
Number with MDUFA decision	1	1	2	1	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	2	0	0
Rate of Withdrawals	0%	0%	0%	0%	N/A
Rate of Not Approvable	0%	0%	100%	0%	N/A

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

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

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	33	20
Closed before RTA action	1	0	1	0	0
Number with accepted RTA review	15	15	25	31	20
Number without a RTA Review and > 15 Days since Date Received	1	1	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	1	2	2	0
Rate of submissions not accepted for filing review	0%	5.88%	7.41%	6.06%	0%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	33	20
Number Accepted	19	16	25	31	20
Completed RTF	19	17	27	33	20
Number Not Filed	0	0	0	3	1
Rate of submissions Not Filed	0%	0%	0%	9.09%	5.00%

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	33	20
SI Goal Met	17	16	26	33	20
SI Goal Not Met	2	1	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	89.47%	94.12%	96.30%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	19	17	27	33	20
Average number of FDA days to Substantive Interaction	137.95	87.71	91.67	90.82	83.60
20th Percentile FDA days to Substantive Interaction	85	87	85	88	85
40th Percentile FDA days to Substantive Interaction	88	88	88	88	88
60th Percentile FDA days to Substantive Interaction	90	89	89	90	88
80th Percentile FDA days to Substantive Interaction	90	90	90	90	89
Maximum FDA days to Substantive Interaction	1,031	91	145	163	90

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	33	20
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	15	16	24	31	19
MDUFA III Decisions Goal Met	13	15	22	31	19
PMAs pending MDUFA III Decision	0	0	0	2	1
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	86.67%	93.75%	91.67%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	4	1	3	0	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	4	1	3	0	0
MDUFA III Decisions Goal Met	2	1	3	0	0
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	50.00%	100%	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	24	31	19
Average FDA days to MDUFA III decision	243.60	174.25	179.92	169.77	179.53
20th Percentile FDA days to MDUFA III decision	177	177	178	174	177
40th Percentile FDA days to MDUFA III decision	180	178	179	178	178
60th Percentile FDA days to MDUFA III decision	180	179	180	180	179
80th Percentile FDA days to MDUFA III decision	200	180	180	180	180
Maximum FDA days to MDUFA III decision	1,031	201	232	256	258
Average Industry days to MDUFA III decision	154.67	29.31	69.67	157.77	54.21
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	55	0	44	48	27
60th Percentile Industry days to MDUFA III decision	99	0	62	107	62
80th Percentile Industry days to MDUFA III decision	262	43	131	367	97
Maximum Industry days to MDUFA III decision	563	161	263	566	169
Average Total days to MDUFA III decision	398.27	203.56	249.58	327.55	233.74
20th Percentile Total days to MDUFA III decision	180	179	180	180	179
40th Percentile Total days to MDUFA III decision	255	179	232	233	215
60th Percentile Total days to MDUFA III decision	319	180	242	295	248
80th Percentile Total days to MDUFA III decision	713	244	310	538	270
Maximum Total days to MDUFA III decision	1,031	338	442	746	349

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	4	1	3	0	0
Average FDA days to MDUFA III decision	500.00	318.00	279.33	0	0
20th Percentile FDA days to MDUFA III decision	316	318	236	0	0
40th Percentile FDA days to MDUFA III decision	386	318	291	0	0
60th Percentile FDA days to MDUFA III decision	598	318	323	0	0
80th Percentile FDA days to MDUFA III decision	681	318	331	0	0
Maximum FDA days to MDUFA III decision	700	318	339	0	0
Average Industry days to MDUFA III decision	182.00	0	44.67	0	0
20th Percentile Industry days to MDUFA III decision	0	0	12	0	0
40th Percentile Industry days to MDUFA III decision	0	0	25	0	0
60th Percentile Industry days to MDUFA III decision	0	0	45	0	0
80th Percentile Industry days to MDUFA III decision	291	0	74	0	0
Maximum Industry days to MDUFA III decision	728	0	103	0	0
Average Total days to MDUFA III decision	682.00	318.00	324.00	0	0
20th Percentile Total days to MDUFA III decision	316	318	256	0	0
40th Percentile Total days to MDUFA III decision	386	318	332	0	0
60th Percentile Total days to MDUFA III decision	598	318	380	0	0
80th Percentile Total days to MDUFA III decision	972	318	401	0	0
Maximum Total days to MDUFA III decision	1,428	318	422	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	33	20
Number with MDUFA decision	15	16	24	31	19
Number of Withdrawals	1	0	0	3	0
Number of Not Approvable	2	0	3	0	2
Rate of Withdrawals	6.67%	0%	0%	9.68%	0%
Rate of Not Approvable	13.33%	0%	12.50%	0%	10.53%

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	0	0
Number with MDUFA decision	4	1	3	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	2	0	0
Rate of Withdrawals	0%	0%	0%	N/A	N/A
Rate of Not Approvable	0%	0%	66.67%	N/A	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	1	2	0	0
Mean FDA days for submissions that missed goal	661	201	189	0	0
Mean industry days for submissions that missed goal	57	43	44	0	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0	0	0
Mean FDA days for submissions that missed goal	684	0	0	0	0
Mean industry days for submissions that missed goal	364	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	6
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	0	2	4	1	5
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	1
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	1	1	0	0	0
Rate of submissions not accepted for filing review	100%	33.33%	0%	0%	0%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	6
Number Accepted	0	2	4	1	6
Completed RTF	1	3	4	1	6
Number Not Filed	0	1	0	0	0
Rate of submissions Not Filed	0%	33.33%	0%	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	6
SI Goal Met	0	2	4	1	6
SI Goal Not Met	1	1	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	0%	66.67%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1	3	4	1	6
Average number of FDA days to Substantive Interaction	92.00	90.33	108.25	90.00	89.67
20th Percentile FDA days to Substantive Interaction	92	90	89	90	90
40th Percentile FDA days to Substantive Interaction	92	90	90	90	90
60th Percentile FDA days to Substantive Interaction	92	90	90	90	90
80th Percentile FDA days to Substantive Interaction	92	91	120	90	90
Maximum FDA days to Substantive Interaction	92	91	166	90	90

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	3	4	1	4
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	1	3	4	1	3
MDUFA III Decisions Goal Met	1	3	4	1	3
PMAs pending MDUFA III Decision	0	0	0	0	1
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

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	4	1	3
Average FDA days to MDUFA III decision	180.00	182.33	211.25	180.00	178.67
20th Percentile FDA days to MDUFA III decision	180	178	172	180	178
40th Percentile FDA days to MDUFA III decision	180	179	192	180	178
60th Percentile FDA days to MDUFA III decision	180	182	233	180	178
80th Percentile FDA days to MDUFA III decision	180	186	251	180	179
Maximum FDA days to MDUFA III decision	180	190	256	180	180
Average Industry days to MDUFA III decision	0	91.67	124.00	84.00	69.00
20th Percentile Industry days to MDUFA III decision	0	48	8	84	16
40th Percentile Industry days to MDUFA III decision	0	69	36	84	32
60th Percentile Industry days to MDUFA III decision	0	97	100	84	65
80th Percentile Industry days to MDUFA III decision	0	132	217	84	116
Maximum Industry days to MDUFA III decision	0	168	360	84	167
Average Total days to MDUFA III decision	180.00	274.00	335.25	264.00	247.67
20th Percentile Total days to MDUFA III decision	180	227	178	264	194
40th Percentile Total days to MDUFA III decision	180	246	218	264	210
60th Percentile Total days to MDUFA III decision	180	276	338	264	244
80th Percentile Total days to MDUFA III decision	180	317	470	264	295
Maximum Total days to MDUFA III decision	180	358	607	264	347

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	1
Average FDA days to MDUFA III decision	0	0	0	0	320.00
20th Percentile FDA days to MDUFA III decision	0	0	0	0	320
40th Percentile FDA days to MDUFA III decision	0	0	0	0	320
60th Percentile FDA days to MDUFA III decision	0	0	0	0	320
80th Percentile FDA days to MDUFA III decision	0	0	0	0	320
Maximum FDA days to MDUFA III decision	0	0	0	0	320
Average Industry days to MDUFA III decision	0	0	0	0	99.00
20th Percentile Industry days to MDUFA III decision	0	0	0	0	99
40th Percentile Industry days to MDUFA III decision	0	0	0	0	99
60th Percentile Industry days to MDUFA III decision	0	0	0	0	99
80th Percentile Industry days to MDUFA III decision	0	0	0	0	99
Maximum Industry days to MDUFA III decision	0	0	0	0	99
Average Total days to MDUFA III decision	0	0	0	0	419.00
20th Percentile Total days to MDUFA III decision	0	0	0	0	419
40th Percentile Total days to MDUFA III decision	0	0	0	0	419
60th Percentile Total days to MDUFA III decision	0	0	0	0	419
80th Percentile Total days to MDUFA III decision	0	0	0	0	419
Maximum Total days to MDUFA III decision	0	0	0	0	419

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	4
Number with MDUFA decision	1	3	4	1	3
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	1	0	0
Rate of Withdrawals	0%	0%	0%	0%	0%
Rate of Not Approvable	0%	0%	25.00%	0%	0%

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	2
Number with MDUFA decision	0	0	0	0	1
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	N/A	N/A	N/A	N/A	0%
Rate of Not Approvable	N/A	N/A	N/A	N/A	0%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	2	5
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	0	4	5	2	4
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	0	2	0	1
Rate of submissions not accepted for filing review	N/A	0%	28.57%	0%	20.00%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	2	5
Number Accepted	2	4	5	2	4
Completed RTF	2	4	6	2	5
Number Not Filed	0	0	0	0	0
Rate of submissions Not Filed	0%	0%	0%	0%	0%

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
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	2	5
SI Goal Met	2	4	5	2	3
SI Goal Not Met	0	0	1	0	2
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	83.33%	100%	60.00%

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	2	5
Average number of FDA days to Substantive Interaction	86.00	100.00	89.33	89.00	97.00
20th Percentile FDA days to Substantive Interaction	86	89	88	88	87
40th Percentile FDA days to Substantive Interaction	86	89	88	89	89
60th Percentile FDA days to Substantive Interaction	86	90	90	89	93
80th Percentile FDA days to Substantive Interaction	86	107	90	90	104
Maximum FDA days to Substantive Interaction	86	133	96	90	126

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	2	5	2	4
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	1	2	5	2	4
MDUFA III Decisions Goal Met	1	2	5	2	4
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

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

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	5	2	4
Average FDA days to MDUFA III decision	175.00	179.50	174.80	179.50	179.75
20th Percentile FDA days to MDUFA III decision	175	179	172	179	180
40th Percentile FDA days to MDUFA III decision	175	179	176	179	180
60th Percentile FDA days to MDUFA III decision	175	180	178	180	180
80th Percentile FDA days to MDUFA III decision	175	180	179	180	180
Maximum FDA days to MDUFA III decision	175	180	179	180	180
Average Industry days to MDUFA III decision	356.00	79.00	165.00	147.00	89.50
20th Percentile Industry days to MDUFA III decision	356	78	0	59	0
40th Percentile Industry days to MDUFA III decision	356	79	133	118	36
60th Percentile Industry days to MDUFA III decision	356	79	231	176	142
80th Percentile Industry days to MDUFA III decision	356	80	268	235	179
Maximum Industry days to MDUFA III decision	356	81	358	294	180
Average Total days to MDUFA III decision	531.00	258.50	339.80	326.50	269.25
20th Percentile Total days to MDUFA III decision	531	258	176	238	180
40th Percentile Total days to MDUFA III decision	531	258	312	297	216
60th Percentile Total days to MDUFA III decision	531	259	410	356	322
80th Percentile Total days to MDUFA III decision	531	259	446	415	358
Maximum Total days to MDUFA III decision	531	260	532	474	359

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	2	1	0	1
Average FDA days to MDUFA III decision	219.00	345.00	317.00	0	320.00
20th Percentile FDA days to MDUFA III decision	219	326	317	0	320
40th Percentile FDA days to MDUFA III decision	219	339	317	0	320
60th Percentile FDA days to MDUFA III decision	219	351	317	0	320
80th Percentile FDA days to MDUFA III decision	219	364	317	0	320
Maximum FDA days to MDUFA III decision	219	376	317	0	320
Average Industry days to MDUFA III decision	186.00	230.00	110.00	0	149.00
20th Percentile Industry days to MDUFA III decision	186	153	110	0	149
40th Percentile Industry days to MDUFA III decision	186	204	110	0	149
60th Percentile Industry days to MDUFA III decision	186	256	110	0	149
80th Percentile Industry days to MDUFA III decision	186	307	110	0	149
Maximum Industry days to MDUFA III decision	186	359	110	0	149
Average Total days to MDUFA III decision	405.00	575.00	427.00	0	469.00
20th Percentile Total days to MDUFA III decision	405	479	427	0	469
40th Percentile Total days to MDUFA III decision	405	543	427	0	469
60th Percentile Total days to MDUFA III decision	405	607	427	0	469
80th Percentile Total days to MDUFA III decision	405	671	427	0	469
Maximum Total days to MDUFA III decision	405	735	427	0	469

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	2	5	2	4
Number with MDUFA decision	1	2	5	2	4
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	1	1	1	1	1
Rate of Withdrawals	0%	0%	0%	0%	0%
Rate of Not Approvable	100%	50.00%	20.00%	50.00%	25.00%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	2	1	0	1
Number with MDUFA decision	1	2	1	0	1
Number of Withdrawals	1	0	0	0	0
Number of Not Approvable	0	1	0	0	1
Rate of Withdrawals	100%	0%	0%	N/A	0%
Rate of Not Approvable	0%	50.00%	0%	N/A	100%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	5	2
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	4	1	5	5	1
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	1	0	0	0	1
Rate of submissions not accepted for filing review	20.00%	0%	0%	0%	50.00%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	5	2
Number Accepted	5	1	5	5	1
Completed RTF	6	1	5	5	2
Number Not Filed	1	0	0	0	0
Rate of submissions Not Filed	16.67%	0%	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	5	2
SI Goal Met	6	1	4	5	2
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	80.00%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	6	1	5	5	2
Average number of FDA days to Substantive Interaction	88.50	81.00	87.40	89.00	90.00
20th Percentile FDA days to Substantive Interaction	88	81	86	88	90
40th Percentile FDA days to Substantive Interaction	88	81	88	89	90
60th Percentile FDA days to Substantive Interaction	89	81	88	90	90
80th Percentile FDA days to Substantive Interaction	90	81	90	90	90
Maximum FDA days to Substantive Interaction	90	81	93	90	90

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	2	1	5	5	2
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	2	1	5	5	2
MDUFA III Decisions Goal Met	2	1	5	5	2
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	4	0	0	0	0
MDUFA III Decisions Goal Met	4	0	0	0	0
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	N/A	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	5	5	2
Average FDA days to MDUFA III decision	178.50	170.00	179.40	179.20	177.00
20th Percentile FDA days to MDUFA III decision	178	170	179	178	176
40th Percentile FDA days to MDUFA III decision	178	170	180	179	177
60th Percentile FDA days to MDUFA III decision	179	170	180	180	177
80th Percentile FDA days to MDUFA III decision	179	170	180	180	178
Maximum FDA days to MDUFA III decision	180	170	180	180	178
Average Industry days to MDUFA III decision	108.50	0	126.00	71.20	71.00
20th Percentile Industry days to MDUFA III decision	43	0	0	21	48
40th Percentile Industry days to MDUFA III decision	87	0	59	63	63
60th Percentile Industry days to MDUFA III decision	130	0	131	94	79
80th Percentile Industry days to MDUFA III decision	174	0	214	111	94
Maximum Industry days to MDUFA III decision	217	0	351	139	110
Average Total days to MDUFA III decision	287.00	170.00	305.40	250.40	248.00
20th Percentile Total days to MDUFA III decision	221	170	179	200	225
40th Percentile Total days to MDUFA III decision	265	170	239	243	240
60th Percentile Total days to MDUFA III decision	309	170	311	273	256
80th Percentile Total days to MDUFA III decision	353	170	394	289	271
Maximum Total days to MDUFA III decision	397	170	531	319	286

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	4	0	0	0	0
Average FDA days to MDUFA III decision	413.25	0	0	0	0
20th Percentile FDA days to MDUFA III decision	247	0	0	0	0
40th Percentile FDA days to MDUFA III decision	334	0	0	0	0
60th Percentile FDA days to MDUFA III decision	468	0	0	0	0
80th Percentile FDA days to MDUFA III decision	575	0	0	0	0
Maximum FDA days to MDUFA III decision	669	0	0	0	0
Average Industry days to MDUFA III decision	247.75	0	0	0	0
20th Percentile Industry days to MDUFA III decision	85	0	0	0	0
40th Percentile Industry days to MDUFA III decision	171	0	0	0	0
60th Percentile Industry days to MDUFA III decision	263	0	0	0	0
80th Percentile Industry days to MDUFA III decision	399	0	0	0	0
Maximum Industry days to MDUFA III decision	557	0	0	0	0
Average Total days to MDUFA III decision	661.00	0	0	0	0
20th Percentile Total days to MDUFA III decision	310	0	0	0	0
40th Percentile Total days to MDUFA III decision	419	0	0	0	0
60th Percentile Total days to MDUFA III decision	709	0	0	0	0
80th Percentile Total days to MDUFA III decision	973	0	0	0	0
Maximum Total days to MDUFA III decision	1,226	0	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	5	2
Number with MDUFA decision	2	1	5	5	2
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	1	0	0
Rate of Withdrawals	0%	0%	0%	0%	0%
Rate of Not Approvable	0%	0%	20.00%	0%	0%

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	0
Number with MDUFA decision	4	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	0%	N/A	N/A	N/A	N/A
Rate of Not Approvable	0%	N/A	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	2	4
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	1	3	2	1	4
Number without a RTA Review and > 15 Days since Date Received	0	0	1	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	3	2	0	1	0
Rate of submissions not accepted for filing review	75.00%	40.00%	0%	50.00%	0%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	2	4
Number Accepted	1	3	3	1	4
Completed RTF	4	5	2	2	4
Number Not Filed	2	0	0	0	1
Rate of submissions Not Filed	50.00%	0%	0%	0%	25.00%

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	2	4
SI Goal Met	4	5	2	2	4
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	100%	100%	100%

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	2	4
Average number of FDA days to Substantive Interaction	88.50	97.80	122.00	88.50	88.00
20th Percentile FDA days to Substantive Interaction	88	88	100	88	86
40th Percentile FDA days to Substantive Interaction	88	88	115	88	88
60th Percentile FDA days to Substantive Interaction	88	89	129	89	89
80th Percentile FDA days to Substantive Interaction	89	99	144	89	90
Maximum FDA days to Substantive Interaction	90	136	158	90	90

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	4	1	1	4
Average FDA days to MDUFA III decision	180.00	193.50	250.00	177.00	170.25
20th Percentile FDA days to MDUFA III decision	180	124	250	177	162
40th Percentile FDA days to MDUFA III decision	180	154	250	177	168
60th Percentile FDA days to MDUFA III decision	180	174	250	177	176
80th Percentile FDA days to MDUFA III decision	180	252	250	177	179
Maximum FDA days to MDUFA III decision	180	359	250	177	180
Average Industry days to MDUFA III decision	260.00	108.50	36.00	68.00	178.50
20th Percentile Industry days to MDUFA III decision	260	54	36	68	57
40th Percentile Industry days to MDUFA III decision	260	82	36	68	97
60th Percentile Industry days to MDUFA III decision	260	126	36	68	205
80th Percentile Industry days to MDUFA III decision	260	161	36	68	289
Maximum Industry days to MDUFA III decision	260	193	36	68	360
Average Total days to MDUFA III decision	440.00	302.00	286.00	245.00	348.75
20th Percentile Total days to MDUFA III decision	440	267	286	245	236
40th Percentile Total days to MDUFA III decision	440	282	286	245	273
60th Percentile Total days to MDUFA III decision	440	286	286	245	373
80th Percentile Total days to MDUFA III decision	440	330	286	245	451
Maximum Total days to MDUFA III decision	440	392	286	245	517

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	1	1	1	0
Average FDA days to MDUFA III decision	376.00	359.00	206.00	300.00	0
20th Percentile FDA days to MDUFA III decision	313	359	206	300	0
40th Percentile FDA days to MDUFA III decision	314	359	206	300	0
60th Percentile FDA days to MDUFA III decision	352	359	206	300	0
80th Percentile FDA days to MDUFA III decision	427	359	206	300	0
Maximum FDA days to MDUFA III decision	501	359	206	300	0
Average Industry days to MDUFA III decision	180.33	358.00	119.00	110.00	0
20th Percentile Industry days to MDUFA III decision	112	358	119	110	0
40th Percentile Industry days to MDUFA III decision	156	358	119	110	0
60th Percentile Industry days to MDUFA III decision	201	358	119	110	0
80th Percentile Industry days to MDUFA III decision	248	358	119	110	0
Maximum Industry days to MDUFA III decision	295	358	119	110	0
Average Total days to MDUFA III decision	556.33	717.00	325.00	410.00	0
20th Percentile Total days to MDUFA III decision	522	717	325	410	0
40th Percentile Total days to MDUFA III decision	553	717	325	410	0
60th Percentile Total days to MDUFA III decision	577	717	325	410	0
80th Percentile Total days to MDUFA III decision	594	717	325	410	0
Maximum Total days to MDUFA III decision	610	717	325	410	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	4	1	1	4
Number with MDUFA decision	1	4	1	1	4
Number of Withdrawals	0	1	0	0	0
Number of Not Approvable	0	1	0	0	3
Rate of Withdrawals	0%	25.00%	0%	0%	0%
Rate of Not Approvable	0%	25.00%	0%	0%	75.00%

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	1	0
Number with MDUFA decision	3	1	1	1	0
Number of Withdrawals	0	1	1	0	0
Number of Not Approvable	2	0	0	0	0
Rate of Withdrawals	0%	100%	100%	0%	N/A
Rate of Not Approvable	66.67%	0%	0%	0%	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	2	5
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	0	4	4	0	4
Number without a RTA Review and > 15 Days since Date Received	0	0	1	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	2	1	2	1
Rate of submissions not accepted for filing review	N/A	33.33%	16.67%	100%	20.00%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	2	5
Number Accepted	0	4	5	0	4
Completed RTF	0	5	5	2	5
Number Not Filed	0	0	0	0	0
Rate of submissions Not Filed	N/A	0%	0%	0%	0%

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

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

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	2	5
Average number of FDA days to Substantive Interaction	0	88.80	85.60	88.50	88.20
20th Percentile FDA days to Substantive Interaction	0	88	82	88	87
40th Percentile FDA days to Substantive Interaction	0	90	85	88	88
60th Percentile FDA days to Substantive Interaction	0	90	87	89	89
80th Percentile FDA days to Substantive Interaction	0	90	88	89	90
Maximum FDA days to Substantive Interaction	0	90	90	90	90

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

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	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	0	2	0	0	0
MDUFA III Decisions Goal Met	0	2	0	0	0
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	100%	N/A	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	5	2	5
Average FDA days to MDUFA III decision	0	177.33	179.00	179.00	177.80
20th Percentile FDA days to MDUFA III decision	0	175	178	179	177
40th Percentile FDA days to MDUFA III decision	0	178	179	179	179
60th Percentile FDA days to MDUFA III decision	0	179	180	179	179
80th Percentile FDA days to MDUFA III decision	0	180	180	179	180
Maximum FDA days to MDUFA III decision	0	180	180	179	180
Average Industry days to MDUFA III decision	0	49.00	159.80	203.50	35.20
20th Percentile Industry days to MDUFA III decision	0	46	88	110	0
40th Percentile Industry days to MDUFA III decision	0	47	110	172	0
60th Percentile Industry days to MDUFA III decision	0	49	138	235	33
80th Percentile Industry days to MDUFA III decision	0	52	201	297	85
Maximum Industry days to MDUFA III decision	0	55	356	359	93
Average Total days to MDUFA III decision	0	226.33	338.80	382.50	213.00
20th Percentile Total days to MDUFA III decision	0	222	268	289	177
40th Percentile Total days to MDUFA III decision	0	223	290	351	180
60th Percentile Total days to MDUFA III decision	0	226	317	414	213
80th Percentile Total days to MDUFA III decision	0	230	378	476	264
Maximum Total days to MDUFA III decision	0	234	534	538	273

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	0
Average FDA days to MDUFA III decision	0	349.50	0	0	0
20th Percentile FDA days to MDUFA III decision	0	332	0	0	0
40th Percentile FDA days to MDUFA III decision	0	344	0	0	0
60th Percentile FDA days to MDUFA III decision	0	355	0	0	0
80th Percentile FDA days to MDUFA III decision	0	367	0	0	0
Maximum FDA days to MDUFA III decision	0	379	0	0	0
Average Industry days to MDUFA III decision	0	99.00	0	0	0
20th Percentile Industry days to MDUFA III decision	0	52	0	0	0
40th Percentile Industry days to MDUFA III decision	0	83	0	0	0
60th Percentile Industry days to MDUFA III decision	0	115	0	0	0
80th Percentile Industry days to MDUFA III decision	0	146	0	0	0
Maximum Industry days to MDUFA III decision	0	178	0	0	0
Average Total days to MDUFA III decision	0	448.50	0	0	0
20th Percentile Total days to MDUFA III decision	0	419	0	0	0
40th Percentile Total days to MDUFA III decision	0	439	0	0	0
60th Percentile Total days to MDUFA III decision	0	458	0	0	0
80th Percentile Total days to MDUFA III decision	0	478	0	0	0
Maximum Total days to MDUFA III decision	0	498	0	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	2	5
Number with MDUFA decision	0	3	5	2	5
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	1	0	0
Rate of Withdrawals	N/A	0%	0%	0%	0%
Rate of Not Approvable	N/A	0%	20.00%	0%	0%

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	0
Number with MDUFA decision	0	2	0	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	N/A	0%	N/A	N/A	N/A
Rate of Not Approvable	N/A	0%	N/A	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	4	9
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	2	2	8	4	8
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	0	0	0	1
Rate of submissions not accepted for filing review	0%	0%	0%	0%	11.11%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	4	9
Number Accepted	2	2	8	4	8
Completed RTF	2	2	8	4	8
Number Not Filed	0	0	0	0	0
Rate of submissions Not Filed	0%	0%	0%	0%	0%

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	4	8
SI Goal Met	2	2	8	4	7
SI Goal Not Met	0	0	0	0	1
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	100%	100%	87.50%

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	4	8
Average number of FDA days to Substantive Interaction	90.00	88.00	80.25	86.50	83.88
20th Percentile FDA days to Substantive Interaction	90	87	71	85	76
40th Percentile FDA days to Substantive Interaction	90	88	85	85	89
60th Percentile FDA days to Substantive Interaction	90	88	86	86	90
80th Percentile FDA days to Substantive Interaction	90	89	89	88	90
Maximum FDA days to Substantive Interaction	90	89	90	90	91

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	7	4	7
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	2	2	7	4	6
MDUFA III Decisions Goal Met	2	2	7	4	6
PMAs pending MDUFA III Decision	0	0	0	0	1
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

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	7	4	6
Average FDA days to MDUFA III decision	176.50	179.50	177.29	156.25	177.50
20th Percentile FDA days to MDUFA III decision	175	179	176	140	177
40th Percentile FDA days to MDUFA III decision	176	179	176	168	179
60th Percentile FDA days to MDUFA III decision	177	180	178	175	180
80th Percentile FDA days to MDUFA III decision	178	180	179	178	180
Maximum FDA days to MDUFA III decision	179	180	180	179	281
Average Industry days to MDUFA III decision	266.50	119.00	97.57	133.75	49.50
20th Percentile Industry days to MDUFA III decision	186	48	4	16	0
40th Percentile Industry days to MDUFA III decision	240	95	55	70	0
60th Percentile Industry days to MDUFA III decision	293	143	122	201	0
80th Percentile Industry days to MDUFA III decision	347	190	139	252	82
Maximum Industry days to MDUFA III decision	400	238	283	264	215
Average Total days to MDUFA III decision	443.00	298.50	274.86	290.00	227.00
20th Percentile Total days to MDUFA III decision	361	227	183	156	177
40th Percentile Total days to MDUFA III decision	416	275	232	238	180
60th Percentile Total days to MDUFA III decision	470	322	301	376	180
80th Percentile Total days to MDUFA III decision	525	370	314	430	261
Maximum Total days to MDUFA III decision	579	418	459	443	496

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	1	0	1
Average FDA days to MDUFA III decision	0	0	299.00	0	281.00
20th Percentile FDA days to MDUFA III decision	0	0	299	0	281
40th Percentile FDA days to MDUFA III decision	0	0	299	0	281
60th Percentile FDA days to MDUFA III decision	0	0	299	0	281
80th Percentile FDA days to MDUFA III decision	0	0	299	0	281
Maximum FDA days to MDUFA III decision	0	0	299	0	281
Average Industry days to MDUFA III decision	0	0	153.00	0	322.00
20th Percentile Industry days to MDUFA III decision	0	0	153	0	322
40th Percentile Industry days to MDUFA III decision	0	0	153	0	322
60th Percentile Industry days to MDUFA III decision	0	0	153	0	322
80th Percentile Industry days to MDUFA III decision	0	0	153	0	322
Maximum Industry days to MDUFA III decision	0	0	153	0	322
Average Total days to MDUFA III decision	0	0	452.00	0	603.00
20th Percentile Total days to MDUFA III decision	0	0	452	0	603
40th Percentile Total days to MDUFA III decision	0	0	452	0	603
60th Percentile Total days to MDUFA III decision	0	0	452	0	603
80th Percentile Total days to MDUFA III decision	0	0	452	0	603
Maximum Total days to MDUFA III decision	0	0	452	0	603

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	7	4	7
Number with MDUFA decision	2	2	7	4	6
Number of Withdrawals	0	0	0	0	2
Number of Not Approvable	0	0	1	1	0
Rate of Withdrawals	0%	0%	0%	0%	33.33%
Rate of Not Approvable	0%	0%	14.29%	25.00%	0%

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	1	0	1
Number with MDUFA decision	0	0	1	0	1
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	N/A	N/A	0%	N/A	0%
Rate of Not Approvable	N/A	N/A	0%	N/A	0%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	0	0	0	0	0
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	0	0	0	0
Rate of submissions not accepted for filing review	N/A	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 FY 2013 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	0
Number Accepted	0	0	0	0	0
Completed RTF	0	0	0	0	0
Number Not Filed	0	0	0	0	0
Rate of submissions Not Filed	N/A	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	0
SI Goal Met	0	0	0	0	0
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	N/A	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	0
Average number of FDA days to Substantive Interaction	0	0	0	0	0
20th Percentile FDA days to Substantive Interaction	0	0	0	0	0
40th Percentile FDA days to Substantive Interaction	0	0	0	0	0
60th Percentile FDA days to Substantive Interaction	0	0	0	0	0
80th Percentile FDA days to Substantive Interaction	0	0	0	0	0
Maximum FDA days to Substantive Interaction	0	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	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions Goal Met	0	0	0	0	0
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	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	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions Goal Met	0	0	0	0	0
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	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	0
Average FDA days to MDUFA III decision	0	0	0	0	0
20th Percentile FDA days to MDUFA III decision	0	0	0	0	0
40th Percentile FDA days to MDUFA III decision	0	0	0	0	0
60th Percentile FDA days to MDUFA III decision	0	0	0	0	0
80th Percentile FDA days to MDUFA III decision	0	0	0	0	0
Maximum FDA days to MDUFA III decision	0	0	0	0	0
Average Industry days to MDUFA III decision	0	0	0	0	0
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	0	0
60th Percentile Industry days to MDUFA III decision	0	0	0	0	0
80th Percentile Industry days to MDUFA III decision	0	0	0	0	0
Maximum Industry days to MDUFA III decision	0	0	0	0	0
Average Total days to MDUFA III decision	0	0	0	0	0
20th Percentile Total days to MDUFA III decision	0	0	0	0	0
40th Percentile Total days to MDUFA III decision	0	0	0	0	0
60th Percentile Total days to MDUFA III decision	0	0	0	0	0
80th Percentile Total days to MDUFA III decision	0	0	0	0	0
Maximum Total days to MDUFA III decision	0	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	0
Average FDA days to MDUFA III decision	0	0	0	0	0
20th Percentile FDA days to MDUFA III decision	0	0	0	0	0
40th Percentile FDA days to MDUFA III decision	0	0	0	0	0
60th Percentile FDA days to MDUFA III decision	0	0	0	0	0
80th Percentile FDA days to MDUFA III decision	0	0	0	0	0
Maximum FDA days to MDUFA III decision	0	0	0	0	0
Average Industry days to MDUFA III decision	0	0	0	0	0
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	0	0
60th Percentile Industry days to MDUFA III decision	0	0	0	0	0
80th Percentile Industry days to MDUFA III decision	0	0	0	0	0
Maximum Industry days to MDUFA III decision	0	0	0	0	0
Average Total days to MDUFA III decision	0	0	0	0	0
20th Percentile Total days to MDUFA III decision	0	0	0	0	0
40th Percentile Total days to MDUFA III decision	0	0	0	0	0
60th Percentile Total days to MDUFA III decision	0	0	0	0	0
80th Percentile Total days to MDUFA III decision	0	0	0	0	0
Maximum Total days to MDUFA III decision	0	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	0
Number with MDUFA decision	0	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	N/A	N/A	N/A	N/A	N/A
Rate of Not Approvable	N/A	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	0
Number with MDUFA decision	0	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	N/A	N/A	N/A	N/A	N/A
Rate of Not Approvable	N/A	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	8	3
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	2	1	3	8	2
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	0	0	0	1
Rate of submissions not accepted for filing review	0%	0%	0%	0%	33.33%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	8	3
Number Accepted	2	1	3	8	2
Completed RTF	2	1	3	8	3
Number Not Filed	0	0	0	0	0
Rate of submissions Not Filed	0%	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	8	3
SI Goal Met	2	1	2	8	3
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	66.67%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2	1	3	8	3
Average number of FDA days to Substantive Interaction	86.00	83.00	88.67	81.00	84.67
20th Percentile FDA days to Substantive Interaction	86	83	87	83	82
40th Percentile FDA days to Substantive Interaction	86	83	88	85	85
60th Percentile FDA days to Substantive Interaction	86	83	89	87	87
80th Percentile FDA days to Substantive Interaction	86	83	90	88	88
Maximum FDA days to Substantive Interaction	86	83	91	90	88

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	8	3
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	1	1	3	8	2
MDUFA III Decisions Goal Met	1	1	3	8	2
PMAs pending MDUFA III Decision	0	0	0	0	1
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	1	0	0	0	0
MDUFA III Decisions Goal Met	1	0	0	0	0
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	N/A	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	8	2
Average FDA days to MDUFA III decision	177.00	179.00	167.33	175.50	173.00
20th Percentile FDA days to MDUFA III decision	177	179	163	174	171
40th Percentile FDA days to MDUFA III decision	177	179	168	176	172
60th Percentile FDA days to MDUFA III decision	177	179	171	177	174
80th Percentile FDA days to MDUFA III decision	177	179	172	178	175
Maximum FDA days to MDUFA III decision	177	179	173	180	176
Average Industry days to MDUFA III decision	107.00	0	26.00	97.25	28.00
20th Percentile Industry days to MDUFA III decision	107	0	0	14	11
40th Percentile Industry days to MDUFA III decision	107	0	0	42	22
60th Percentile Industry days to MDUFA III decision	107	0	16	87	34
80th Percentile Industry days to MDUFA III decision	107	0	47	134	45
Maximum Industry days to MDUFA III decision	107	0	78	357	56
Average Total days to MDUFA III decision	284.00	179.00	193.33	272.75	201.00
20th Percentile Total days to MDUFA III decision	284	179	171	191	186
40th Percentile Total days to MDUFA III decision	284	179	172	218	196
60th Percentile Total days to MDUFA III decision	284	179	186	263	206
80th Percentile Total days to MDUFA III decision	284	179	211	305	216
Maximum Total days to MDUFA III decision	284	179	237	537	226

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	0
Average FDA days to MDUFA III decision	297.00	0	0	0	0
20th Percentile FDA days to MDUFA III decision	297	0	0	0	0
40th Percentile FDA days to MDUFA III decision	297	0	0	0	0
60th Percentile FDA days to MDUFA III decision	297	0	0	0	0
80th Percentile FDA days to MDUFA III decision	297	0	0	0	0
Maximum FDA days to MDUFA III decision	297	0	0	0	0
Average Industry days to MDUFA III decision	0	0	0	0	0
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	0	0
60th Percentile Industry days to MDUFA III decision	0	0	0	0	0
80th Percentile Industry days to MDUFA III decision	0	0	0	0	0
Maximum Industry days to MDUFA III decision	0	0	0	0	0
Average Total days to MDUFA III decision	297.00	0	0	0	0
20th Percentile Total days to MDUFA III decision	297	0	0	0	0
40th Percentile Total days to MDUFA III decision	297	0	0	0	0
60th Percentile Total days to MDUFA III decision	297	0	0	0	0
80th Percentile Total days to MDUFA III decision	297	0	0	0	0
Maximum Total days to MDUFA III decision	297	0	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	8	3
Number with MDUFA decision	1	1	3	8	2
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	1	0
Rate of Withdrawals	0%	0%	0%	0%	0%
Rate of Not Approvable	0%	0%	0%	12.50%	0%

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	0
Number with MDUFA decision	1	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	0%	N/A	N/A	N/A	N/A
Rate of Not Approvable	0%	N/A	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	11	11
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	2	1	6	11	10
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	0	0	0	1
Rate of submissions not accepted for filing review	0%	0%	0%	0%	9.09%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	11	11
Number Accepted	4	1	6	11	10
Completed RTF	4	1	6	10	10
Number Not Filed	0	0	0	0	0
Rate of submissions Not Filed	0%	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	10	10
SI Goal Met	4	1	6	9	10
SI Goal Not Met	0	0	0	1	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	100%	90.00%	100%

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	10	10
Average number of FDA days to Substantive Interaction	95.25	86.00	86.83	82.80	95.20
20th Percentile FDA days to Substantive Interaction	90	86	90	79	88
40th Percentile FDA days to Substantive Interaction	90	86	90	86	89
60th Percentile FDA days to Substantive Interaction	90	86	90	88	90
80th Percentile FDA days to Substantive Interaction	99	86	90	90	90
Maximum FDA days to Substantive Interaction	112	86	90	94	155

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	10	10
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	2	1	6	10	10
MDUFA III Decisions Goal Met	2	1	6	10	10
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	2	1	6	10	10
Average FDA days to MDUFA III decision	107.50	86.00	128.00	122.20	159.30
20th Percentile FDA days to MDUFA III decision	102	86	95	97	138
40th Percentile FDA days to MDUFA III decision	106	86	114	115	154
60th Percentile FDA days to MDUFA III decision	109	86	133	128	167
80th Percentile FDA days to MDUFA III decision	113	86	164	137	178
Maximum FDA days to MDUFA III decision	116	86	171	177	245
Average Industry days to MDUFA III decision	94.50	0	40.67	110.30	49.70
20th Percentile Industry days to MDUFA III decision	80	0	0	49	0
40th Percentile Industry days to MDUFA III decision	90	0	39	88	22
60th Percentile Industry days to MDUFA III decision	99	0	58	127	37
80th Percentile Industry days to MDUFA III decision	109	0	63	148	89
Maximum Industry days to MDUFA III decision	118	0	84	267	170
Average Total days to MDUFA III decision	202.00	86.00	168.67	232.50	209.00
20th Percentile Total days to MDUFA III decision	193	86	164	170	179
40th Percentile Total days to MDUFA III decision	199	86	172	197	188
60th Percentile Total days to MDUFA III decision	205	86	179	251	213
80th Percentile Total days to MDUFA III decision	211	86	196	302	250
Maximum Total days to MDUFA III decision	217	86	210	357	260

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	0
Average FDA days to MDUFA III decision	320.00	0	0	0	0
20th Percentile FDA days to MDUFA III decision	317	0	0	0	0
40th Percentile FDA days to MDUFA III decision	319	0	0	0	0
60th Percentile FDA days to MDUFA III decision	321	0	0	0	0
80th Percentile FDA days to MDUFA III decision	323	0	0	0	0
Maximum FDA days to MDUFA III decision	325	0	0	0	0
Average Industry days to MDUFA III decision	147.00	0	0	0	0
20th Percentile Industry days to MDUFA III decision	122	0	0	0	0
40th Percentile Industry days to MDUFA III decision	139	0	0	0	0
60th Percentile Industry days to MDUFA III decision	155	0	0	0	0
80th Percentile Industry days to MDUFA III decision	172	0	0	0	0
Maximum Industry days to MDUFA III decision	189	0	0	0	0
Average Total days to MDUFA III decision	467.00	0	0	0	0
20th Percentile Total days to MDUFA III decision	445	0	0	0	0
40th Percentile Total days to MDUFA III decision	460	0	0	0	0
60th Percentile Total days to MDUFA III decision	474	0	0	0	0
80th Percentile Total days to MDUFA III decision	489	0	0	0	0
Maximum Total days to MDUFA III decision	504	0	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	10	10
Number with MDUFA decision	2	1	6	10	10
Number of Withdrawals	0	0	0	1	2
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	0%	0%	0%	10.00%	20.00%
Rate of Not Approvable	0%	0%	0%	0%	0%

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	0
Number with MDUFA decision	2	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	1	0	0	0	0
Rate of Withdrawals	0%	N/A	N/A	N/A	N/A
Rate of Not Approvable	50.00%	N/A	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	3	2
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	1	1	0	2	2
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	1	0	1	0
Rate of submissions not accepted for filing review	0%	50.00%	N/A	33.33%	0%

*RTA was not in place 1st quarter, thus the rate submissions not accepted for filing review for FY 2013 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	3	2
Number Accepted	2	1	0	2	2
Completed RTF	2	2	0	3	2
Number Not Filed	0	0	0	0	2
Rate of submissions Not Filed	0%	0%	N/A	0%	100%

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	3	1
SI Goal Met	2	2	0	3	1
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	N/A	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2	2	0	3	1
Average number of FDA days to Substantive Interaction	77.50	86.50	0	79.33	90.00
20th Percentile FDA days to Substantive Interaction	70	86	0	74	90
40th Percentile FDA days to Substantive Interaction	75	86	0	81	90
60th Percentile FDA days to Substantive Interaction	80	87	0	85	90
80th Percentile FDA days to Substantive Interaction	85	87	0	86	90
Maximum FDA days to Substantive Interaction	90	88	0	87	90

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

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0	0	0	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	1	0	0	0	0
MDUFA III Decisions Goal Met	1	0	0	0	0
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	N/A	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	3	0
Average FDA days to MDUFA III decision	167.00	178.00	0	162.33	0
20th Percentile FDA days to MDUFA III decision	167	177	0	156	0
40th Percentile FDA days to MDUFA III decision	167	178	0	159	0
60th Percentile FDA days to MDUFA III decision	167	178	0	163	0
80th Percentile FDA days to MDUFA III decision	167	179	0	168	0
Maximum FDA days to MDUFA III decision	167	179	0	173	0
Average Industry days to MDUFA III decision	81.00	113.00	0	69.67	0
20th Percentile Industry days to MDUFA III decision	81	109	0	12	0
40th Percentile Industry days to MDUFA III decision	81	112	0	25	0
60th Percentile Industry days to MDUFA III decision	81	114	0	60	0
80th Percentile Industry days to MDUFA III decision	81	117	0	119	0
Maximum Industry days to MDUFA III decision	81	120	0	178	0
Average Total days to MDUFA III decision	248.00	291.00	0	232.00	0
20th Percentile Total days to MDUFA III decision	248	286	0	170	0
40th Percentile Total days to MDUFA III decision	248	289	0	179	0
60th Percentile Total days to MDUFA III decision	248	293	0	217	0
80th Percentile Total days to MDUFA III decision	248	296	0	284	0
Maximum Total days to MDUFA III decision	248	299	0	351	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	0
Average FDA days to MDUFA III decision	206.00	0	0	0	0
20th Percentile FDA days to MDUFA III decision	206	0	0	0	0
40th Percentile FDA days to MDUFA III decision	206	0	0	0	0
60th Percentile FDA days to MDUFA III decision	206	0	0	0	0
80th Percentile FDA days to MDUFA III decision	206	0	0	0	0
Maximum FDA days to MDUFA III decision	206	0	0	0	0
Average Industry days to MDUFA III decision	0.00	0	0	0	0
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	0	0
60th Percentile Industry days to MDUFA III decision	0	0	0	0	0
80th Percentile Industry days to MDUFA III decision	0	0	0	0	0
Maximum Industry days to MDUFA III decision	0	0	0	0	0
Average Total days to MDUFA III decision	206.00	0	0	0	0
20th Percentile Total days to MDUFA III decision	206	0	0	0	0
40th Percentile Total days to MDUFA III decision	206	0	0	0	0
60th Percentile Total days to MDUFA III decision	206	0	0	0	0
80th Percentile Total days to MDUFA III decision	206	0	0	0	0
Maximum Total days to MDUFA III decision	206	0	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	3	1
Number with MDUFA decision	1	2	0	3	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	1	0	0	1	0
Rate of Withdrawals	0%	0%	N/A	0%	N/A
Rate of Not Approvable	100%	0%	N/A	33.33%	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	0
Number with MDUFA decision	1	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	0%	N/A	N/A	N/A	N/A
Rate of Not Approvable	0%	N/A	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

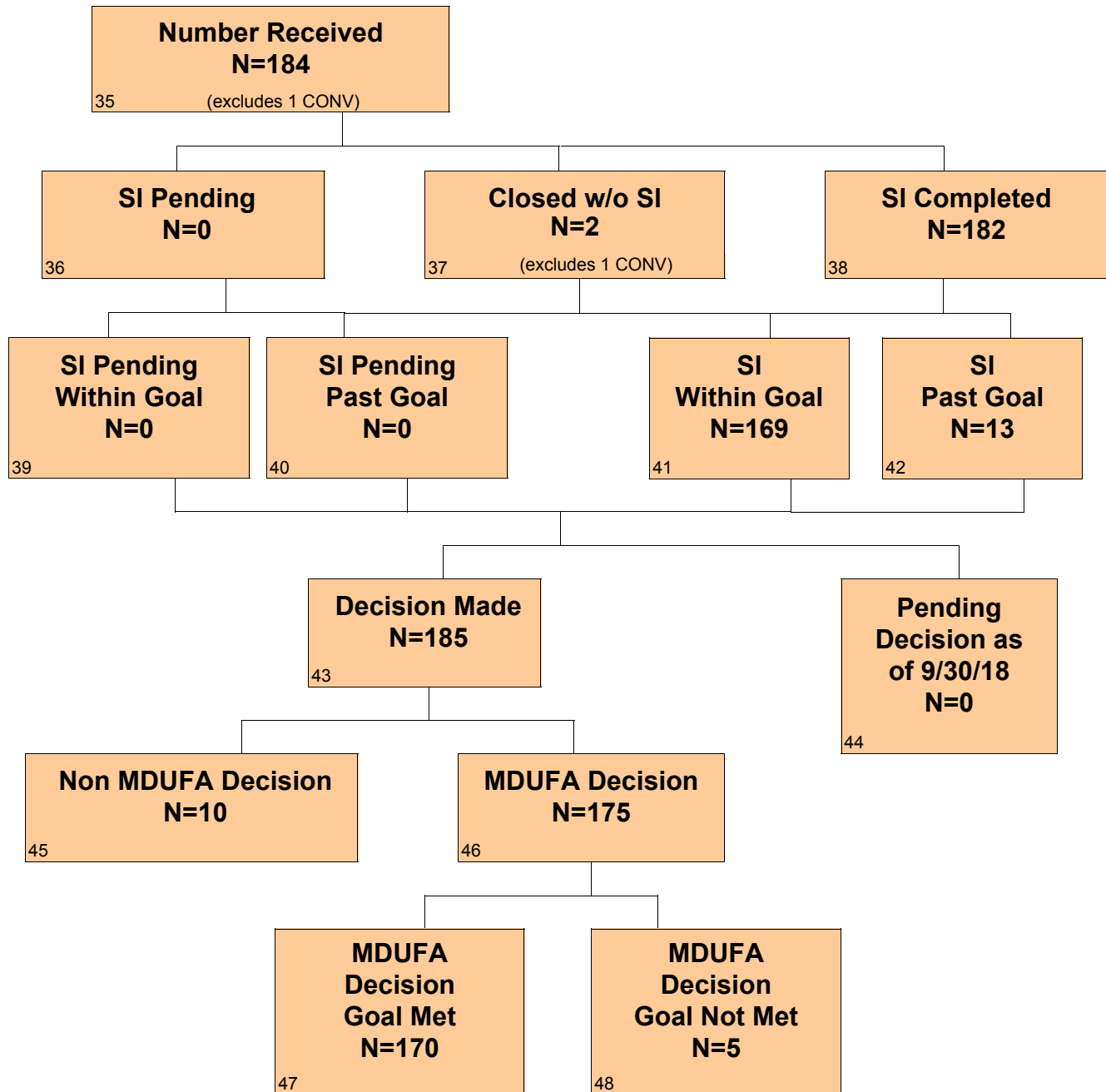
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	0	0	0	0

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

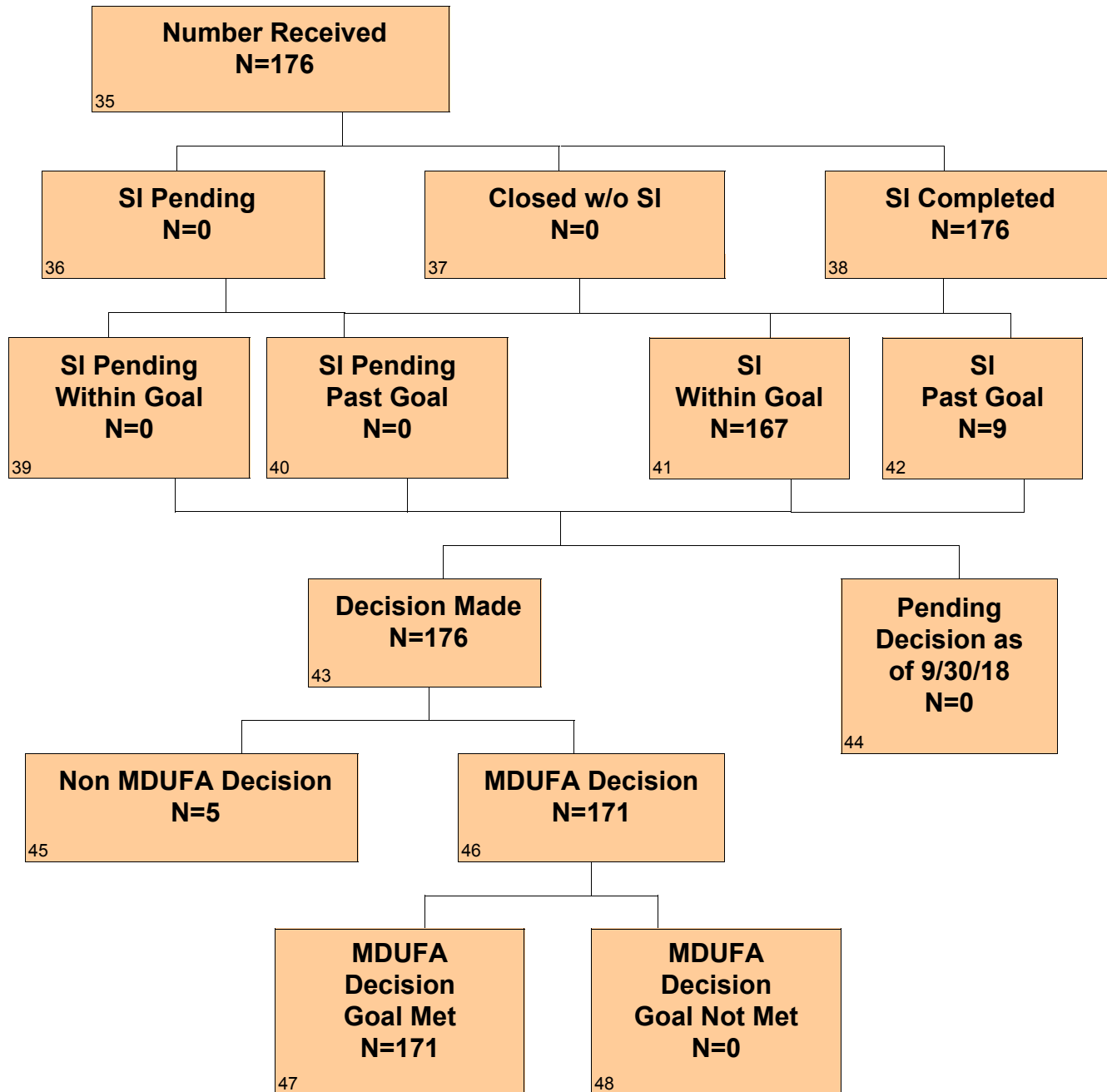
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	0	0	0	0

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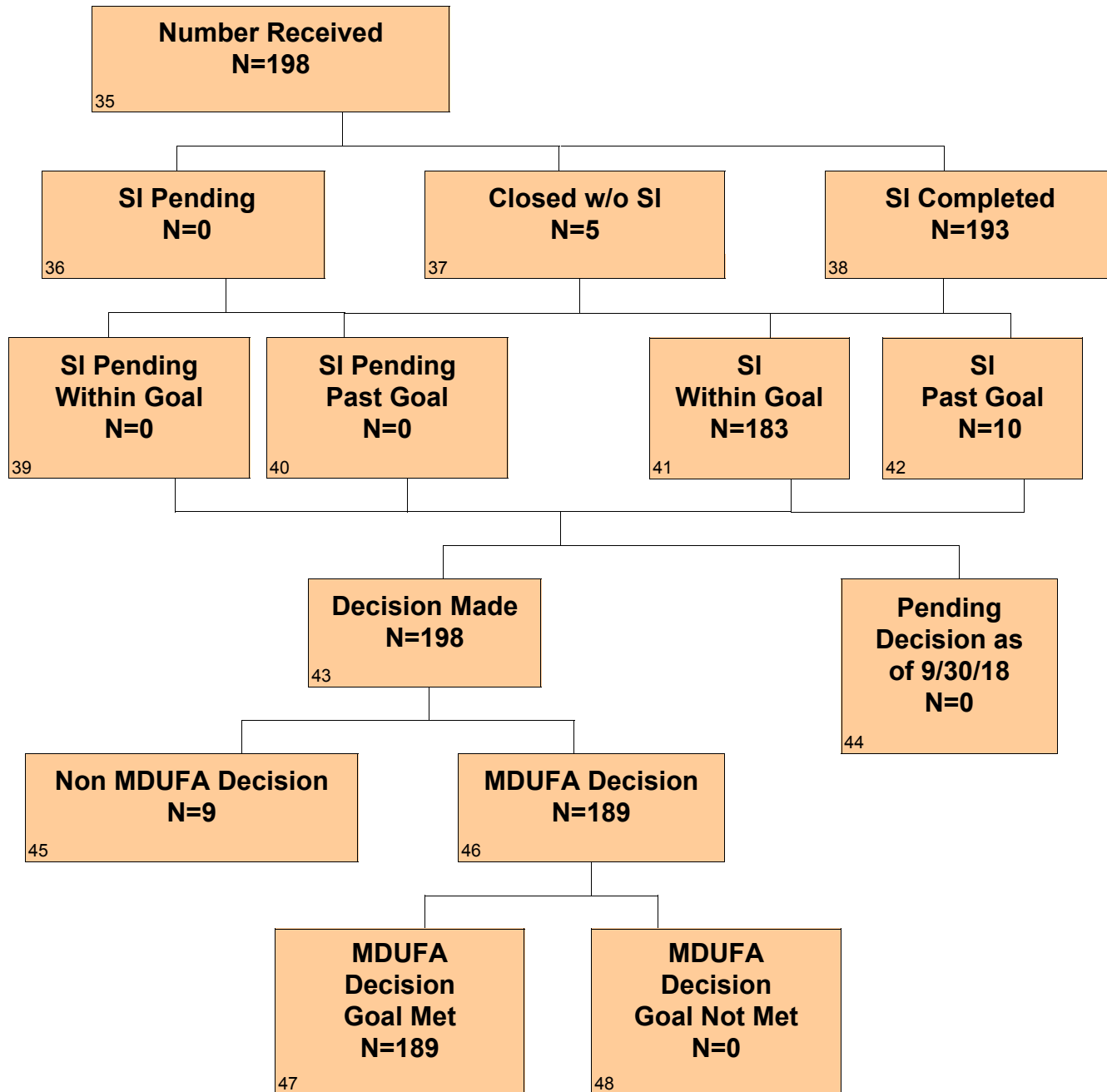
CDRH PMA 180 Day Supplements - FY 2013 As of 9/30/18



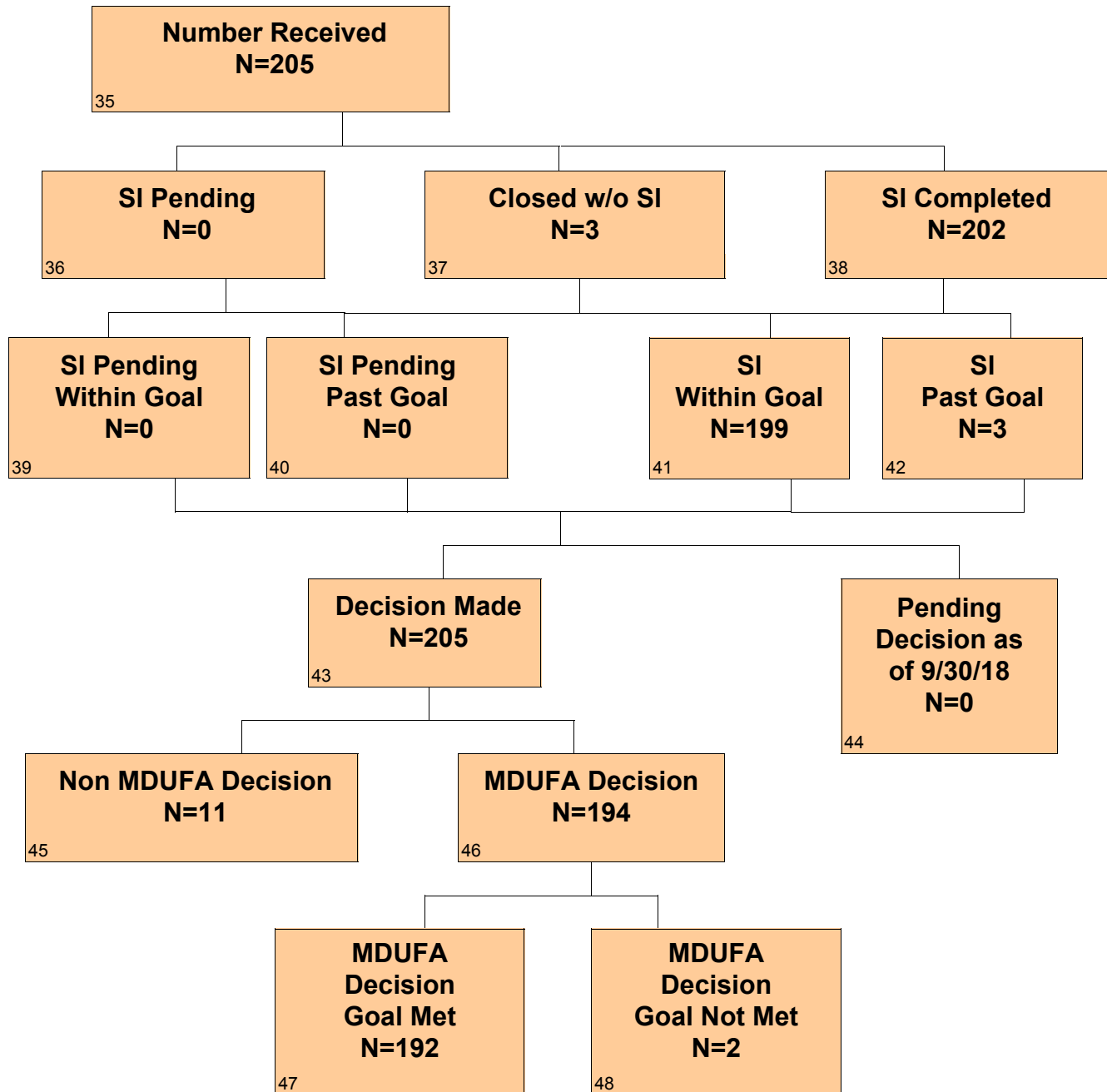
CDRH PMA 180 Day Supplements - FY 2014 As of 9/30/18



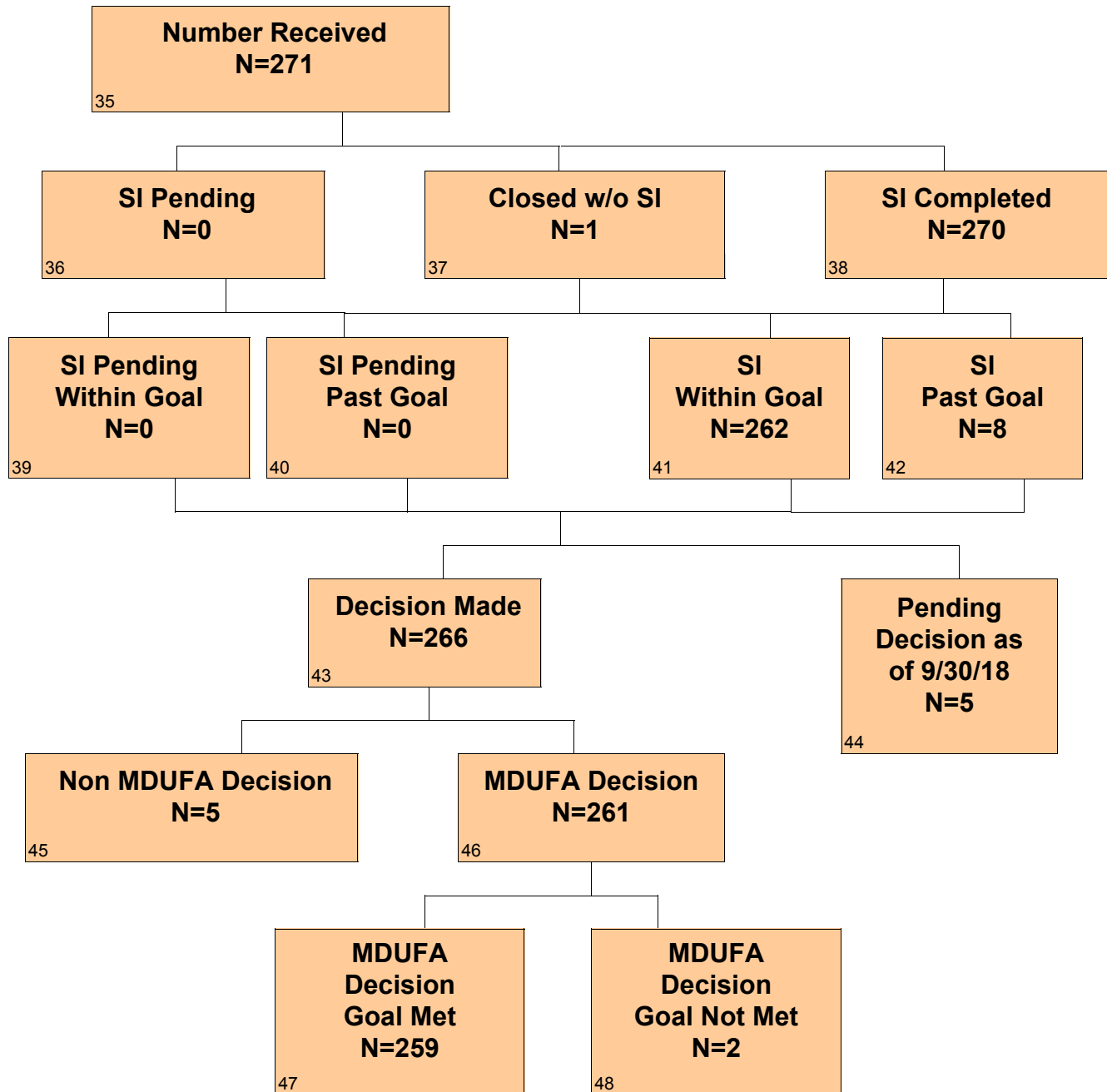
CDRH PMA 180 Day Supplements - FY 2015 As of 9/30/18



CDRH PMA 180 Day Supplements - FY 2016 As of 9/30/18



CDRH PMA 180 Day Supplements - FY 2017 As of 9/30/18



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	185	176	198	205	271
SI Goal Met	169	167	183	199	262
SI Goal Not Met	13	9	10	3	8
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	3	0	5	3	1
Current SI Performance Percent Goal Met	92.86%	94.89%	94.82%	98.51%	97.04%

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	185	176	198	205	271
Non-MDUFA III Decisions	10	5	9	11	5
MDUFA III Decisions	175	171	189	194	261
MDUFA III Decisions Goal Met	170	171	189	192	259
Supplements pending MDUFA III Decision	0	0	0	0	5
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	97.14%	100%	100%	98.97%	99.23%

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	185	176	198	205	271
Number with MDUFA decision	175	171	189	194	261
Number of Not Approvable	11	5	11	1	9
Rate of Not Approvable	6.29%	2.92%	5.82%	0.52%	3.45%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	5	0	0	2	2
Mean FDA days for submissions that missed goal	240	0	0	181	195
Mean Industry days for submissions that missed goal	231	0	0	0	2

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	164	163	164	182	220
SI Goal Met	148	154	150	176	211
SI Goal Not Met	13	9	9	3	8
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	3	0	5	3	1
Current SI Performance Percent Goal Met	91.93%	94.48%	94.34%	98.32%	96.35%

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	164	163	164	182	220
Non-MDUFA III Decisions	9	4	7	10	4
MDUFA III Decisions	155	159	157	172	211
MDUFA III Decisions Goal Met	150	159	157	170	210
Supplements pending MDUFA III Decision	0	0	0	0	5
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	96.77%	100%	100%	98.84%	99.53%

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	164	163	164	182	220
Number with MDUFA decision	155	159	157	172	211
Number of Not Approvable	11	5	7	1	6
Rate of Not Approvable	7.10%	3.14%	4.46%	0.58%	2.84%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	5	0	0	2	1
Mean FDA days for submissions that missed goal	240	0	0	181	199
Mean Industry days for submissions that missed goal	231	0	0	0	4

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	21	13	34	23	51
SI Goal Met	21	13	33	23	51
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	97.06%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	21	13	34	23	51
Non-MDUFA III Decisions	1	1	2	1	1
MDUFA III Decisions	20	12	32	22	50
MDUFA III Decisions Goal Met	20	12	32	22	49
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	98.00%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	21	13	34	23	52
Number with MDUFA decision	20	12	32	22	50
Number of Not Approvable	0	0	4	0	3
Rate of Not Approvable	0%	0%	12.50%	0%	6.00%

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	1
Mean FDA days for submissions that missed goal	0	0	0	0	190
Mean Industry days for submissions that missed goal	0	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	7	12
SI Goal Met	8	7	6	5	7
SI Goal Not Met	2	2	1	1	5
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	80.00%	77.78%	85.71%	83.33%	58.33%

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	7	12
Non-MDUFA III Decisions	2	1	0	1	0
MDUFA III Decisions	8	8	7	6	11
MDUFA III Decisions Goal Met	6	8	7	6	11
Supplements pending MDUFA III Decision	0	0	0	0	1
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	75.00%	100%	100%	100%	100%

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	7	12
Number with MDUFA decision	8	8	7	6	11
Number of Not Approvable	1	2	1	0	2
Rate of Not Approvable	12.50%	25.00%	14.29%	0%	18.18%

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	0
Mean FDA days for submissions that missed goal	197	0	0	0	0
Mean Industry days for submissions that missed goal	313	0	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	117	94	104	116	141
SI Goal Met	108	93	97	114	137
SI Goal Not Met	6	1	2	2	3
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	3	0	5	0	1
Current SI Performance Percent Goal Met	94.74%	98.94%	97.98%	98.28%	97.86%

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	117	94	104	116	141
Non-MDUFA III Decisions	4	1	6	5	3
MDUFA III Decisions	113	93	98	111	138
MDUFA III Decisions Goal Met	112	93	98	111	138
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	99.12%	100%	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	117	94	104	116	141
Number with MDUFA decision	113	93	98	111	138
Number of Not Approvable	6	0	5	1	3
Rate of Not Approvable	5.31%	0%	5.10%	0.90%	2.17%

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	0
Mean FDA days for submissions that missed goal	182	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	7	13	14	17	20
SI Goal Met	6	13	13	17	20
SI Goal Not Met	1	0	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	85.71%	100%	92.86%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	7	13	14	17	20
Non-MDUFA III Decisions	2	0	0	1	0
MDUFA III Decisions	5	13	14	16	19
MDUFA III Decisions Goal Met	5	13	14	16	19
Supplements pending MDUFA III Decision	0	0	0	0	1
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	13	14	17	20
Number with MDUFA decision	5	13	14	16	19
Number of Not Approvable	1	0	0	0	0
Rate of Not Approvable	20.00%	0%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	3	4	6	8	7
SI Goal Met	3	2	5	7	7
SI Goal Not Met	0	2	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	100%	50.00%	83.33%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	3	4	6	8	7
Non-MDUFA III Decisions	0	0	0	1	0
MDUFA III Decisions	3	4	6	7	7
MDUFA III Decisions Goal Met	3	4	6	7	7
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	4	6	8	7
Number with MDUFA decision	3	4	6	7	7
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0%	0%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	18	23
SI Goal Met	11	24	17	17	23
SI Goal Not Met	1	0	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	91.67%	100%	94.44%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	12	24	18	18	23
Non-MDUFA III Decisions	0	2	0	2	0
MDUFA III Decisions	12	22	18	16	22
MDUFA III Decisions Goal Met	12	22	18	14	22
Supplements pending MDUFA III Decision	0	0	0	0	1
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	87.50%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	12	24	18	18	23
Number with MDUFA decision	12	22	18	16	22
Number of Not Approvable	1	1	0	0	1
Rate of Not Approvable	8.33%	4.55%	0%	0%	4.55%

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	2	0
Mean FDA days for submissions that missed goal	0	0	0	181	0
Mean Industry days for submissions that missed goal	0	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	11	8
SI Goal Met	9	7	8	11	8
SI Goal Not Met	1	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	90.00%	100%	100%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	10	7	8	11	8
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	10	7	8	11	7
MDUFA III Decisions Goal Met	10	7	8	11	6
Supplements pending MDUFA III Decision	0	0	0	0	1
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	85.71%

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	11	8
Number with MDUFA decision	10	7	8	11	7
Number of Not Approvable	1	1	0	0	0
Rate of Not Approvable	10.00%	14.29%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	1
Mean FDA days for submissions that missed goal	0	0	0	0	199
Mean Industry days for submissions that missed goal	0	0	0	0	4

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	5	12	7	5	9
SI Goal Met	3	8	4	5	9
SI Goal Not Met	2	4	3	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	60.00%	66.67%	57.14%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	5	12	7	5	9
Non-MDUFA III Decisions	1	0	1	0	1
MDUFA III Decisions	4	12	6	5	7
MDUFA III Decisions Goal Met	2	12	6	5	7
Supplements pending MDUFA III Decision	0	0	0	0	1
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	50.00%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	12	7	5	9
Number with MDUFA decision	4	12	6	5	7
Number of Not Approvable	1	1	1	0	0
Rate of Not Approvable	25.00%	8.33%	16.67%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0	0	0
Mean FDA days for submissions that missed goal	312	0	0	0	0
Mean Industry days for submissions that missed goal	266	0	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	3	6
SI Goal Met	3	3	3	3	6
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	75.00%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	3	3	4	3	6
Non-MDUFA III Decisions	0	0	0	1	0
MDUFA III Decisions	3	3	4	2	6
MDUFA III Decisions Goal Met	3	3	4	2	6
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	3	4	3	7
Number with MDUFA decision	3	3	4	2	6
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0%	0%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	5
SI Goal Met	1	1	3	2	5
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	100%	100%	100%

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

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

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	5
Number with MDUFA decision	1	0	3	2	5
Number of Not Approvable	0	0	2	0	1
Rate of Not Approvable	0%	N/A	66.67%	0%	20.00%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	7	23
SI Goal Met	7	4	14	7	23
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	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	7	23
Non-MDUFA III Decisions	1	0	1	0	0
MDUFA III Decisions	6	4	13	7	23
MDUFA III Decisions Goal Met	6	4	13	7	23
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	4	14	7	23
Number with MDUFA decision	6	4	13	7	23
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0%	0%	0%	0%	0%

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

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

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	5	4	9	4	15
SI Goal Met	5	4	9	4	15
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	5	4	9	4	15
Non-MDUFA III Decisions	0	0	1	0	1
MDUFA III Decisions	5	4	8	4	14
MDUFA III Decisions Goal Met	5	4	8	4	13
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	92.86%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	4	9	4	15
Number with MDUFA decision	5	4	8	4	14
Number of Not Approvable	0	0	0	0	2
Rate of Not Approvable	0%	0%	0%	0%	14.29%

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	1
Mean FDA days for submissions that missed goal	0	0	0	0	190
Mean Industry days for submissions that missed goal	0	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	7	2
SI Goal Met	5	1	4	7	2
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100%	100%	100%	100%	100%

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

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

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

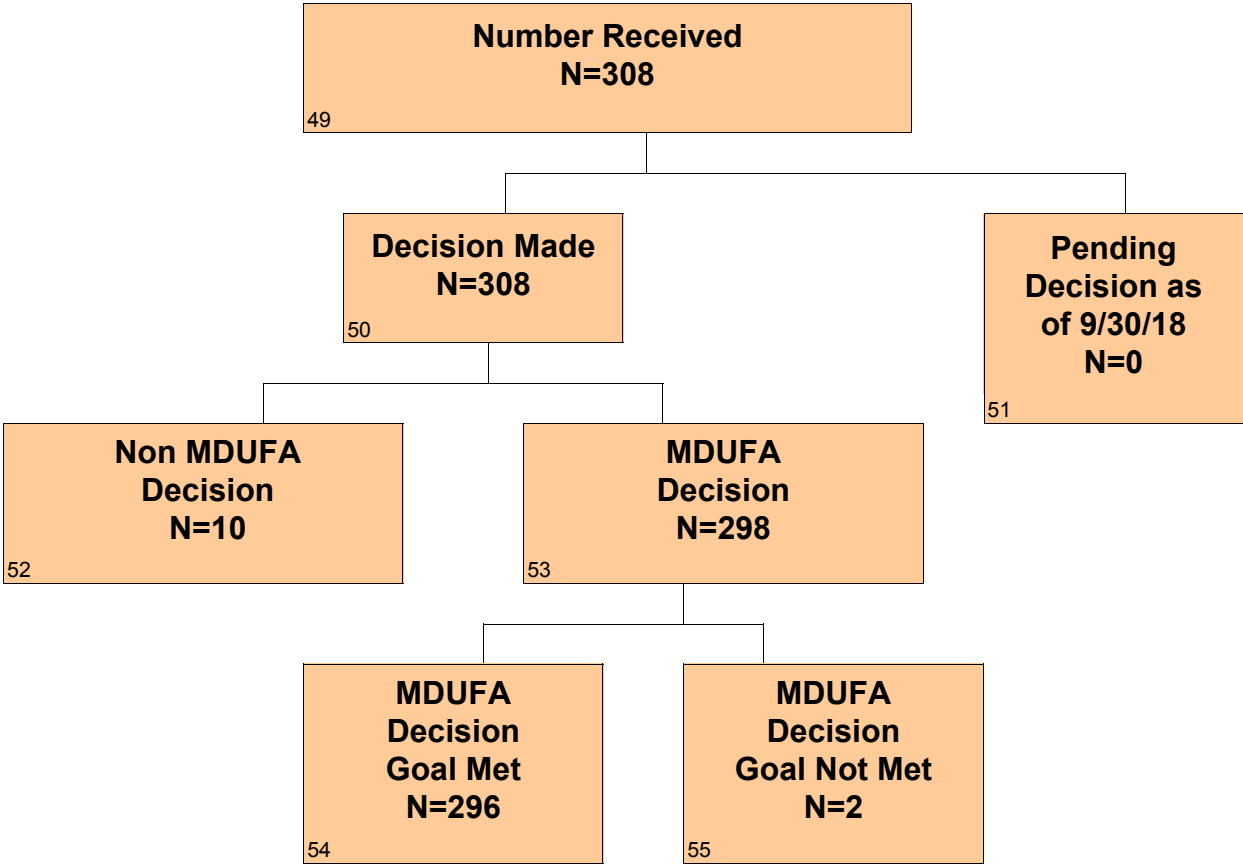
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1	4	7	2
Number with MDUFA decision	5	1	4	7	2
Number of Not Approvable	0	0	2	0	0
Rate of Not Approvable	0%	0%	50.00%	0%	0%

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

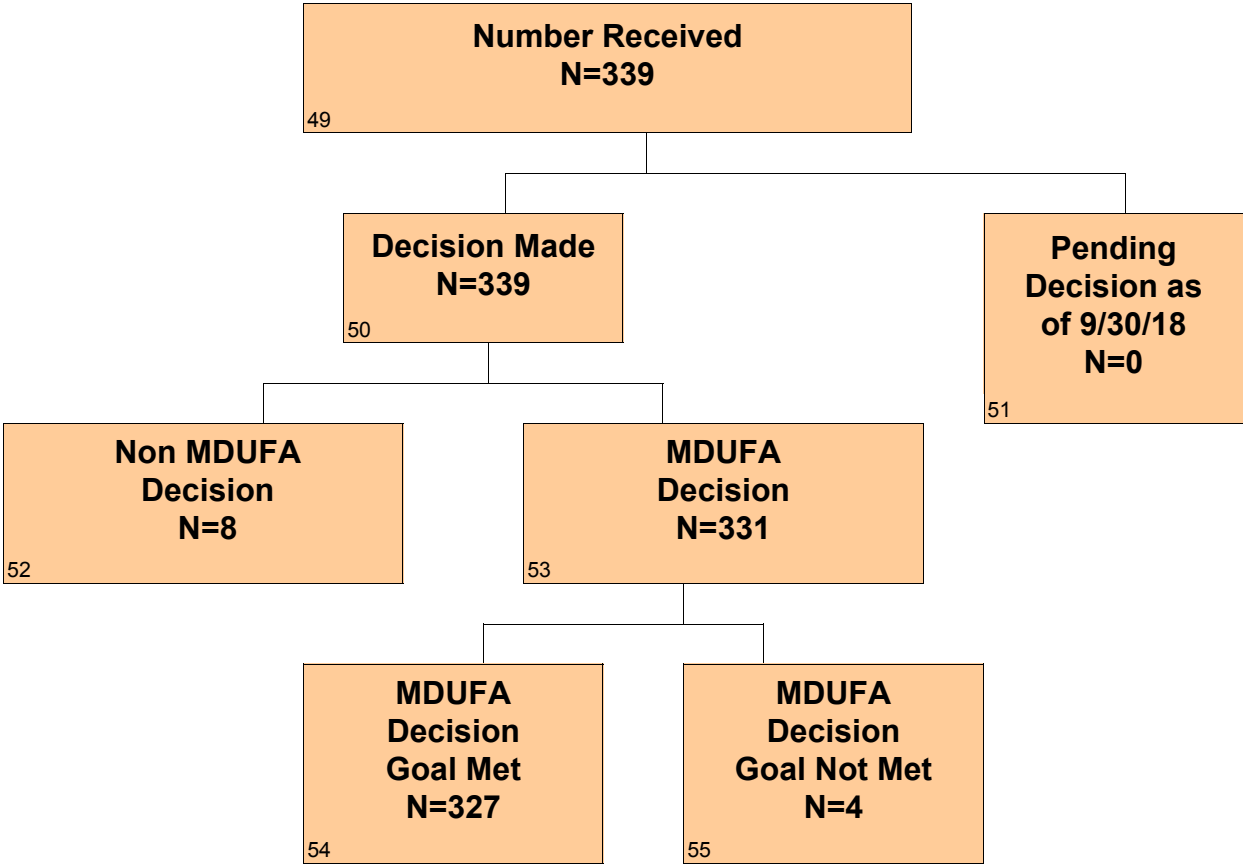
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	0	0	0	0

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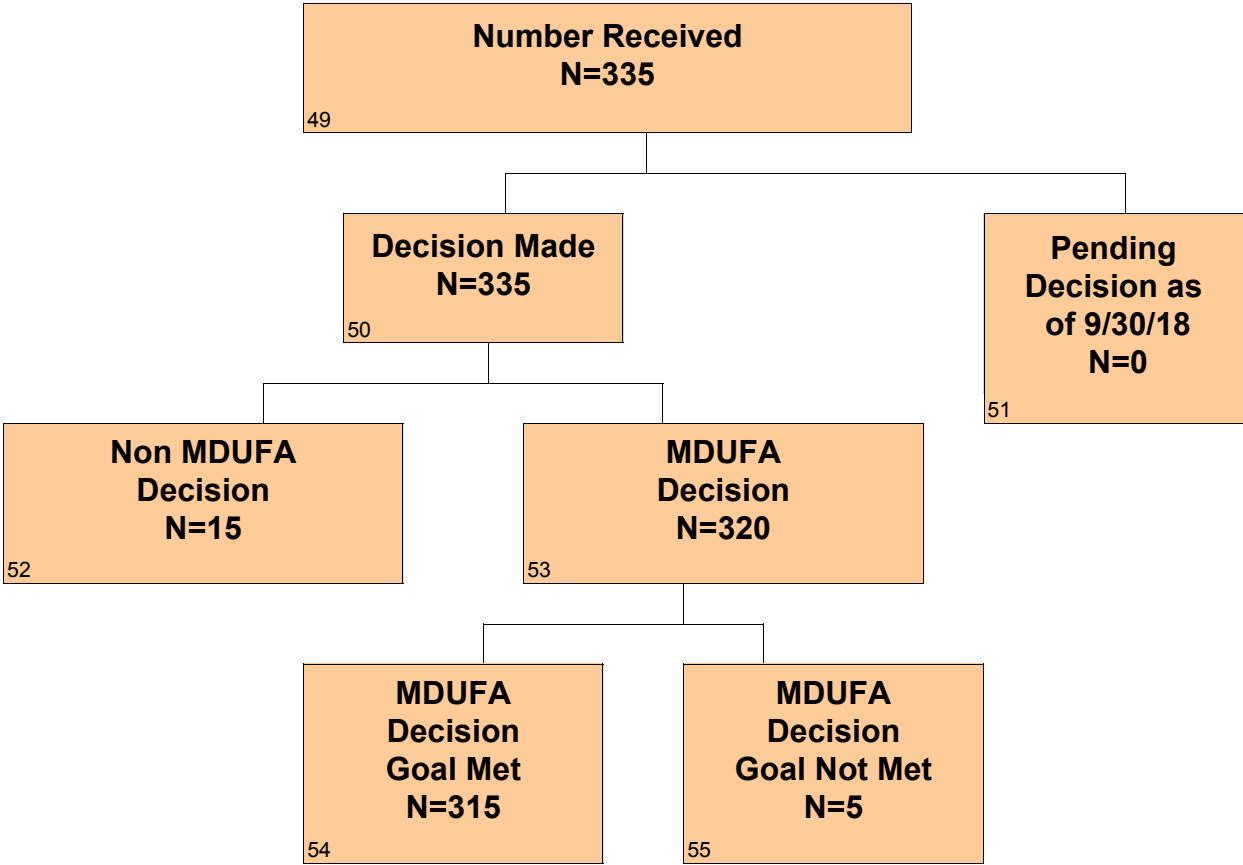
CDRH PMA Real Time Supplements - FY 2013 As of 9/30/18



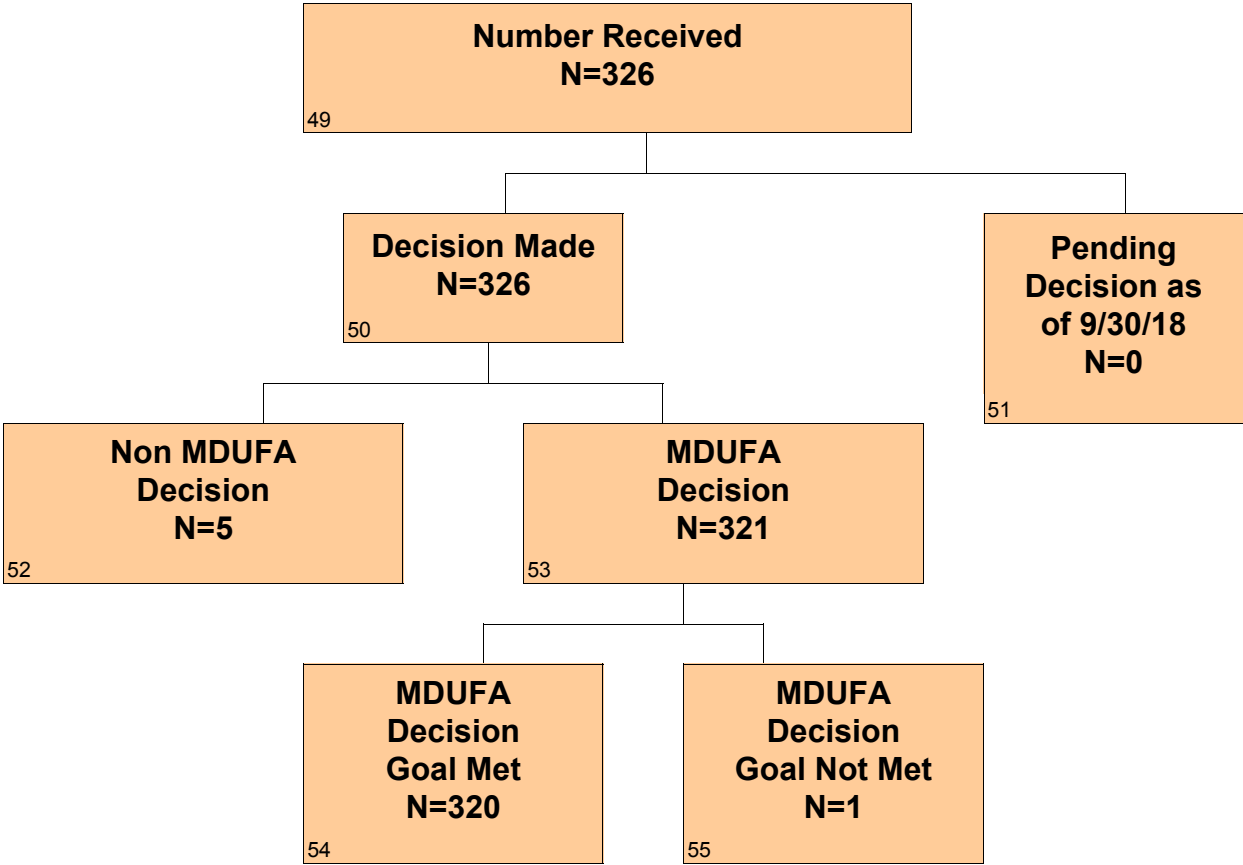
CDRH PMA Real Time Supplements - FY 2014 As of 9/30/18



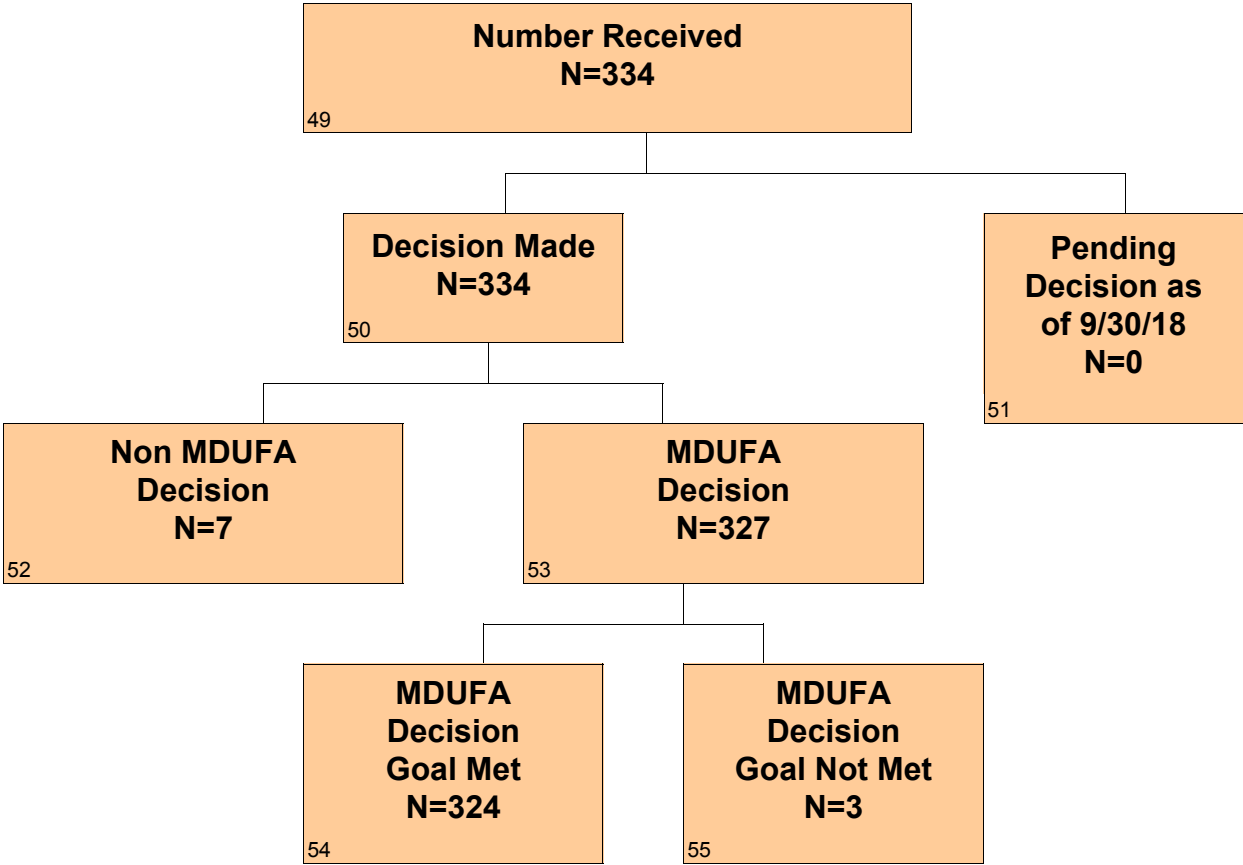
CDRH PMA Real Time Supplements - FY 2015 As of 9/30/18



CDRH PMA Real Time Supplements - FY 2016 As of 9/30/18



CDRH PMA Real Time Supplements - FY 2017 As of 9/30/18



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Section 3 PMA Real Time Supplements - Center Level Metrics

Table 3.1 CDRH – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	308	339	335	326	334
Non-MDUFA III Decisions	10	8	15	5	7
MDUFA III Decisions	298	331	320	321	327
MDUFA III Decisions Goal Met	296	327	315	320	324
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	99.33%	98.79%	98.44%	99.69%	99.08%

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	326	334
Number with MDUFA decision	298	331	320	321	327
Number of Not Approvable	20	3	20	6	11
Rate of Not Approvable	6.71%	0.91%	6.25%	1.87%	3.36%

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	4	5	1	3
Mean FDA days for submissions that missed goal	143	101	144	91	91
Mean Industry days for submissions that missed goal	0	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	284	281
Non-MDUFA III Decisions	9	6	14	5	2
MDUFA III Decisions	260	277	269	279	279
MDUFA III Decisions Goal Met	258	273	264	278	276
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	99.23%	98.56%	98.14%	99.64%	98.92%

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	284	281
Number with MDUFA decision	260	277	269	279	279
Number of Not Approvable	15	3	14	4	4
Rate of Not Approvable	5.77%	1.08%	5.20%	1.43%	1.43%

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	4	5	1	3
Mean FDA days for submissions that missed goal	143	101	144	91	91
Mean Industry days for submissions that missed goal	0	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	42	53
Non-MDUFA III Decisions	1	2	1	0	5
MDUFA III Decisions	38	54	51	42	48
MDUFA III Decisions Goal Met	38	54	51	42	48
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	39	56	52	42	53
Number with MDUFA decision	38	54	51	42	48
Number of Not Approvable	5	0	6	2	7
Rate of Not Approvable	13.16%	0%	11.76%	4.76%	14.58%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	11	6
Non-MDUFA III Decisions	0	1	0	1	0
MDUFA III Decisions	13	7	6	10	6
MDUFA III Decisions Goal Met	13	5	5	9	6
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	71.43%	83.33%	90.00%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	13	8	6	11	6
Number with MDUFA decision	13	7	6	10	6
Number of Not Approvable	1	1	2	1	0
Rate of Not Approvable	7.69%	14.29%	33.33%	10.00%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	2	1	1	0
Mean FDA days for submissions that missed goal	0	101	183	91	0
Mean Industry days for submissions that missed goal	0	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	194	191
Non-MDUFA III Decisions	6	3	11	3	1
MDUFA III Decisions	170	215	189	191	190
MDUFA III Decisions Goal Met	170	215	185	191	190
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	97.88%	100%	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	194	191
Number with MDUFA decision	170	215	189	191	190
Number of Not Approvable	7	1	10	0	3
Rate of Not Approvable	4.12%	0.47%	5.29%	0%	1.58%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	4	0	0
Mean FDA days for submissions that missed goal	0	0	134	0	0
Mean Industry days for submissions that missed goal	0	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	16	22	22	23
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	23	16	22	22	23
MDUFA III Decisions Goal Met	23	14	22	22	23
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	87.50%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	23	16	22	22	23
Number with MDUFA decision	23	16	22	22	23
Number of Not Approvable	1	1	0	0	0
Rate of Not Approvable	4.35%	6.25%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	2	0	0	0
Mean FDA days for submissions that missed goal	0	101	0	0	0
Mean Industry days for submissions that missed goal	0	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	11	15	10	9
Non-MDUFA III Decisions	0	2	2	0	0
MDUFA III Decisions	8	9	13	10	9
MDUFA III Decisions Goal Met	8	9	13	10	9
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	11	15	10	9
Number with MDUFA decision	8	9	13	10	9
Number of Not Approvable	2	0	0	1	1
Rate of Not Approvable	25.00%	0%	0%	10.00%	11.11%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	20	23
Non-MDUFA III Decisions	0	0	1	1	0
MDUFA III Decisions	16	17	21	19	23
MDUFA III Decisions Goal Met	16	17	21	19	20
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	86.96%

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	20	23
Number with MDUFA decision	16	17	21	19	23
Number of Not Approvable	0	0	0	2	0
Rate of Not Approvable	0%	0%	0%	10.53%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	3
Mean FDA days for submissions that missed goal	0	0	0	0	91
Mean Industry days for submissions that missed goal	0	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	18	18
Non-MDUFA III Decisions	2	0	0	0	0
MDUFA III Decisions	17	2	11	18	18
MDUFA III Decisions Goal Met	17	2	11	18	18
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	19	2	11	18	18
Number with MDUFA decision	17	2	11	18	18
Number of Not Approvable	1	0	0	0	0
Rate of Not Approvable	5.88%	0%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	9	11
Non-MDUFA III Decisions	1	0	0	0	1
MDUFA III Decisions	13	11	7	9	10
MDUFA III Decisions Goal Met	11	11	7	9	10
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	84.62%	100%	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	9	11
Number with MDUFA decision	13	11	7	9	10
Number of Not Approvable	3	0	2	0	0
Rate of Not Approvable	23.08%	0%	28.57%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0	0	0
Mean FDA days for submissions that missed goal	143	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	18	27
Non-MDUFA III Decisions	0	2	0	0	4
MDUFA III Decisions	6	17	20	18	23
MDUFA III Decisions Goal Met	6	17	20	18	23
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	19	20	18	27
Number with MDUFA decision	6	17	20	18	23
Number of Not Approvable	0	0	4	1	3
Rate of Not Approvable	0%	0%	20.00%	5.56%	13.04%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	8
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	12	10	4	0	8
MDUFA III Decisions Goal Met	12	10	4	0	8
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	N/A	100%

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	8
Number with MDUFA decision	12	10	4	0	8
Number of Not Approvable	2	0	0	0	4
Rate of Not Approvable	16.67%	0%	0%	N/A	50.00%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	9	7
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	13	12	13	9	7
MDUFA III Decisions Goal Met	13	12	13	9	7
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	13	12	13	9	7
Number with MDUFA decision	13	12	13	9	7
Number of Not Approvable	3	0	0	1	0
Rate of Not Approvable	23.08%	0%	0%	11.11%	0%

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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	15	8
Non-MDUFA III Decisions	1	0	0	0	0
MDUFA III Decisions	7	13	12	15	8
MDUFA III Decisions Goal Met	7	13	12	15	8
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	13	12	15	8
Number with MDUFA decision	7	13	12	15	8
Number of Not Approvable	0	0	2	0	0
Rate of Not Approvable	0%	0%	16.67%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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	3
Non-MDUFA III Decisions	0	0	1	0	1
MDUFA III Decisions	0	2	2	0	2
MDUFA III Decisions Goal Met	0	2	2	0	2
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	100%	100%	N/A	100%

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean Industry days for submissions that missed goal	0	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, 2017 and September 30, 2018.

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Section 5 PMA Annual Metrics and Goals

Table 5.1 CDRH – PMAs (All Review Tracks) Annual General Metrics – PMAs Received by Type

PMA Submissions Received	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Premarket Report Submissions	0	0	0	0	0
Original PMAs (Panel) – Priority	0	0	0	0	0
Original PMAs (No Panel) – Priority	0	0	0	0	1
Original PMAs (Panel) – Non-Priority	11	5	5	1	5
Original PMAs (No Panel) – Non-Priority	18	24	41	55	36
Panel-Tracked Supplements (Panel) – Priority	0	0	0	0	0
Panel-Tracked Supplements (No Panel) – Priority	0	0	0	0	0
Panel-Tracked Supplements (Panel) – Non-Priority	6	1	1	0	0
Panel-Tracked Supplements (No Panel) – Non-Priority	10	13	25	16	26
PMA Modules	52	67	98	84	88
180-Day Supplements	185	176	198	205	271
Real-Time Supplements	308	339	335	326	334

Table 5.2 CDRH – PMA Originals and Panel Tracked Supplements Annual Shared Outcome Goal – Percent Cohorts Closed

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	44	42	68	71	65
Number with a decision (MDUFA or Non-MDUFA)	44	42	68	69	60
% of FY closed	100%	100%	100%	97.18%	92.31%

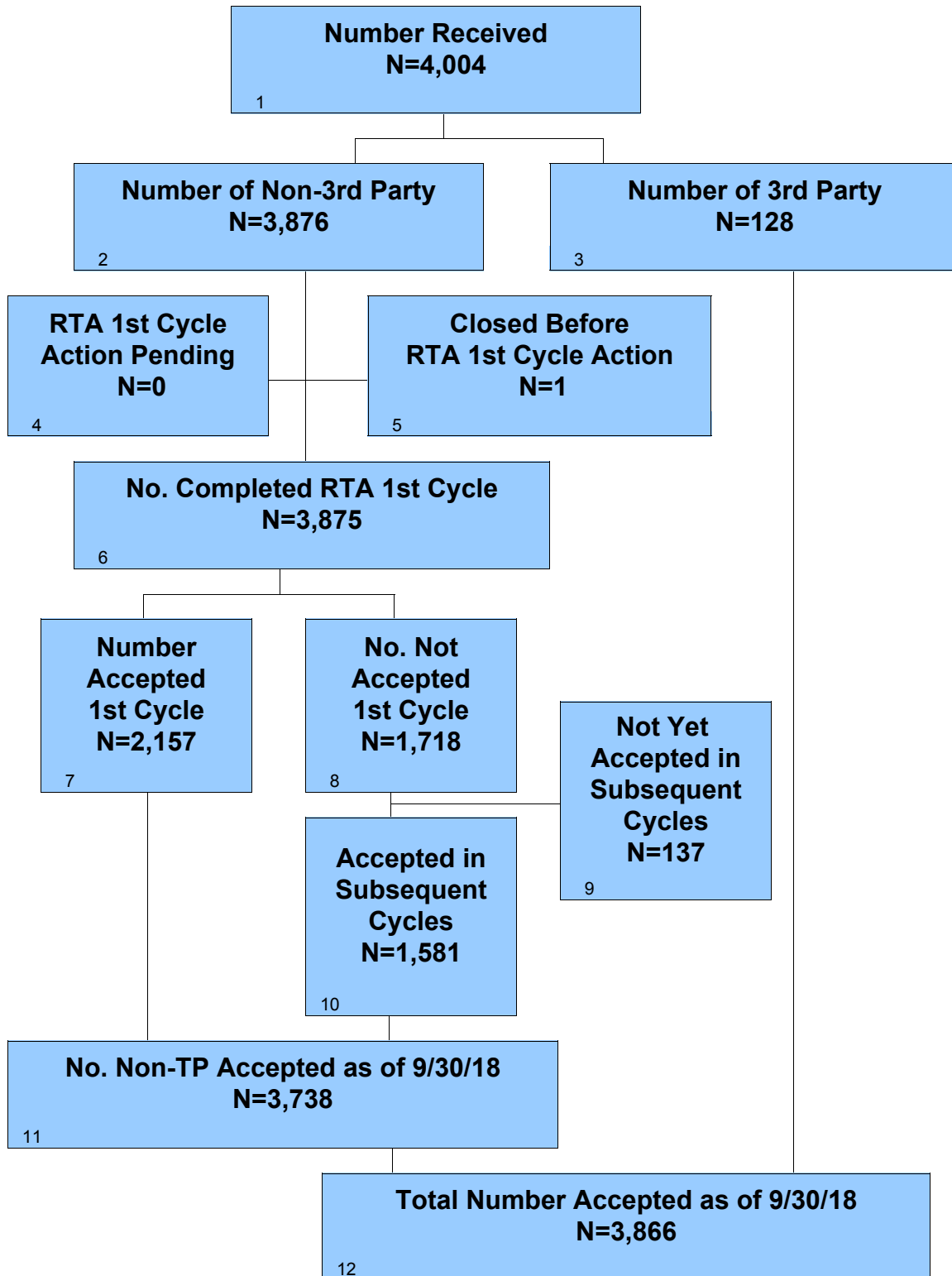
Table 5.3 CDRH – PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-year Rolling Average Time to MDUFA Decision

Performance Metric	FY 2013 3 year cohort 395 days	FY 2014 3 year cohort 395 days	FY 2015 3 year cohort 390 days	FY 2016 3 year cohort 390 days	FY 2017 3 year cohort 385 days
Number with a MDUFA decision	121	113	147	166	N/A
Number with a MDUFA decision after trimming the upper and lower 5%	109	101	133	156	N/A
Three-year Rolling Average Total Time to MDUFA decision	316.83	302.18	292.48	263.71	N/A

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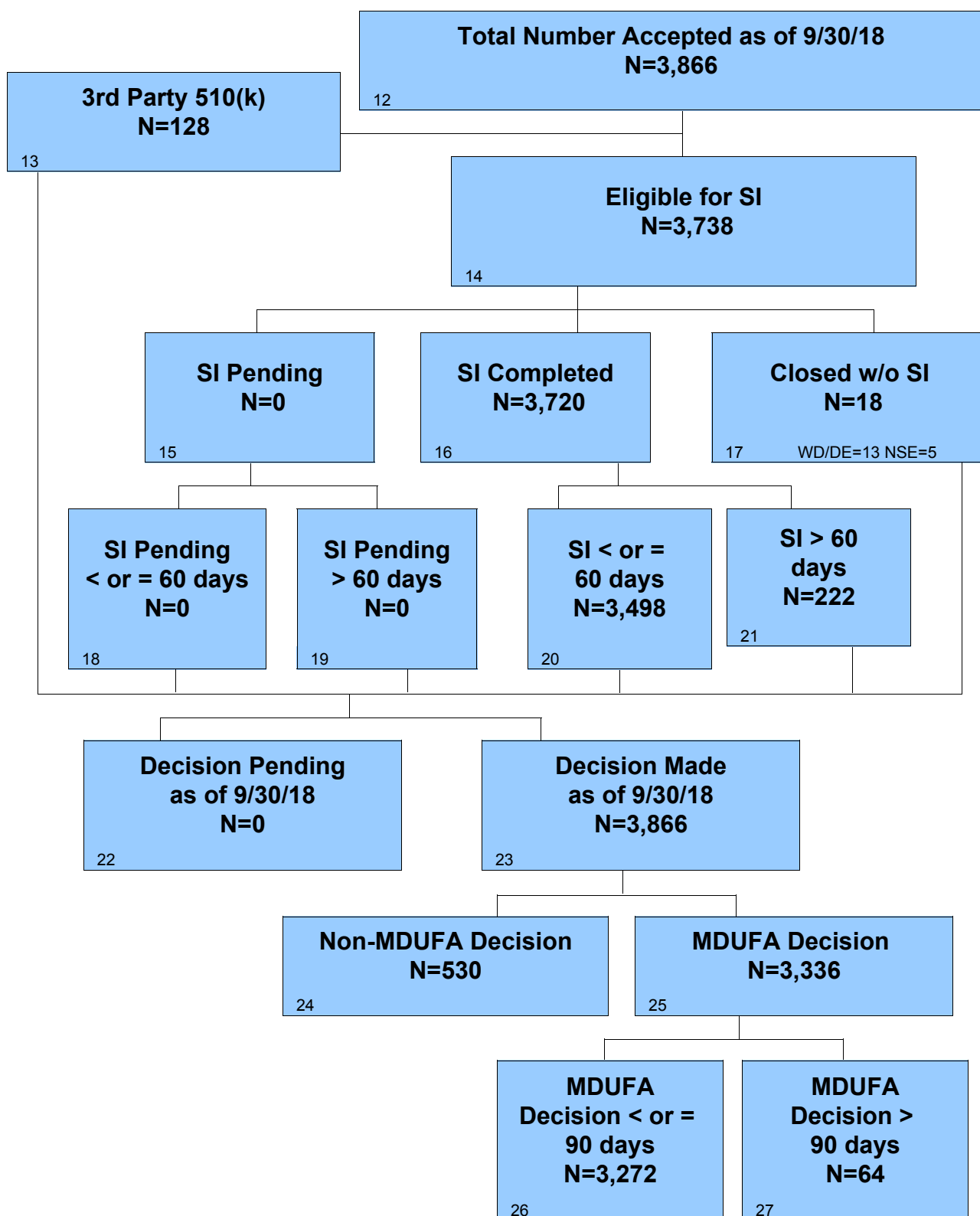
CDRH 510(k)s - FY 2013

As of 9/30/18



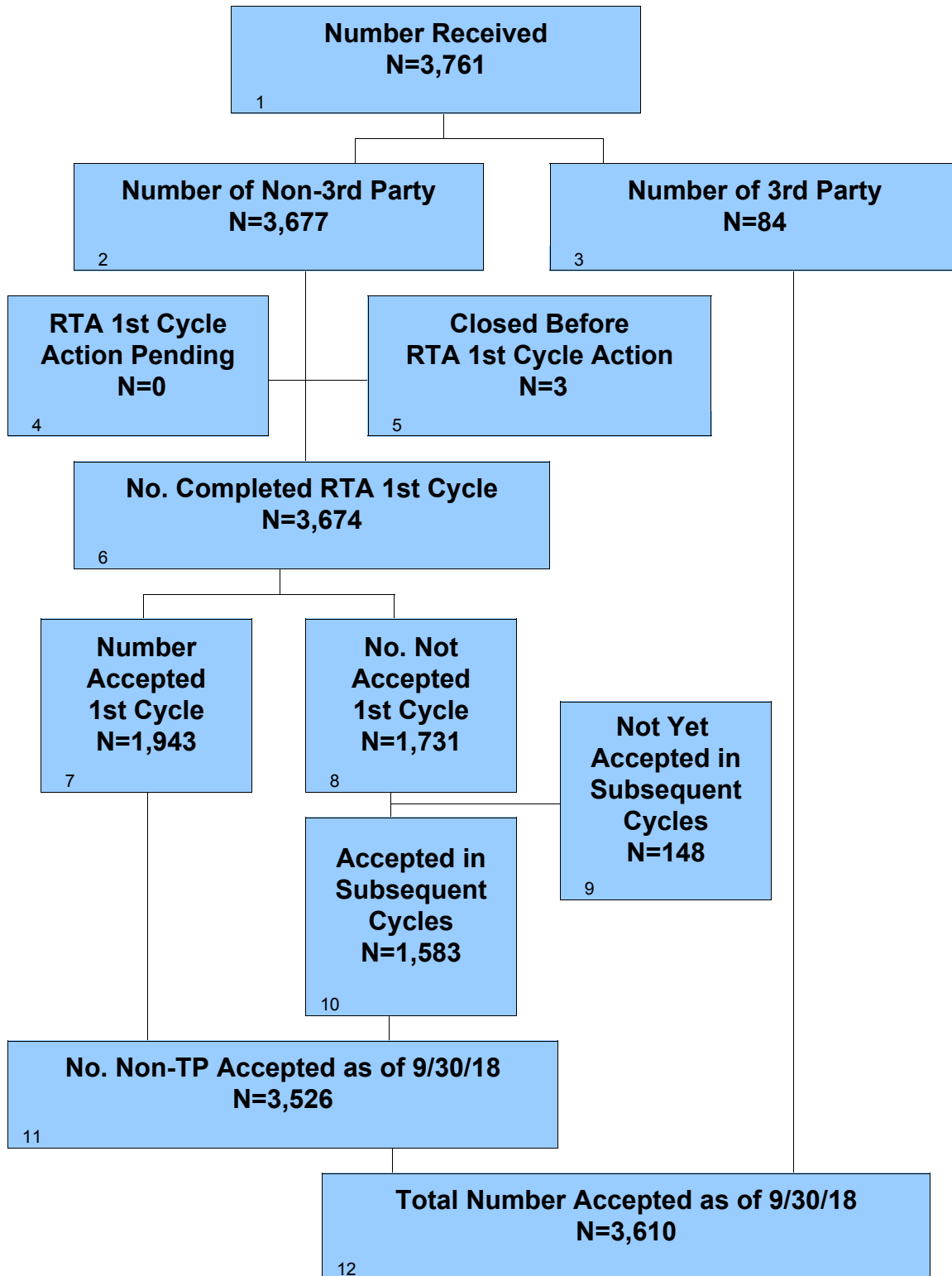
CDRH 510(k)s - FY 2013

As of 9/30/18 Continued



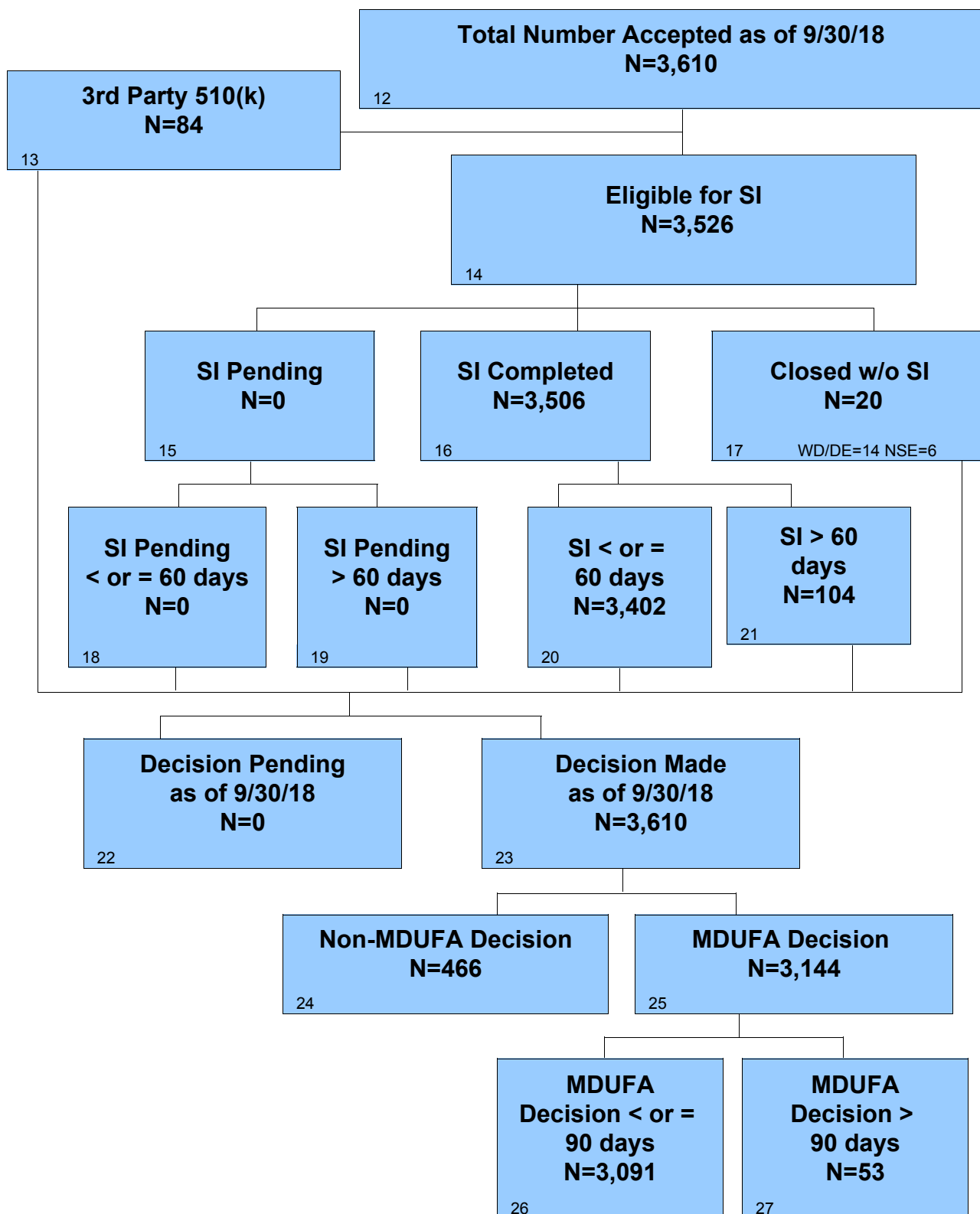
CDRH 510(k)s - FY 2014

As of 9/30/18



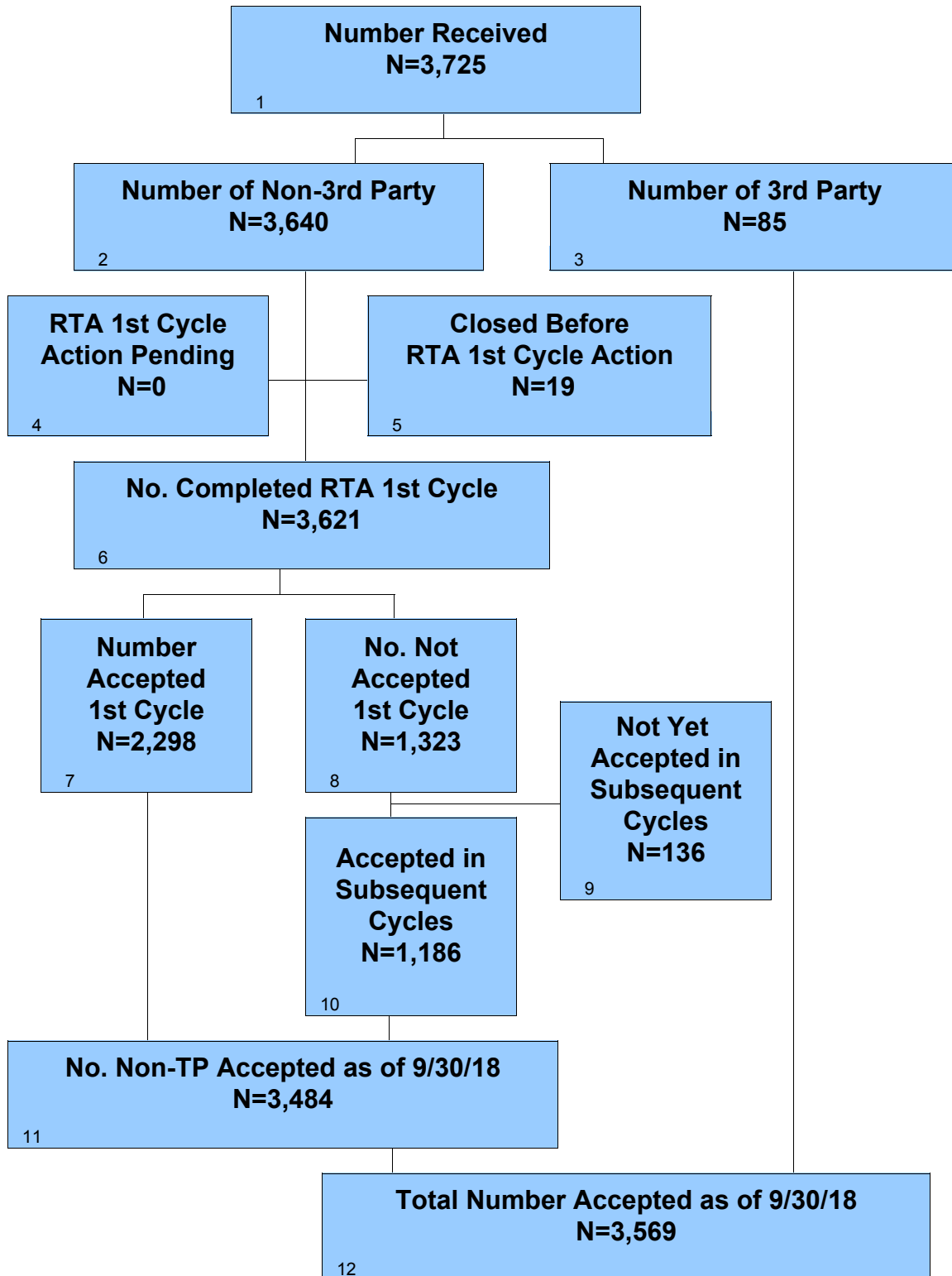
CDRH 510(k)s - FY 2014

As of 9/30/18 Continued



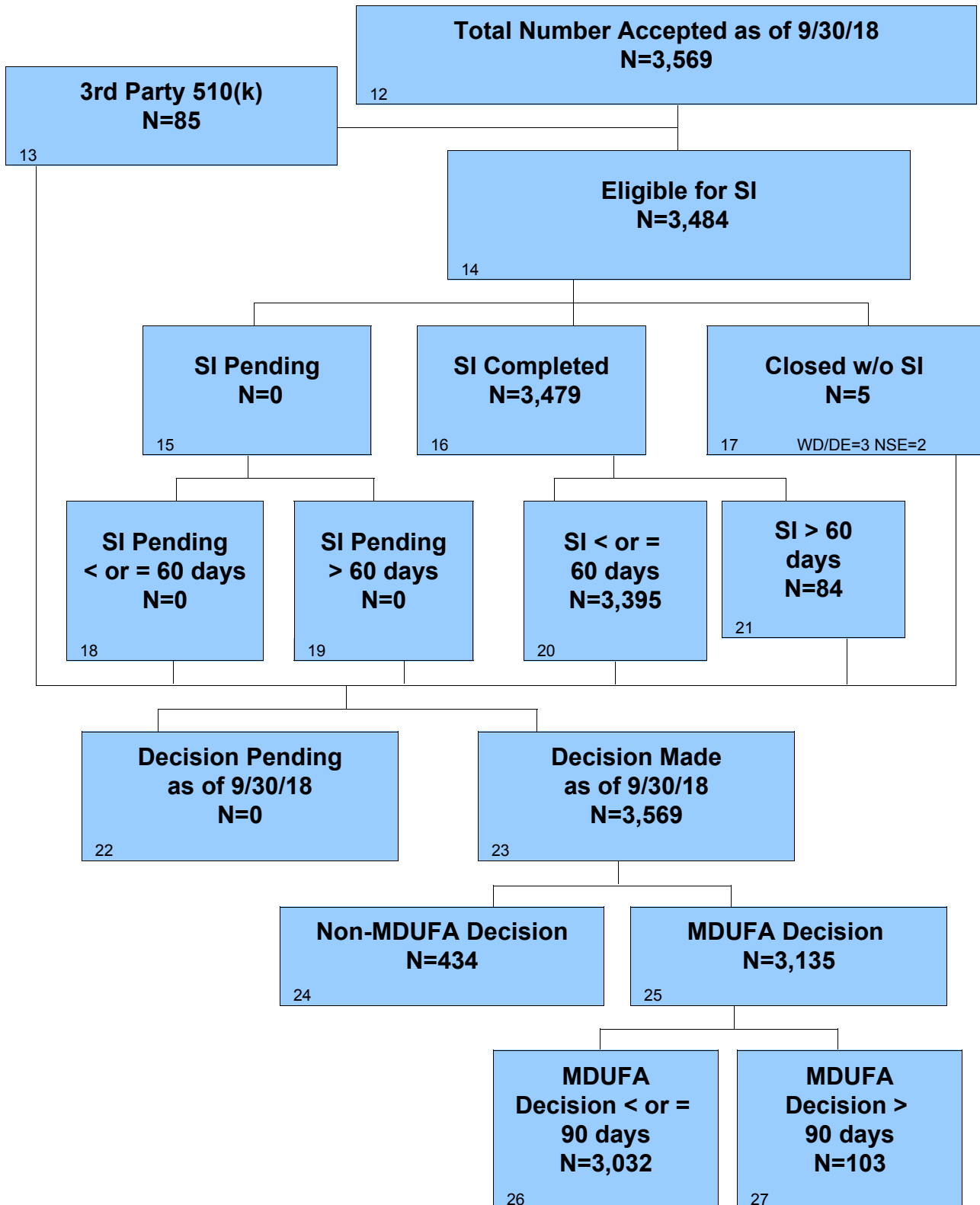
CDRH 510(k)s - FY 2015

As of 9/30/18



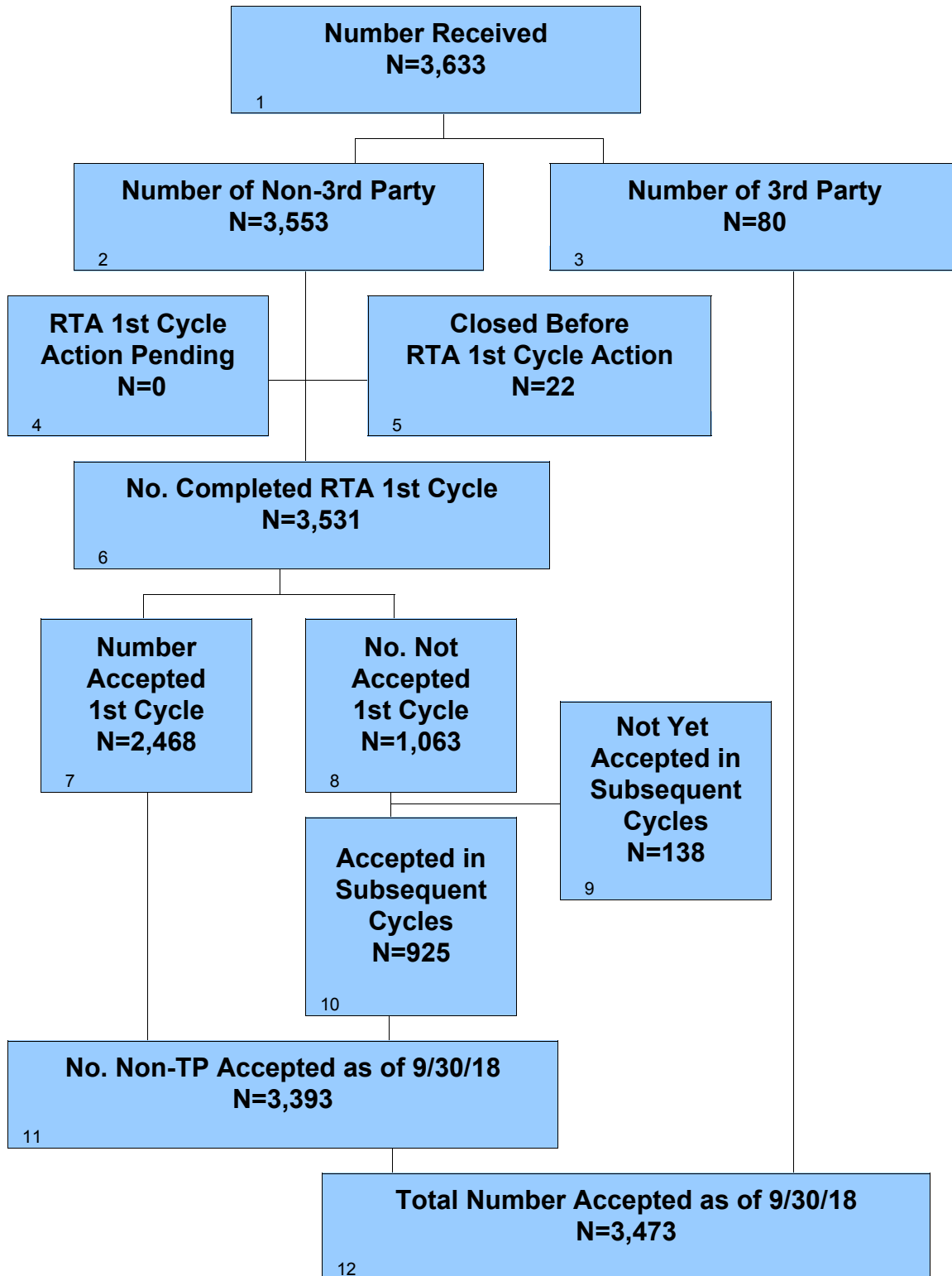
CDRH 510(k)s - FY 2015

As of 9/30/18 Continued



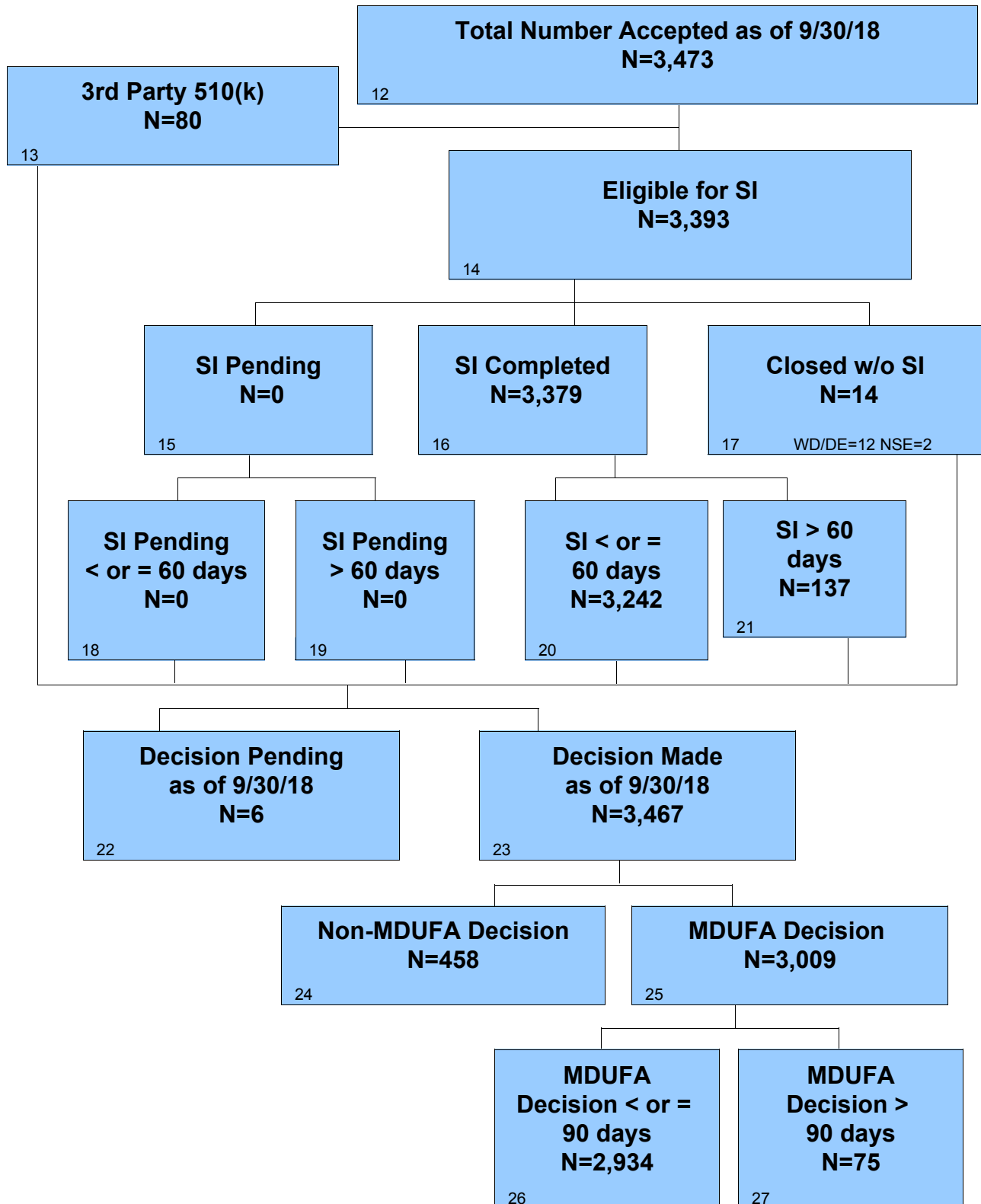
CDRH 510(k)s - FY 2016

As of 9/30/18



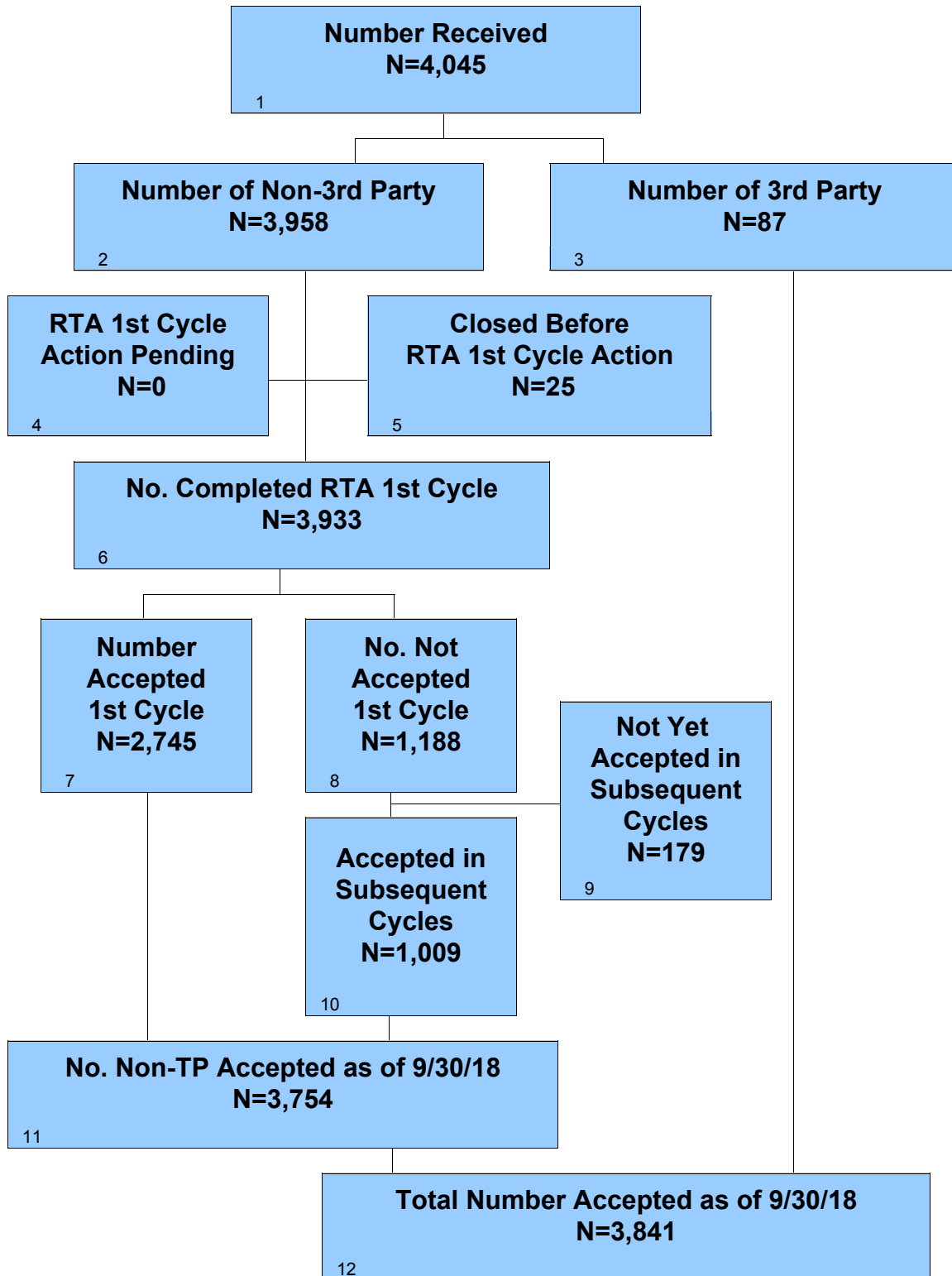
CDRH 510(k)s - FY 2016

As of 9/30/18 Continued



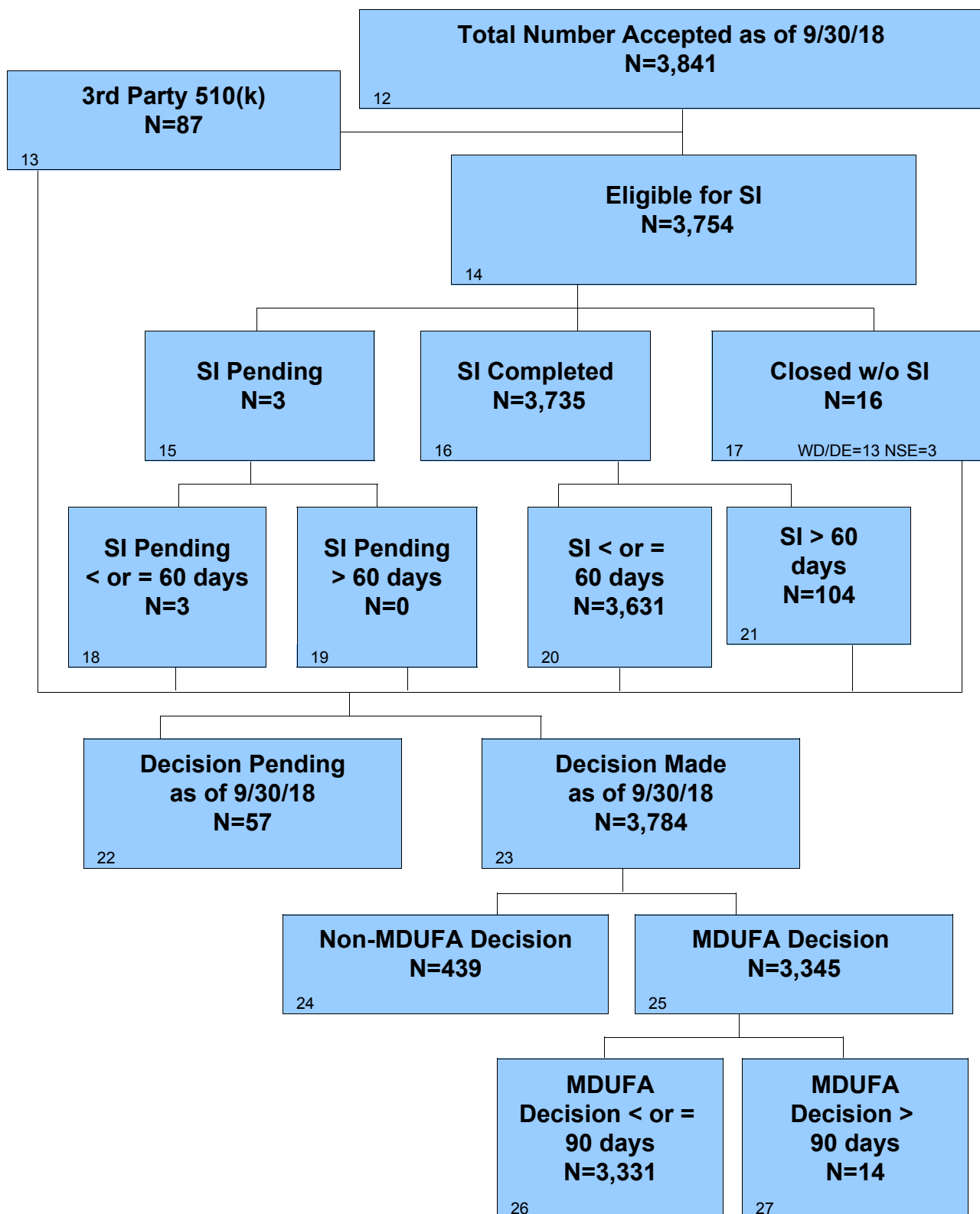
CDRH 510(k)s - FY 2017

As of 9/30/18



CDRH 510(k)s - FY 2017

As of 9/30/18 Continued



Section 6 510(k) Center Level Metrics

Table 6.1 CDRH – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,954	3,677	3,640	3,553	3,958
Closed before RTA action	1	3	19	22	25
Number Accepted	1,197	1,886	2,272	2,441	2,711
Number without a RTA Review and > 15 Days since Date Received	41	57	26	27	34
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	1,715	1,731	1,323	1,063	1,188
Rate of submissions not accepted for filing review	58.08%	47.11%	36.54%	30.10%	30.21%

* 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

Substantive Interaction (SI) Goal	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	3,738	3,526	3,484	3,393	3,754
Deleted or withdrawn prior to SI	13	14	3	12	13
SI within 60 FDA days	3,498	3,402	3,395	3,242	3,631
SI over 60 FDA days	222	104	84	137	104
SI pending within 60 FDA days	0	0	0	0	3
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	5	6	2	2	3
Current SI Performance Percent within 60 FDA days	93.91%	96.87%	97.53%	95.89%	97.14%

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	3,720	3,506	3,479	3,379	3,735
Average number of FDA days to Substantive Interaction	47.61	49.43	50.02	50.43	50.64
20th Percentile FDA days to Substantive Interaction	30	33	39	41	42
40th Percentile FDA days to Substantive Interaction	48	52	53	53	53
60th Percentile FDA days to Substantive Interaction	56	57	57	57	58
80th Percentile FDA days to Substantive Interaction	59	59	59	59	60
Maximum FDA days to Substantive Interaction	98	188	140	151	90

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	3,866	3,610	3,569	3,473	3,841
Non-MDUFA III Decisions	530	466	434	458	439
MDUFA III Decisions (SE/NSE)	3,336	3,144	3,135	3,009	3,345
MDUFA III Decisions within 90 FDA Days	3,272	3,091	3,032	2,934	3,331
510(k)s pending MDUFA III Decision	0	0	0	6	57
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	98.08%	98.31%	96.71%	97.51%	99.58%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.74	1.72	1.73	1.80	1.70
Number with MDUFA III decision	3,336	3,144	3,135	3,009	3,345
Average FDA days to MDUFA III decision	70.76	72.09	73.56	74.03	72.02
20th Percentile FDA days to MDUFA III decision	48	51	54	56	53
40th Percentile FDA days to MDUFA III decision	76	80	81	83	79
60th Percentile FDA days to MDUFA III decision	86	87	87	88	87
80th Percentile FDA days to MDUFA III decision	89	89	89	89	89
Maximum FDA days to MDUFA III decision	342	245	373	267	220
Average Industry days to MDUFA III decision	57.22	55.76	61.85	67.05	61.82
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	14	14	15	24	15
60th Percentile Industry days to MDUFA III decision	44	45	53	63	56
80th Percentile Industry days to MDUFA III decision	116	117	138	145	142
Maximum Industry days to MDUFA III decision	489	469	597	533	368
Average Total days to MDUFA III decision	127.98	127.85	135.41	141.07	133.85
20th Percentile Total days to MDUFA III decision	56	58	58	63	58
40th Percentile Total days to MDUFA III decision	90	90	95	105	93
60th Percentile Total days to MDUFA III decision	127	128	137	148	139
80th Percentile Total days to MDUFA III decision	199	203	224	229	226
Maximum Total days to MDUFA III decision	691	556	744	628	483

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	3,866	3,610	3,569	3,473	3,841
Number with MDUFA decision	3,336	3,144	3,135	3,009	3,345
Number of SE decisions	3,203	3,057	3,040	2,880	3,218
Number of NSE decisions	133	87	95	129	127
Number of Withdrawals	230	213	199	189	209
Number deleted	279	221	224	253	211
Rate of SE decisions	96.01%	97.23%	96.97%	95.71%	96.20%
Rate of NSE decisions	3.99%	2.77%	3.03%	4.29%	3.80%
Rate of Withdrawals	5.95%	5.90%	5.58%	5.44%	5.44%
Rate of Deleted	7.22%	6.12%	6.28%	7.28%	5.49%

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	53	103	75	14
Mean FDA days for submissions that missed goal	119	106	116	109	111
Mean industry days for submissions that missed goal	138	128	147	127	150

Section 6 510(k) Office Level Metrics

Table 6.1 ODE – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,376	2,942	2,977	2,863	3,203
Closed before RTA action	1	2	17	18	10
Number Accepted	819	1,335	1,725	1,851	2,090
Number without a RTA Review and > 15 Days since Date Received	23	49	22	23	20
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	1,533	1,556	1,213	971	1,083
Rate of submissions not accepted for filing review	64.55%	52.93%	40.98%	34.13%	33.92%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	2,969	2,820	2,843	2,726	3,040
Deleted or withdrawn prior to SI	12	14	2	9	9
SI within 60 FDA days	2,773	2,711	2,759	2,581	2,924
SI over 60 FDA days	179	89	80	134	101
SI pending within 60 FDA days	0	0	0	0	3
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	5	6	2	2	3
Current SI Performance Percent within 60 FDA days	93.78%	96.61%	97.11%	94.99%	96.57%

Table 6.3 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	2,952	2,800	2,839	2,715	3,025
Average number of FDA days to Substantive Interaction	48.27	50.39	51.07	51.55	51.55
20th Percentile FDA days to Substantive Interaction	30	38	43	45	45
40th Percentile FDA days to Substantive Interaction	49	54	54	55	55
60th Percentile FDA days to Substantive Interaction	56	58	58	58	58
80th Percentile FDA days to Substantive Interaction	59	60	60	60	60
Maximum FDA days to Substantive Interaction	98	188	140	151	90

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	3,043	2,867	2,895	2,763	3,093
Non-MDUFA III Decisions	444	390	367	389	367
MDUFA III Decisions (SE/NSE)	2,599	2,477	2,528	2,368	2,678
MDUFA III Decisions within 90 FDA Days	2,542	2,439	2,427	2,298	2,664
510(k)s pending MDUFA III Decision	0	0	0	6	48
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	97.81%	98.47%	96.00%	97.04%	99.48%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.76	1.72	1.75	1.82	1.71
Number with MDUFA III decision	2,599	2,477	2,528	2,368	2,678
Average FDA days to MDUFA III decision	72.78	73.84	75.99	76.40	73.68
20th Percentile FDA days to MDUFA III decision	53	55	57	58	56
40th Percentile FDA days to MDUFA III decision	80	83	85	85	81
60th Percentile FDA days to MDUFA III decision	87	87	88	88	87
80th Percentile FDA days to MDUFA III decision	89	89	90	90	89
Maximum FDA days to MDUFA III decision	342	245	373	267	220
Average Industry days to MDUFA III decision	57.34	56.26	63.07	68.80	62.69
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	17	17	17	28	20
60th Percentile Industry days to MDUFA III decision	46	48	55	69	61
80th Percentile Industry days to MDUFA III decision	116	118	140	147	144
Maximum Industry days to MDUFA III decision	438	408	597	529	348
Average Total days to MDUFA III decision	130.12	130.10	139.06	145.20	136.36
20th Percentile Total days to MDUFA III decision	59	61	63	74	60
40th Percentile Total days to MDUFA III decision	94	94	100	111	99
60th Percentile Total days to MDUFA III decision	129	132	141	154	143
80th Percentile Total days to MDUFA III decision	200	205	226	233	227
Maximum Total days to MDUFA III decision	691	512	744	628	483

Table 6.6 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	3,043	2,867	2,895	2,763	3,093
Number with MDUFA decision	2,599	2,477	2,528	2,368	2,678
Number of SE decisions	2,489	2,409	2,452	2,257	2,560
Number of NSE decisions	110	68	76	111	118
Number of Withdrawals	188	175	166	159	176
Number deleted	237	185	191	215	178
Rate of SE decisions	95.77%	97.25%	96.99%	95.31%	95.59%
Rate of NSE decisions	4.23%	2.75%	3.01%	4.69%	4.41%
Rate of Withdrawals	6.18%	6.10%	5.73%	5.75%	5.69%
Rate of Deleted	7.79%	6.45%	6.60%	7.78%	5.75%

Table 6.7 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	57	38	101	70	14
Mean FDA days for submissions that missed goal	121	109	115	106	111
Mean industry days for submissions that missed goal	137	153	146	122	150

Section 6 510(k) Office Level Metrics

Table 6.1 OIR – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	578	735	663	690	755
Closed before RTA action	0	1	2	4	15
Number Accepted	378	551	547	590	621
Number without a RTA Review and > 15 Days since Date Received	18	8	4	4	14
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	182	175	110	92	105
Rate of submissions not accepted for filing review	31.49%	23.84%	16.64%	13.41%	14.19%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	769	706	641	667	714
Deleted or withdrawn prior to SI	1	0	1	3	4
SI within 60 FDA days	725	691	636	661	707
SI over 60 FDA days	43	15	4	3	3
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	94.40%	97.88%	99.38%	99.55%	99.58%

Table 6.3 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	768	706	640	664	710
Average number of FDA days to Substantive Interaction	45.06	45.60	45.34	45.85	46.79
20th Percentile FDA days to Substantive Interaction	29	30	29	29	30
40th Percentile FDA days to Substantive Interaction	43	45	45	46	49
60th Percentile FDA days to Substantive Interaction	51	53	53	54	55
80th Percentile FDA days to Substantive Interaction	58	58	58	58	58
Maximum FDA days to Substantive Interaction	91	93	70	129	61

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	823	743	674	710	748
Non-MDUFA III Decisions	86	76	67	69	72
MDUFA III Decisions (SE/NSE)	737	667	607	641	667
MDUFA III Decisions within 90 FDA Days	730	652	605	636	667
510(k)s pending MDUFA III Decision	0	0	0	0	9
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	99.05%	97.75%	99.67%	99.22%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.69	1.70	1.68	1.75	1.65
Number with MDUFA III decision	737	667	607	641	667
Average FDA days to MDUFA III decision	63.64	65.58	63.43	65.26	65.39
20th Percentile FDA days to MDUFA III decision	34	32	30	30	30
40th Percentile FDA days to MDUFA III decision	58	60	59	63	66
60th Percentile FDA days to MDUFA III decision	81	84	80	82	82
80th Percentile FDA days to MDUFA III decision	88	88	87	88	88
Maximum FDA days to MDUFA III decision	121	137	232	229	90
Average Industry days to MDUFA III decision	56.80	53.91	56.78	60.56	58.35
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	7	0
60th Percentile Industry days to MDUFA III decision	36	38	40	45	43
80th Percentile Industry days to MDUFA III decision	112	106	126	135	133
Maximum Industry days to MDUFA III decision	489	469	477	533	368
Average Total days to MDUFA III decision	120.44	119.50	120.21	125.82	123.74
20th Percentile Total days to MDUFA III decision	36	34	32	36	33
40th Percentile Total days to MDUFA III decision	77	85	75	85	84
60th Percentile Total days to MDUFA III decision	111	113	115	121	120
80th Percentile Total days to MDUFA III decision	194	189	207	212	218
Maximum Total days to MDUFA III decision	579	556	564	623	456

Table 6.6 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	823	743	674	710	748
Number with MDUFA decision	737	667	607	641	667
Number of SE decisions	714	648	588	623	658
Number of NSE decisions	23	19	19	18	9
Number of Withdrawals	42	38	33	30	33
Number deleted	42	36	33	38	33
Rate of SE decisions	96.88%	97.15%	96.87%	97.19%	98.65%
Rate of NSE decisions	3.12%	2.85%	3.13%	2.81%	1.35%
Rate of Withdrawals	5.10%	5.11%	4.90%	4.23%	4.41%
Rate of Deleted	5.10%	4.85%	4.90%	5.35%	4.41%

Table 6.7 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	7	15	2	5	0
Mean FDA days for submissions that missed goal	103	100	162	149	0
Mean industry days for submissions that missed goal	143	68	172	193	0

Section 6 510(k) Division Level Metrics

Table 6.1 DAGRID – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	630	766	754	759	825
Closed before RTA action	1	0	3	3	3
Number Accepted	186	320	370	317	336
Number without a RTA Review and > 15 Days since Date Received	5	14	5	4	11
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	438	432	376	435	475
Rate of submissions not accepted for filing review	69.63%	56.40%	50.07%	57.54%	57.79%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	780	715	701	692	748
Deleted or withdrawn prior to SI	2	6	0	2	0
SI within 60 FDA days	748	701	685	623	691
SI over 60 FDA days	27	4	14	67	53
SI pending within 60 FDA days	0	0	0	0	3
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	3	4	2	0	1
Current SI Performance Percent within 60 FDA days	96.14%	98.87%	97.72%	90.29%	92.75%

Table 6.3 DAGRID – 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	705	699	690	744
Average number of FDA days to Substantive Interaction	50.88	53.12	54.51	55.66	55.27
20th Percentile FDA days to Substantive Interaction	43	50	52	53	53
40th Percentile FDA days to Substantive Interaction	54	56	57	58	58
60th Percentile FDA days to Substantive Interaction	58	59	58	59	59
80th Percentile FDA days to Substantive Interaction	60	60	60	60	60
Maximum FDA days to Substantive Interaction	90	188	79	89	82

Table 6.4 DAGRID – 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	796	729	716	707	767
Non-MDUFA III Decisions	164	114	101	104	97
MDUFA III Decisions (SE/NSE)	632	615	615	601	642
MDUFA III Decisions within 90 FDA Days	613	597	545	564	640
510(k)s pending MDUFA III Decision	0	0	0	2	28
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	96.99%	97.07%	88.62%	93.84%	99.69%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.80	1.82	1.88	1.98	1.88
Number with MDUFA III decision	632	615	615	601	642
Average FDA days to MDUFA III decision	77.98	80.05	86.05	84.60	81.15
20th Percentile FDA days to MDUFA III decision	63	77	85	85	80
40th Percentile FDA days to MDUFA III decision	84	86	88	88	86
60th Percentile FDA days to MDUFA III decision	88	88	89	89	88
80th Percentile FDA days to MDUFA III decision	90	90	90	90	90
Maximum FDA days to MDUFA III decision	280	210	373	267	93
Average Industry days to MDUFA III decision	64.51	69.40	81.21	84.64	81.49
20th Percentile Industry days to MDUFA III decision	0	0	7	21	13
40th Percentile Industry days to MDUFA III decision	21	28	36	53	45
60th Percentile Industry days to MDUFA III decision	55	70	88	95	97
80th Percentile Industry days to MDUFA III decision	141	146	163	158	162
Maximum Industry days to MDUFA III decision	420	361	597	360	341
Average Total days to MDUFA III decision	142.49	149.44	167.26	169.24	162.65
20th Percentile Total days to MDUFA III decision	78	86	90	107	94
40th Percentile Total days to MDUFA III decision	103	114	122	140	130
60th Percentile Total days to MDUFA III decision	140	157	178	183	183
80th Percentile Total days to MDUFA III decision	221	235	253	245	250
Maximum Total days to MDUFA III decision	610	505	744	453	431

Table 6.6 DAGRID – 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	796	729	716	707	767
Number with MDUFA decision	632	615	615	601	642
Number of SE decisions	603	588	593	558	604
Number of NSE decisions	29	27	22	43	38
Number of Withdrawals	55	49	40	39	40
Number deleted	104	53	57	59	55
Rate of SE decisions	95.41%	95.61%	96.42%	92.85%	94.08%
Rate of NSE decisions	4.59%	4.39%	3.58%	7.15%	5.92%
Rate of Withdrawals	6.91%	6.72%	5.59%	5.52%	5.22%
Rate of Deleted	13.07%	7.27%	7.96%	8.35%	7.17%

Table 6.7 DAGRID – 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	18	70	37	2
Mean FDA days for submissions that missed goal	125	104	115	106	93
Mean industry days for submissions that missed goal	157	170	135	89	138

Section 6 510(k) Division Level Metrics

Table 6.1 DCD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	340	410	411	405	464
Closed before RTA action	0	1	2	6	4
Number Accepted	151	192	279	282	339
Number without a RTA Review and > 15 Days since Date Received	9	10	5	13	5
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	180	207	125	104	116
Rate of submissions not accepted for filing review	52.94%	50.61%	30.56%	26.07%	25.22%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	439	403	402	391	447
Deleted or withdrawn prior to SI	1	2	1	4	2
SI within 60 FDA days	400	382	385	367	434
SI over 60 FDA days	38	19	16	20	11
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	91.32%	95.26%	96.01%	94.83%	97.53%

Table 6.3 DCD – 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	438	401	401	387	445
Average number of FDA days to Substantive Interaction	45.81	47.00	47.64	49.93	50.09
20th Percentile FDA days to Substantive Interaction	29	30	29	30	30
40th Percentile FDA days to Substantive Interaction	44	48	50	52	54
60th Percentile FDA days to Substantive Interaction	51	56	56	57	58
80th Percentile FDA days to Substantive Interaction	58	59	59	60	60
Maximum FDA days to Substantive Interaction	98	90	140	116	70

Table 6.4 DCD – 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	463	416	414	400	462
Non-MDUFA III Decisions	27	42	37	54	46
MDUFA III Decisions (SE/NSE)	436	374	377	346	411
MDUFA III Decisions within 90 FDA Days	421	369	365	336	408
510(k)s pending MDUFA III Decision	0	0	0	0	5
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	96.56%	98.66%	96.82%	97.11%	99.27%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.74	1.66	1.70	1.83	1.73
Number with MDUFA III decision	436	374	377	346	411
Average FDA days to MDUFA III decision	68.29	69.00	69.51	74.20	71.73
20th Percentile FDA days to MDUFA III decision	41	49	37	56	52
40th Percentile FDA days to MDUFA III decision	60	62	64	85	80
60th Percentile FDA days to MDUFA III decision	86	87	88	89	88
80th Percentile FDA days to MDUFA III decision	89	89	90	90	90
Maximum FDA days to MDUFA III decision	237	140	190	135	150
Average Industry days to MDUFA III decision	48.25	48.77	49.17	66.82	66.69
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	14	10	13	24	22
60th Percentile Industry days to MDUFA III decision	39	35	42	63	66
80th Percentile Industry days to MDUFA III decision	85	112	100	138	155
Maximum Industry days to MDUFA III decision	358	226	381	360	348
Average Total days to MDUFA III decision	116.54	117.76	118.68	141.02	138.42
20th Percentile Total days to MDUFA III decision	43	49	43	60	57
40th Percentile Total days to MDUFA III decision	87	89	90	106	101
60th Percentile Total days to MDUFA III decision	120	119	127	148	147
80th Percentile Total days to MDUFA III decision	175	197	190	225	232
Maximum Total days to MDUFA III decision	451	315	478	457	483

Table 6.6 DCD – 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	463	416	414	400	462
Number with MDUFA decision	436	374	377	346	411
Number of SE decisions	426	370	369	323	384
Number of NSE decisions	10	4	8	23	27
Number of Withdrawals	13	21	19	28	22
Number deleted	14	21	18	23	23
Rate of SE decisions	97.71%	98.93%	97.88%	93.35%	93.43%
Rate of NSE decisions	2.29%	1.07%	2.12%	6.65%	6.57%
Rate of Withdrawals	2.81%	5.05%	4.59%	7.00%	4.76%
Rate of Deleted	3.02%	5.05%	4.35%	5.75%	4.98%

Table 6.7 DCD – 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	12	10	3
Mean FDA days for submissions that missed goal	123	110	116	109	120
Mean industry days for submissions that missed goal	114	104	132	138	271

Section 6 510(k) Division Level Metrics

Table 6.1 DNPMD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	199	215	241	245	272
Closed before RTA action	0	0	0	1	1
Number Accepted	44	89	115	177	165
Number without a RTA Review and > 15 Days since Date Received	1	4	4	2	1
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	154	122	122	65	105
Rate of submissions not accepted for filing review	77.39%	56.74%	50.62%	26.64%	38.75%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	238	198	229	234	254
Deleted or withdrawn prior to SI	2	1	0	0	1
SI within 60 FDA days	205	189	227	227	253
SI over 60 FDA days	31	8	2	7	0
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	86.86%	95.94%	99.13%	97.01%	100%

Table 6.3 DNPMD – 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	236	197	229	234	253
Average number of FDA days to Substantive Interaction	51.72	54.37	54.45	54.06	53.37
20th Percentile FDA days to Substantive Interaction	42	53	53	51	51
40th Percentile FDA days to Substantive Interaction	54	58	57	57	58
60th Percentile FDA days to Substantive Interaction	58	59	59	59	59
80th Percentile FDA days to Substantive Interaction	60	60	60	60	60
Maximum FDA days to Substantive Interaction	84	87	62	151	60

Table 6.4 DNPMD – 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	245	202	236	238	258
Non-MDUFA III Decisions	33	43	35	51	25
MDUFA III Decisions (SE/NSE)	212	159	201	183	227
MDUFA III Decisions within 90 FDA Days	206	153	197	179	227
510(k)s pending MDUFA III Decision	0	0	0	4	6
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	97.17%	96.23%	98.01%	97.81%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.90	1.88	1.92	1.92	1.68
Number with MDUFA III decision	212	159	201	183	227
Average FDA days to MDUFA III decision	82.84	83.25	81.67	80.32	76.26
20th Percentile FDA days to MDUFA III decision	85	85	83	75	62
40th Percentile FDA days to MDUFA III decision	88	88	88	87	86
60th Percentile FDA days to MDUFA III decision	89	89	89	89	88
80th Percentile FDA days to MDUFA III decision	90	90	90	90	90
Maximum FDA days to MDUFA III decision	148	245	174	100	90
Average Industry days to MDUFA III decision	76.65	74.78	81.19	77.54	58.11
20th Percentile Industry days to MDUFA III decision	9	7	11	11	0
40th Percentile Industry days to MDUFA III decision	40	40	38	38	18
60th Percentile Industry days to MDUFA III decision	83	78	94	80	59
80th Percentile Industry days to MDUFA III decision	149	156	162	152	124
Maximum Industry days to MDUFA III decision	345	291	359	529	320
Average Total days to MDUFA III decision	159.50	158.03	162.86	157.86	134.37
20th Percentile Total days to MDUFA III decision	90	90	91	90	75
40th Percentile Total days to MDUFA III decision	125	126	126	120	99
60th Percentile Total days to MDUFA III decision	172	163	182	170	141
80th Percentile Total days to MDUFA III decision	238	250	250	242	209
Maximum Total days to MDUFA III decision	435	385	508	628	410

Table 6.6 DNPMD – 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	245	202	236	238	258
Number with MDUFA decision	212	159	201	183	227
Number of SE decisions	196	150	196	178	218
Number of NSE decisions	16	9	5	5	9
Number of Withdrawals	14	20	10	18	13
Number deleted	14	20	24	30	9
Rate of SE decisions	92.45%	94.34%	97.51%	97.27%	96.04%
Rate of NSE decisions	7.55%	5.66%	2.49%	2.73%	3.96%
Rate of Withdrawals	5.71%	9.90%	4.24%	7.56%	5.04%
Rate of Deleted	5.71%	9.90%	10.17%	12.61%	3.49%

Table 6.7 DNPMD – 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	4	4	0
Mean FDA days for submissions that missed goal	105	133	122	99	0
Mean industry days for submissions that missed goal	122	152	236	265	0

Section 6 510(k) Division Level Metrics

Table 6.1 DOD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	539	670	673	588	682
Closed before RTA action	0	1	3	4	0
Number Accepted	190	318	397	419	532
Number without a RTA Review and > 15 Days since Date Received	0	2	0	1	2
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	349	349	273	164	148
Rate of submissions not accepted for filing review	64.75%	52.17%	40.75%	28.08%	21.70%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	673	659	660	576	677
Deleted or withdrawn prior to SI	3	1	0	1	0
SI within 60 FDA days	639	641	642	566	654
SI over 60 FDA days	31	16	18	9	23
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	1	0	0	0
Current SI Performance Percent within 60 FDA days	95.37%	97.42%	97.27%	98.43%	96.60%

Table 6.3 DOD – 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	670	657	660	575	677
Average number of FDA days to Substantive Interaction	47.95	48.80	48.83	48.72	49.69
20th Percentile FDA days to Substantive Interaction	30	29	34	33	40
40th Percentile FDA days to Substantive Interaction	48	52	51	52	52
60th Percentile FDA days to Substantive Interaction	56	57	56	56	57
80th Percentile FDA days to Substantive Interaction	59	59	59	59	59
Maximum FDA days to Substantive Interaction	88	90	92	105	90

Table 6.4 DOD – 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	675	659	660	576	677
Non-MDUFA III Decisions	74	50	62	58	53
MDUFA III Decisions (SE/NSE)	601	609	598	518	622
MDUFA III Decisions within 90 FDA Days	597	607	596	513	613
510(k)s pending MDUFA III Decision	0	0	0	0	2
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	99.33%	99.67%	99.67%	99.03%	98.55%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.61	1.57	1.60	1.70	1.67
Number with MDUFA III decision	601	609	598	518	622
Average FDA days to MDUFA III decision	69.86	69.05	69.81	71.36	71.51
20th Percentile FDA days to MDUFA III decision	49	47	50	53	54
40th Percentile FDA days to MDUFA III decision	73	74	72	77	76
60th Percentile FDA days to MDUFA III decision	85	85	85	85	86
80th Percentile FDA days to MDUFA III decision	88	88	88	88	89
Maximum FDA days to MDUFA III decision	100	94	106	130	220
Average Industry days to MDUFA III decision	40.68	38.52	41.57	56.00	49.78
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	13	10
60th Percentile Industry days to MDUFA III decision	29	23	25	48	39
80th Percentile Industry days to MDUFA III decision	75	78	82	126	104
Maximum Industry days to MDUFA III decision	430	264	354	360	284
Average Total days to MDUFA III decision	110.55	107.57	111.38	127.35	121.29
20th Percentile Total days to MDUFA III decision	52	50	53	58	58
40th Percentile Total days to MDUFA III decision	85	84	86	90	88
60th Percentile Total days to MDUFA III decision	110	106	105	130	121
80th Percentile Total days to MDUFA III decision	163	162	164	209	183
Maximum Total days to MDUFA III decision	520	352	443	461	397

Table 6.6 DOD – 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	675	659	660	576	677
Number with MDUFA decision	601	609	598	518	622
Number of SE decisions	581	602	586	506	605
Number of NSE decisions	20	7	12	12	17
Number of Withdrawals	37	26	36	26	28
Number deleted	36	24	26	31	24
Rate of SE decisions	96.67%	98.85%	97.99%	97.68%	97.27%
Rate of NSE decisions	3.33%	1.15%	2.01%	2.32%	2.73%
Rate of Withdrawals	5.48%	3.95%	5.45%	4.51%	4.14%
Rate of Deleted	5.33%	3.64%	3.94%	5.38%	3.55%

Table 6.7 DOD – 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	2	5	9
Mean FDA days for submissions that missed goal	97	93	102	109	113
Mean industry days for submissions that missed goal	104	53	103	183	112

Section 6 510(k) Division Level Metrics

Table 6.1 DOED – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	117	141	144	133	132
Closed before RTA action	0	0	1	0	0
Number Accepted	56	74	79	100	101
Number without a RTA Review and > 15 Days since Date Received	5	2	1	1	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	56	65	63	32	31
Rate of submissions not accepted for filing review	47.86%	46.10%	44.06%	24.06%	23.48%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	137	136	139	130	126
Deleted or withdrawn prior to SI	0	1	0	0	3
SI within 60 FDA days	130	135	137	128	123
SI over 60 FDA days	7	0	2	2	0
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	94.89%	100.00%	98.56%	98.46%	100%

Table 6.3 DOED – 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	137	135	139	130	123
Average number of FDA days to Substantive Interaction	48.71	51.32	52.50	49.01	50.38
20th Percentile FDA days to Substantive Interaction	43	46	49	44	46
40th Percentile FDA days to Substantive Interaction	49	53	55	49	50
60th Percentile FDA days to Substantive Interaction	54	57	58	53	54
80th Percentile FDA days to Substantive Interaction	58	59	60	59	59
Maximum FDA days to Substantive Interaction	88	60	64	64	60

Table 6.4 DOED – 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	144	138	142	131	128
Non-MDUFA III Decisions	20	25	20	17	19
MDUFA III Decisions (SE/NSE)	124	113	122	114	109
MDUFA III Decisions within 90 FDA Days	121	112	122	114	109
510(k)s pending MDUFA III Decision	0	0	0	0	0
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	97.58%	99.12%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.86	1.80	1.73	1.81	1.66
Number with MDUFA III decision	124	113	122	114	109
Average FDA days to MDUFA III decision	74.98	78.62	76.26	76.30	72.32
20th Percentile FDA days to MDUFA III decision	56	62	57	58	50
40th Percentile FDA days to MDUFA III decision	83	87	86	86	78
60th Percentile FDA days to MDUFA III decision	88	89	88	89	86
80th Percentile FDA days to MDUFA III decision	90	90	90	90	89
Maximum FDA days to MDUFA III decision	91	98	90	90	90
Average Industry days to MDUFA III decision	64.18	57.73	57.30	54.05	48.86
20th Percentile Industry days to MDUFA III decision	0	0	0	3	0
40th Percentile Industry days to MDUFA III decision	21	19	15	21	8
60th Percentile Industry days to MDUFA III decision	62	42	48	56	32
80th Percentile Industry days to MDUFA III decision	163	117	133	96	102
Maximum Industry days to MDUFA III decision	250	333	180	189	181
Average Total days to MDUFA III decision	139.15	136.35	133.56	130.35	121.18
20th Percentile Total days to MDUFA III decision	68	74	64	69	55
40th Percentile Total days to MDUFA III decision	104	104	100	105	89
60th Percentile Total days to MDUFA III decision	135	132	134	141	116
80th Percentile Total days to MDUFA III decision	241	205	222	180	191
Maximum Total days to MDUFA III decision	332	423	270	279	271

Table 6.6 DOED – 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	144	138	142	131	128
Number with MDUFA decision	124	113	122	114	109
Number of SE decisions	119	106	111	109	103
Number of NSE decisions	5	7	11	5	6
Number of Withdrawals	8	6	10	6	11
Number deleted	11	17	9	10	8
Rate of SE decisions	95.97%	93.81%	90.98%	95.61%	94.50%
Rate of NSE decisions	4.03%	6.19%	9.02%	4.39%	5.50%
Rate of Withdrawals	5.56%	4.35%	7.04%	4.58%	8.59%
Rate of Deleted	7.64%	12.32%	6.34%	7.63%	6.25%

Table 6.7 DOED – 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	1	0	0	0
Mean FDA days for submissions that missed goal	91	98	0	0	0
Mean industry days for submissions that missed goal	123	187	0	0	0

Section 6 510(k) Division Level Metrics

Table 6.1 DRGUD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	222	287	272	282	328
Closed before RTA action	0	0	7	3	1
Number Accepted	71	148	190	214	260
Number without a RTA Review and > 15 Days since Date Received	0	7	2	2	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	151	132	73	63	67
Rate of submissions not accepted for filing review	68.02%	45.99%	27.55%	22.58%	20.49%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	279	280	250	270	316
Deleted or withdrawn prior to SI	1	3	1	1	0
SI within 60 FDA days	265	268	247	267	315
SI over 60 FDA days	11	8	2	2	0
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	2	1	0	0	1
Current SI Performance Percent within 60 FDA days	95.32%	96.75%	99.20%	99.26%	99.68%

Table 6.3 DRGUD – 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	276	276	249	269	315
Average number of FDA days to Substantive Interaction	48.13	48.94	48.60	49.85	50.16
20th Percentile FDA days to Substantive Interaction	35	38	38	42	43
40th Percentile FDA days to Substantive Interaction	50	50	49	51	50
60th Percentile FDA days to Substantive Interaction	56	57	56	57	57
80th Percentile FDA days to Substantive Interaction	58	59	59	59	59
Maximum FDA days to Substantive Interaction	73	100	87	67	60

Table 6.4 DRGUD – 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	292	286	254	275	323
Non-MDUFA III Decisions	43	37	25	43	50
MDUFA III Decisions (SE/NSE)	249	249	229	232	273
MDUFA III Decisions within 90 FDA Days	249	249	227	229	273
510(k)s pending MDUFA III Decision	0	0	0	0	0
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	100%	100%	99.13%	98.71%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.84	1.79	1.74	1.73	1.71
Number with MDUFA III decision	249	249	229	232	273
Average FDA days to MDUFA III decision	70.87	71.39	73.99	72.35	71.96
20th Percentile FDA days to MDUFA III decision	52	52	56	47	55
40th Percentile FDA days to MDUFA III decision	78	77	82	82	77
60th Percentile FDA days to MDUFA III decision	85	86	87	87	86
80th Percentile FDA days to MDUFA III decision	88	88	89	89	89
Maximum FDA days to MDUFA III decision	90	90	136	142	90
Average Industry days to MDUFA III decision	70.80	58.71	78.29	76.80	79.91
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	27	22	22	16	34
60th Percentile Industry days to MDUFA III decision	69	55	92	91	94
80th Percentile Industry days to MDUFA III decision	152	118	168	167	172
Maximum Industry days to MDUFA III decision	416	236	540	440	253
Average Total days to MDUFA III decision	141.67	130.10	152.28	149.15	151.86
20th Percentile Total days to MDUFA III decision	58	63	69	52	60
40th Percentile Total days to MDUFA III decision	107	103	101	97	113
60th Percentile Total days to MDUFA III decision	150	133	176	167	181
80th Percentile Total days to MDUFA III decision	237	202	250	255	253
Maximum Total days to MDUFA III decision	506	316	676	582	343

Table 6.6 DRGUD – 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	292	286	254	275	323
Number with MDUFA decision	249	249	229	232	273
Number of SE decisions	234	244	222	222	265
Number of NSE decisions	15	5	7	10	8
Number of Withdrawals	19	11	11	17	23
Number deleted	22	22	13	26	27
Rate of SE decisions	93.98%	97.99%	96.94%	95.69%	97.07%
Rate of NSE decisions	6.02%	2.01%	3.06%	4.31%	2.93%
Rate of Withdrawals	6.51%	3.85%	4.33%	6.18%	7.12%
Rate of Deleted	7.53%	7.69%	5.12%	9.45%	8.36%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	2	3	0
Mean FDA days for submissions that missed goal	0	0	124	112	0
Mean industry days for submissions that missed goal	0	0	433	208	0

Section 6 510(k) Division Level Metrics

Table 6.1 DSD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	329	453	482	451	500
Closed before RTA action	0	0	1	1	1
Number Accepted	121	194	295	342	357
Number without a RTA Review and > 15 Days since Date Received	3	10	5	0	1
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	205	249	181	108	141
Rate of submissions not accepted for filing review	62.31%	54.97%	37.63%	24.00%	28.26%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	423	429	462	433	472
Deleted or withdrawn prior to SI	3	0	0	1	3
SI within 60 FDA days	386	395	436	403	454
SI over 60 FDA days	34	34	26	27	14
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	2	1
Current SI Performance Percent within 60 FDA days	91.90%	92.07%	94.37%	93.29%	96.80%

Table 6.3 DSD – 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	420	429	462	430	468
Average number of FDA days to Substantive Interaction	44.53	50.29	51.27	50.64	49.96
20th Percentile FDA days to Substantive Interaction	27	35	42	42	36
40th Percentile FDA days to Substantive Interaction	43	53	55	53	54
60th Percentile FDA days to Substantive Interaction	55	57	58	57	57
80th Percentile FDA days to Substantive Interaction	59	60	60	59	59
Maximum FDA days to Substantive Interaction	90	90	93	89	90

Table 6.4 DSD – 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	428	437	473	436	478
Non-MDUFA III Decisions	83	79	87	62	77
MDUFA III Decisions (SE/NSE)	345	358	386	374	394
MDUFA III Decisions within 90 FDA Days	335	352	375	363	394
510(k)s pending MDUFA III Decision	0	0	0	0	7
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	97.10%	98.32%	97.15%	97.06%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.77	1.75	1.73	1.72	1.51
Number with MDUFA III decision	345	358	386	374	394
Average FDA days to MDUFA III decision	68.45	72.43	73.99	72.87	67.01
20th Percentile FDA days to MDUFA III decision	42	54	54	53	38
40th Percentile FDA days to MDUFA III decision	70	80	83	82	66
60th Percentile FDA days to MDUFA III decision	85	87	87	87	85
80th Percentile FDA days to MDUFA III decision	89	89	89	89	88
Maximum FDA days to MDUFA III decision	342	147	150	161	90
Average Industry days to MDUFA III decision	60.63	61.30	64.44	58.18	42.78
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	20	18	19	22	0
60th Percentile Industry days to MDUFA III decision	48	53	57	53	28
80th Percentile Industry days to MDUFA III decision	124	122	150	118	95
Maximum Industry days to MDUFA III decision	438	408	342	354	182
Average Total days to MDUFA III decision	129.08	133.74	138.42	131.05	109.79
20th Percentile Total days to MDUFA III decision	49	59	60	60	43
40th Percentile Total days to MDUFA III decision	92	95	98	97	84
60th Percentile Total days to MDUFA III decision	131	137	142	139	107
80th Percentile Total days to MDUFA III decision	203	211	237	198	173
Maximum Total days to MDUFA III decision	691	512	432	515	272

Table 6.6 DSD – 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	428	437	473	436	478
Number with MDUFA decision	345	358	386	374	394
Number of SE decisions	330	349	375	361	381
Number of NSE decisions	15	9	11	13	13
Number of Withdrawals	42	42	40	25	39
Number deleted	36	28	44	36	32
Rate of SE decisions	95.65%	97.49%	97.15%	96.52%	96.70%
Rate of NSE decisions	4.35%	2.51%	2.85%	3.48%	3.30%
Rate of Withdrawals	9.81%	9.61%	8.46%	5.73%	8.16%
Rate of Deleted	8.41%	6.41%	9.30%	8.26%	6.69%

Table 6.7 DSD – 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	6	11	11	0
Mean FDA days for submissions that missed goal	137	107	114	102	0
Mean industry days for submissions that missed goal	160	168	155	118	0

Section 6 510(k) Division Level Metrics

Table 6.1 DCTD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	187	196	193	177	165
Closed before RTA action	0	1	1	2	6
Number Accepted	118	127	156	142	113
Number without a RTA Review and > 15 Days since Date Received	0	1	1	3	11
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	69	67	35	30	35
Rate of submissions not accepted for filing review	36.90%	34.36%	18.23%	17.14%	22.01%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	247	184	181	163	142
Deleted or withdrawn prior to SI	0	0	0	2	1
SI within 60 FDA days	247	184	179	159	141
SI over 60 FDA days	0	0	2	2	0
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	100.0%	100.0%	98.90%	98.76%	100%

Table 6.3 DCTD – 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	181	161	141
Average number of FDA days to Substantive Interaction	41.03	42.67	43.84	48.24	45.78
20th Percentile FDA days to Substantive Interaction	29	30	29	37	30
40th Percentile FDA days to Substantive Interaction	38	43	42	47	45
60th Percentile FDA days to Substantive Interaction	45	47	49	53	51
80th Percentile FDA days to Substantive Interaction	52	54	58	58	57
Maximum FDA days to Substantive Interaction	60	60	65	129	60

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	247	184	181	164	142
Non-MDUFA III Decisions	34	35	31	39	38
MDUFA III Decisions (SE/NSE)	213	149	150	125	104
MDUFA III Decisions within 90 FDA Days	212	147	149	121	104
510(k)s pending MDUFA III Decision	0	0	0	0	0
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	99.53%	98.66%	99.33%	96.80%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.86	1.94	1.81	2.07	1.88
Number with MDUFA III decision	213	149	150	125	104
Average FDA days to MDUFA III decision	64.94	67.23	68.67	81.42	72.76
20th Percentile FDA days to MDUFA III decision	34	35	33	73	44
40th Percentile FDA days to MDUFA III decision	58	59	68	87	85
60th Percentile FDA days to MDUFA III decision	84	85	85	88	89
80th Percentile FDA days to MDUFA III decision	88	88	89	90	90
Maximum FDA days to MDUFA III decision	99	131	232	229	90
Average Industry days to MDUFA III decision	83.57	85.96	76.70	108.12	97.30
20th Percentile Industry days to MDUFA III decision	0	0	0	9	0
40th Percentile Industry days to MDUFA III decision	12	11	0	58	54
60th Percentile Industry days to MDUFA III decision	69	75	81	143	132
80th Percentile Industry days to MDUFA III decision	166	176	160	181	174
Maximum Industry days to MDUFA III decision	489	469	477	533	347
Average Total days to MDUFA III decision	148.51	153.19	145.37	189.54	170.06
20th Percentile Total days to MDUFA III decision	35	35	33	90	48
40th Percentile Total days to MDUFA III decision	87	84	85	143	141
60th Percentile Total days to MDUFA III decision	148	161	163	232	218
80th Percentile Total days to MDUFA III decision	245	264	242	269	262
Maximum Total days to MDUFA III decision	579	556	564	623	436

Table 6.6 DCTD – 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	181	164	142
Number with MDUFA decision	213	149	150	125	104
Number of SE decisions	207	148	145	114	102
Number of NSE decisions	6	1	5	11	2
Number of Withdrawals	17	20	13	16	19
Number deleted	17	15	18	22	15
Rate of SE decisions	97.18%	99.33%	96.67%	91.20%	98.08%
Rate of NSE decisions	2.82%	0.67%	3.33%	8.80%	1.92%
Rate of Withdrawals	6.88%	10.87%	7.18%	9.76%	13.38%
Rate of Deleted	6.88%	8.15%	9.94%	13.41%	10.56%

Table 6.7 DCTD – 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	1	4	0
Mean FDA days for submissions that missed goal	99	121	232	163	0
Mean industry days for submissions that missed goal	193	257	330	179	0

Section 6 510(k) Division Level Metrics

Table 6.1 DIHD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	55	73	61	65	70
Closed before RTA action	0	0	0	0	3
Number Accepted	38	57	50	60	61
Number without a RTA Review and > 15 Days since Date Received	3	1	2	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	14	15	9	5	6
Rate of submissions not accepted for filing review	25.45%	20.55%	14.75%	7.69%	8.96%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	69	66	58	63	65
Deleted or withdrawn prior to SI	0	0	1	0	2
SI within 60 FDA days	68	66	57	62	62
SI over 60 FDA days	1	0	0	1	1
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	98.55%	100%	100%	98.41%	98.41%

Table 6.3 DIHD – 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	66	57	63	63
Average number of FDA days to Substantive Interaction	47.62	50.38	52.04	51.92	54.38
20th Percentile FDA days to Substantive Interaction	41	46	43	49	55
40th Percentile FDA days to Substantive Interaction	50	51	57	57	58
60th Percentile FDA days to Substantive Interaction	54	57	59	59	59
80th Percentile FDA days to Substantive Interaction	58	59	60	60	60
Maximum FDA days to Substantive Interaction	63	60	60	62	61

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	69	66	58	63	65
Non-MDUFA III Decisions	22	22	13	8	11
MDUFA III Decisions (SE/NSE)	47	44	45	55	53
MDUFA III Decisions within 90 FDA Days	47	43	45	54	53
510(k)s pending MDUFA III Decision	0	0	0	0	1
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	100%	97.73%	100%	98.18%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.96	1.86	1.96	1.98	1.81
Number with MDUFA III decision	47	44	45	55	53
Average FDA days to MDUFA III decision	71.62	79.45	75.76	76.82	82.02
20th Percentile FDA days to MDUFA III decision	50	70	52	69	82
40th Percentile FDA days to MDUFA III decision	77	88	88	87	89
60th Percentile FDA days to MDUFA III decision	86	89	89	89	90
80th Percentile FDA days to MDUFA III decision	88	90	90	90	90
Maximum FDA days to MDUFA III decision	90	91	90	91	90
Average Industry days to MDUFA III decision	115.40	107.23	128.00	108.65	107.68
20th Percentile Industry days to MDUFA III decision	29	46	0	0	0
40th Percentile Industry days to MDUFA III decision	89	63	134	56	78
60th Percentile Industry days to MDUFA III decision	157	154	169	164	169
80th Percentile Industry days to MDUFA III decision	177	176	177	187	178
Maximum Industry days to MDUFA III decision	329	325	355	357	347
Average Total days to MDUFA III decision	187.02	186.68	203.76	185.47	189.70
20th Percentile Total days to MDUFA III decision	91	118	66	90	90
40th Percentile Total days to MDUFA III decision	151	143	212	137	158
60th Percentile Total days to MDUFA III decision	236	237	258	243	251
80th Percentile Total days to MDUFA III decision	264	266	267	276	266
Maximum Total days to MDUFA III decision	417	414	442	444	437

Table 6.6 DIHD – 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	66	58	63	65
Number with MDUFA decision	47	44	45	55	53
Number of SE decisions	43	37	45	55	51
Number of NSE decisions	4	7	0	0	2
Number of Withdrawals	6	8	6	2	4
Number deleted	14	13	6	6	7
Rate of SE decisions	91.49%	84.09%	100%	100%	96.23%
Rate of NSE decisions	8.51%	15.91%	0%	0%	3.77%
Rate of Withdrawals	8.70%	12.12%	10.34%	3.17%	6.15%
Rate of Deleted	20.29%	19.70%	10.34%	9.52%	10.77%

Table 6.7 DIHD – 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	1	0
Mean FDA days for submissions that missed goal	0	91	0	91	0
Mean industry days for submissions that missed goal	0	55	0	253	0

Section 6 510(k) Division Level Metrics

Table 6.1 DMD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	84	69	79	97
Closed before RTA action	0	0	1	1	3
Number Accepted	55	80	66	76	89
Number without a RTA Review and > 15 Days since Date Received	0	1	0	0	1
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	4	3	2	2	4
Rate of submissions not accepted for filing review	6.78%	3.57%	2.94%	2.56%	4.26%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	80	83	67	76	91
Deleted or withdrawn prior to SI	0	0	0	0	0
SI within 60 FDA days	79	82	67	76	91
SI over 60 FDA days	1	1	0	0	0
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	98.75%	98.80%	100%	100%	100%

Table 6.3 DMD – 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	76	91
Average number of FDA days to Substantive Interaction	43.11	47.63	48.34	49.18	52.36
20th Percentile FDA days to Substantive Interaction	28	29	31	29	49
40th Percentile FDA days to Substantive Interaction	39	51	55	54	56
60th Percentile FDA days to Substantive Interaction	53	56	57	56	57
80th Percentile FDA days to Substantive Interaction	57	59	59	58	59
Maximum FDA days to Substantive Interaction	61	61	60	60	60

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	80	83	67	76	91
Non-MDUFA III Decisions	9	7	7	7	3
MDUFA III Decisions (SE/NSE)	71	76	60	69	88
MDUFA III Decisions within 90 FDA Days	71	76	60	69	88
510(k)s pending MDUFA III Decision	0	0	0	0	0
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.31	1.46	1.50	1.48	1.26
Number with MDUFA III decision	71	76	60	69	88
Average FDA days to MDUFA III decision	58.48	65.83	67.03	72.68	76.31
20th Percentile FDA days to MDUFA III decision	29	36	35	42	60
40th Percentile FDA days to MDUFA III decision	55	72	71	82	84
60th Percentile FDA days to MDUFA III decision	78	81	84	88	88
80th Percentile FDA days to MDUFA III decision	81	86	87	89	90
Maximum FDA days to MDUFA III decision	89	90	90	90	90
Average Industry days to MDUFA III decision	31.55	52.45	59.98	57.36	26.39
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	0	0
60th Percentile Industry days to MDUFA III decision	0	24	36	56	0
80th Percentile Industry days to MDUFA III decision	65	131	157	154	39
Maximum Industry days to MDUFA III decision	180	349	358	181	206
Average Total days to MDUFA III decision	90.03	118.28	127.02	130.04	102.69
20th Percentile Total days to MDUFA III decision	29	36	35	47	62
40th Percentile Total days to MDUFA III decision	58	85	86	87	88
60th Percentile Total days to MDUFA III decision	81	97	120	144	90
80th Percentile Total days to MDUFA III decision	133	213	231	243	125
Maximum Total days to MDUFA III decision	267	434	447	270	294

Table 6.6 DMD – 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	76	91
Number with MDUFA decision	71	76	60	69	88
Number of SE decisions	71	73	58	67	88
Number of NSE decisions	0	3	2	2	0
Number of Withdrawals	6	5	6	4	2
Number deleted	3	2	1	3	0
Rate of SE decisions	100%	96.05%	96.67%	97.10%	100%
Rate of NSE decisions	0%	3.95%	3.33%	2.90%	0%
Rate of Withdrawals	7.50%	6.02%	8.96%	5.26%	2.20%
Rate of Deleted	3.75%	2.41%	1.49%	3.95%	0%

Table 6.7 DMD – 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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	0	0	0	0

Section 6 510(k) Division Level Metrics

Table 6.1 DMGP – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	17	9	5	4	13
Closed before RTA action	0	0	0	0	0
Number Accepted	14	9	4	4	11
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	2
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	3	0	1	0	0
Rate of submissions not accepted for filing review	17.65%	0%	20.00%	0%	0%

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

Table 6.2 DMGP – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	18	9	5	4	13
Deleted or withdrawn prior to SI	0	0	0	0	1
SI within 60 FDA days	18	9	5	4	12
SI over 60 FDA days	0	0	0	0	0
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	100%	100%	100%	100%	100%

Table 6.3 DMGP – 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	4	12
Average number of FDA days to Substantive Interaction	51.72	45.78	44.60	43.00	49.54
20th Percentile FDA days to Substantive Interaction	44	29	30	33	40
40th Percentile FDA days to Substantive Interaction	55	47	41	39	58
60th Percentile FDA days to Substantive Interaction	58	56	52	46	58
80th Percentile FDA days to Substantive Interaction	59	58	57	53	59
Maximum FDA days to Substantive Interaction	60	60	58	58	59

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	18	9	5	4	13
Non-MDUFA III Decisions	4	2	4	1	3
MDUFA III Decisions (SE/NSE)	14	7	1	3	10
MDUFA III Decisions within 90 FDA Days	14	7	1	3	10
510(k)s pending MDUFA III Decision	0	0	0	0	0
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	2.36	1.57	3.00	2.00	1.70
Number with MDUFA III decision	14	7	1	3	10
Average FDA days to MDUFA III decision	83.71	78.14	90.00	69.00	66.80
20th Percentile FDA days to MDUFA III decision	81	79	90	53	27
40th Percentile FDA days to MDUFA III decision	88	88	90	76	82
60th Percentile FDA days to MDUFA III decision	88	89	90	88	87
80th Percentile FDA days to MDUFA III decision	89	90	90	89	88
Maximum FDA days to MDUFA III decision	90	90	90	90	90
Average Industry days to MDUFA III decision	151.93	81.71	164.00	177.33	94.90
20th Percentile Industry days to MDUFA III decision	26	0	164	72	0
40th Percentile Industry days to MDUFA III decision	166	16	164	144	0
60th Percentile Industry days to MDUFA III decision	175	122	164	214	113
80th Percentile Industry days to MDUFA III decision	233	177	164	283	193
Maximum Industry days to MDUFA III decision	320	179	164	352	266
Average Total days to MDUFA III decision	235.64	159.86	254.00	246.33	161.70
20th Percentile Total days to MDUFA III decision	103	80	254	125	27
40th Percentile Total days to MDUFA III decision	255	106	254	220	83
60th Percentile Total days to MDUFA III decision	263	211	254	303	202
80th Percentile Total days to MDUFA III decision	317	266	254	372	282
Maximum Total days to MDUFA III decision	408	267	254	442	352

Table 6.6 DMGP – 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	4	13
Number with MDUFA decision	14	7	1	3	10
Number of SE decisions	11	6	1	2	10
Number of NSE decisions	3	1	0	1	0
Number of Withdrawals	3	2	4	1	3
Number deleted	1	0	0	0	0
Rate of SE decisions	78.57%	85.71%	100%	66.67%	100%
Rate of NSE decisions	21.43%	14.29%	0%	33.33%	0%
Rate of Withdrawals	16.67%	22.22%	80.00%	25.00%	23.08%
Rate of Deleted	5.56%	0%	0%	0%	0%

Table 6.7 DMGP – 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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	0	0	0	0

Section 6 510(k) Division Level Metrics

Table 6.1 DRH – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	260	373	335	365	410
Closed before RTA action	0	0	0	1	3
Number Accepted	153	278	271	308	347
Number without a RTA Review and > 15 Days since Date Received	15	5	1	1	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	92	90	63	55	60
Rate of submissions not accepted for filing review	35.38%	24.13%	18.81%	15.11%	14.74%

* 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 – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goal	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	354	364	330	360	403
Deleted or withdrawn prior to SI	47	46	44	43	45
SI within 60 FDA days	31	30	29	28	29
SI over 60 FDA days	44	44	44	43	46
SI pending within 60 FDA days	56	54.8	51	50	52
SI pending over 60 FDA days	59.4	59	57	57	57
510(k)s NSE without SI	91	93	70	60	61
Current SI Performance Percent within 60 FDA days	13.74%	13.27%	14.50%	14.89%	15.03%

Table 6.3 DRH – 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	354	364	330	360	403
Average number of FDA days to Substantive Interaction	47.47	45.76	44.41	43.04	44.56
20th Percentile FDA days to Substantive Interaction	31	30	29	28	29
40th Percentile FDA days to Substantive Interaction	44	44	44	43	46
60th Percentile FDA days to Substantive Interaction	56	55	51	50	52
80th Percentile FDA days to Substantive Interaction	59	59	57	57	57
Maximum FDA days to Substantive Interaction	91	93	70	60	61

Table 6.4 DRH – 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	409	401	363	403	437
Non-MDUFA III Decisions	17	10	12	14	17
MDUFA III Decisions (SE/NSE)	392	391	351	389	412
MDUFA III Decisions within 90 FDA Days	386	379	350	389	412
510(k)s pending MDUFA III Decision	0	0	0	0	8
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	98.47%	96.93%	99.72%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.61	1.64	1.61	1.65	1.66
Number with MDUFA III decision	392	391	351	389	412
Average FDA days to MDUFA III decision	62.19	63.12	58.91	57.08	59.03
20th Percentile FDA days to MDUFA III decision	35	30	29	28	28
40th Percentile FDA days to MDUFA III decision	56	58	56	53	55
60th Percentile FDA days to MDUFA III decision	78	79	72	70	76
80th Percentile FDA days to MDUFA III decision	88	88	81	81	83
Maximum FDA days to MDUFA III decision	121	137	91	90	90
Average Industry days to MDUFA III decision	36.41	35.49	38.28	38.15	48.11
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	0	0
60th Percentile Industry days to MDUFA III decision	21	26	25	27	26
80th Percentile Industry days to MDUFA III decision	62	62	67	64	86
Maximum Industry days to MDUFA III decision	358	346	319	348	368
Average Total days to MDUFA III decision	98.60	98.61	97.20	95.23	107.14
20th Percentile Total days to MDUFA III decision	37	32	30	29	30
40th Percentile Total days to MDUFA III decision	72	77	60	62	62
60th Percentile Total days to MDUFA III decision	90	101	96	98	100
80th Percentile Total days to MDUFA III decision	137	141	146	138	162
Maximum Total days to MDUFA III decision	466	428	406	438	456

Table 6.6 DRH – 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	409	401	363	403	437
Number with MDUFA decision	392	391	351	389	412
Number of SE decisions	382	384	339	385	407
Number of NSE decisions	10	7	12	4	5
Number of Withdrawals	10	3	4	7	5
Number deleted	7	6	8	7	11
Rate of SE decisions	97.45%	98.21%	96.58%	98.97%	98.79%
Rate of NSE decisions	2.55%	1.79%	3.42%	1.03%	1.21%
Rate of Withdrawals	2.44%	0.75%	1.10%	1.74%	1.14%
Rate of Deleted	1.71%	1.50%	2.20%	1.74%	2.52%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	6	12	1	0	0
Mean FDA days for submissions that missed goal	104	98	91	0	0
Mean industry days for submissions that missed goal	135	37	13	0	0

Section 7 510(k) Annual General Metrics

Table 7.1 CDRH – 510(k) Annual General Metrics – 510(k)s Received by Type

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	3,866	3,610	3,569	3,473	3,841
Number of Traditional submissions	3,035	2,903	2,921	2,815	3,186
Number of Special submissions	577	524	488	489	486
Number of Abbreviated submissions	126	99	75	89	82
Average number of days to Accept / Refuse to Accept	10.76	10.11	9.87	10.00	10.25
Number of Third Party submissions	128	84	85	80	87

Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	135 calendar days	135 calendar days	130 calendar days	130 calendar days	124 calendar days
Number Accepted	3,866	3,610	3,569	3,473	3,841
Currently Under Review	0	0	0	6	57
Number with Non-MDUFA Decision	530	466	434	458	439
Number with MDUFA III Decision	3,336	3,144	3,135	3,009	3,345
Percent of cohort closed	100%	100%	100%	100%	98.32%
Number with MDUFA III decision after trimming the upper and lower 2%	3,190	3,004	2,989	2,874	N/A
Average Total Time to MDUFA III decision	123	125	131	138	N/A

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Section 8 De Novo Requests

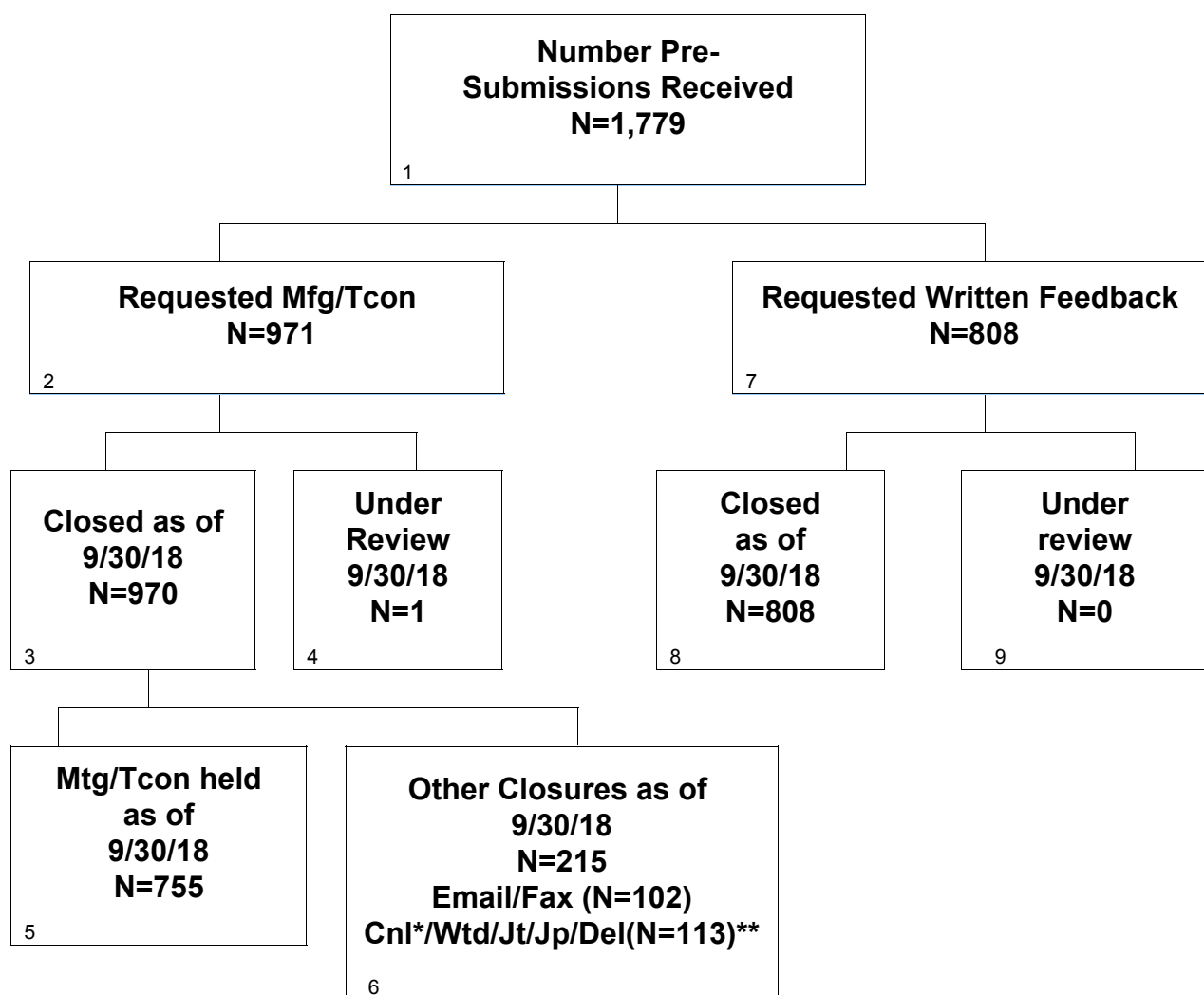
Table 8.1 CDRH – Annual General Metric Report for De Novo Requests

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of De Novo Requests Received	46	42	59	54	99
Number of De Novo Requests with Decision	46	42	59	54	88
Number of De Novo Requests with Decision Pending	0	0	0	0	11
Average Number of Days to Decision	258.35	273.00	277.81	243.39	141.59

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CDRH Pre-Submissions - FY 2013

As of 9/30/18

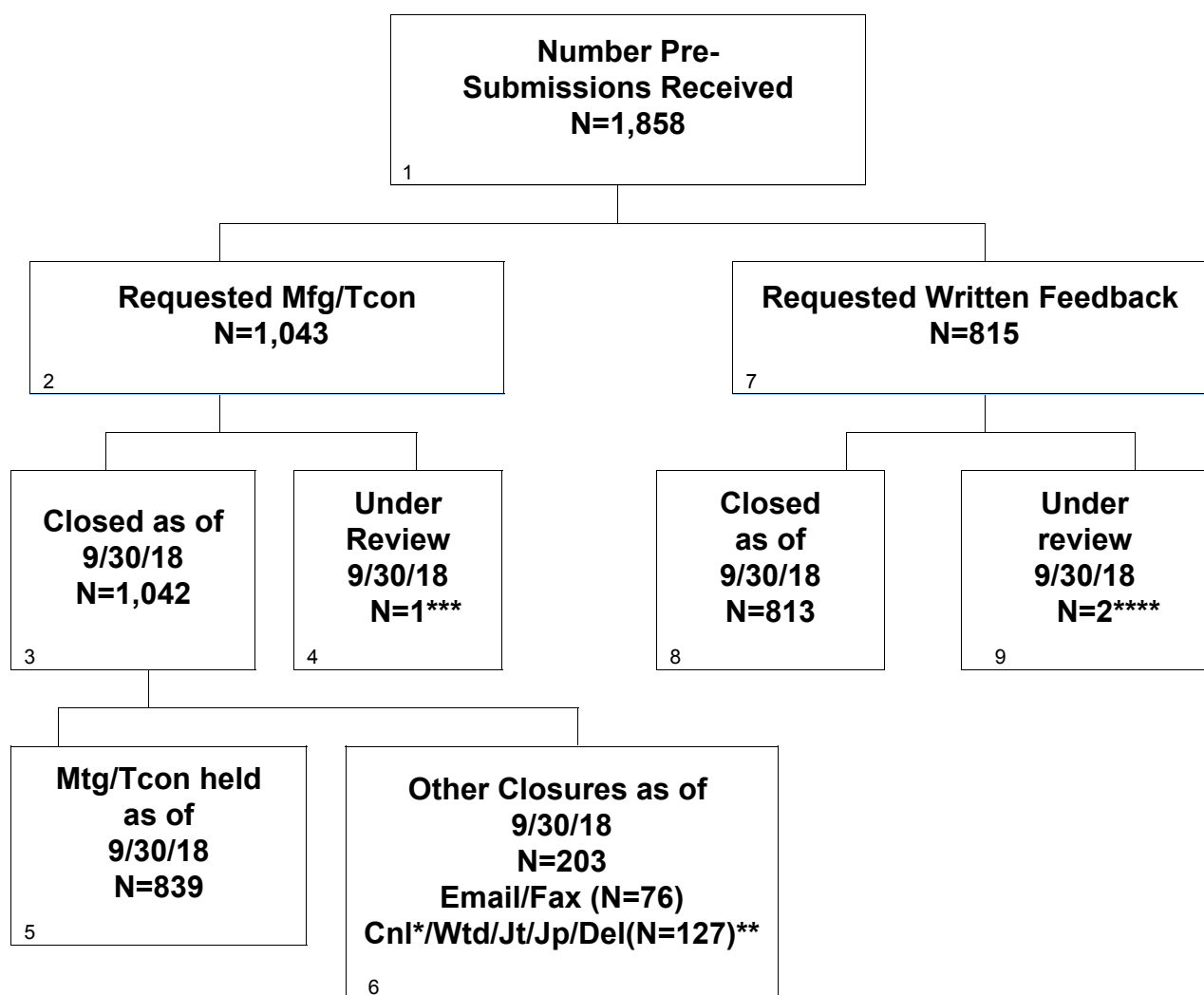


*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

**Cnl/Wtd/Jt/Jp/Del= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending / Deleted Due to No RTA Response

CDRH Pre-Submissions - FY 2014

As of 9/30/18



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

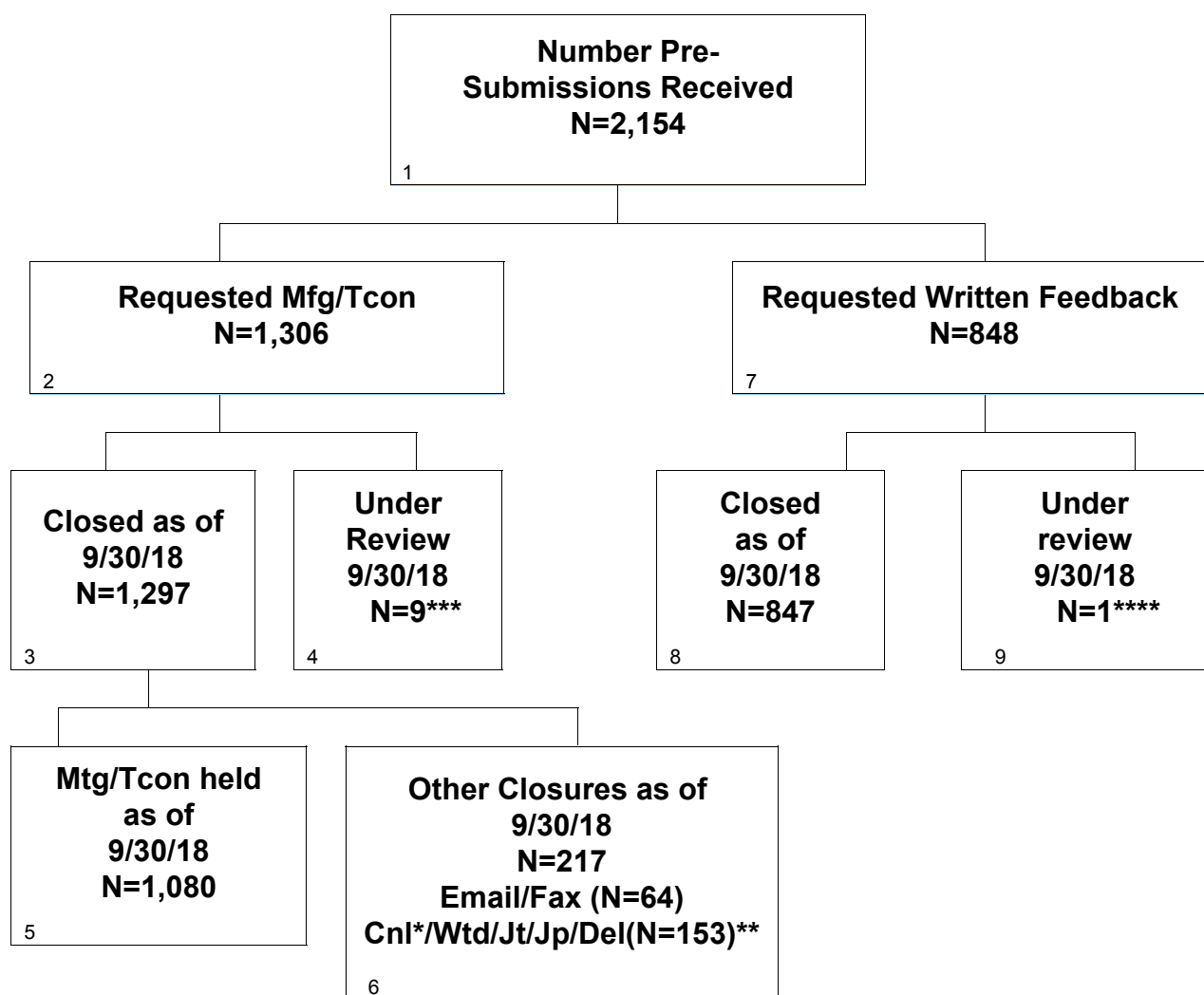
**Cnl/Wtd/Jt/Jp/Del= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending / Deleted Due to No RTA Response

***Includes 1 Pre-Submission on RTA Hold as of 09/30/2018

****Includes 2 Pre-Submissions on RTA Hold as of 09/30/2018

CDRH Pre-Submissions - FY 2015

As of 9/30/18



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

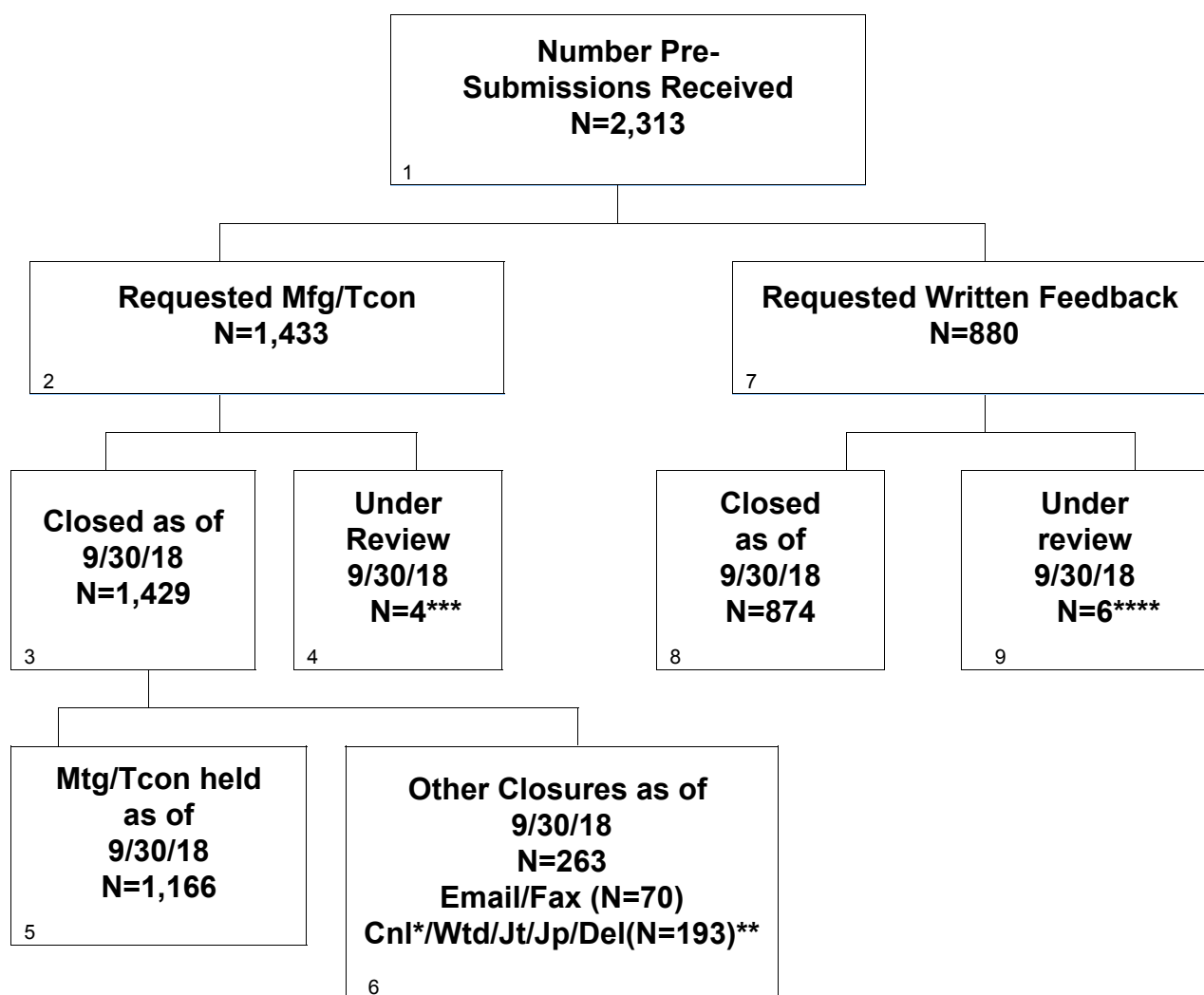
**Cnl/Wtd/Jt/Jp/Del= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending / Deleted Due to No RTA Response

***Includes 4 Pre-Submissions on RTA Hold as of 09/30/2018

****Includes 1 Pre-Submission on RTA Hold as of 09/30/2018

CDRH Pre-Submissions - FY 2016

As of 9/30/18



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

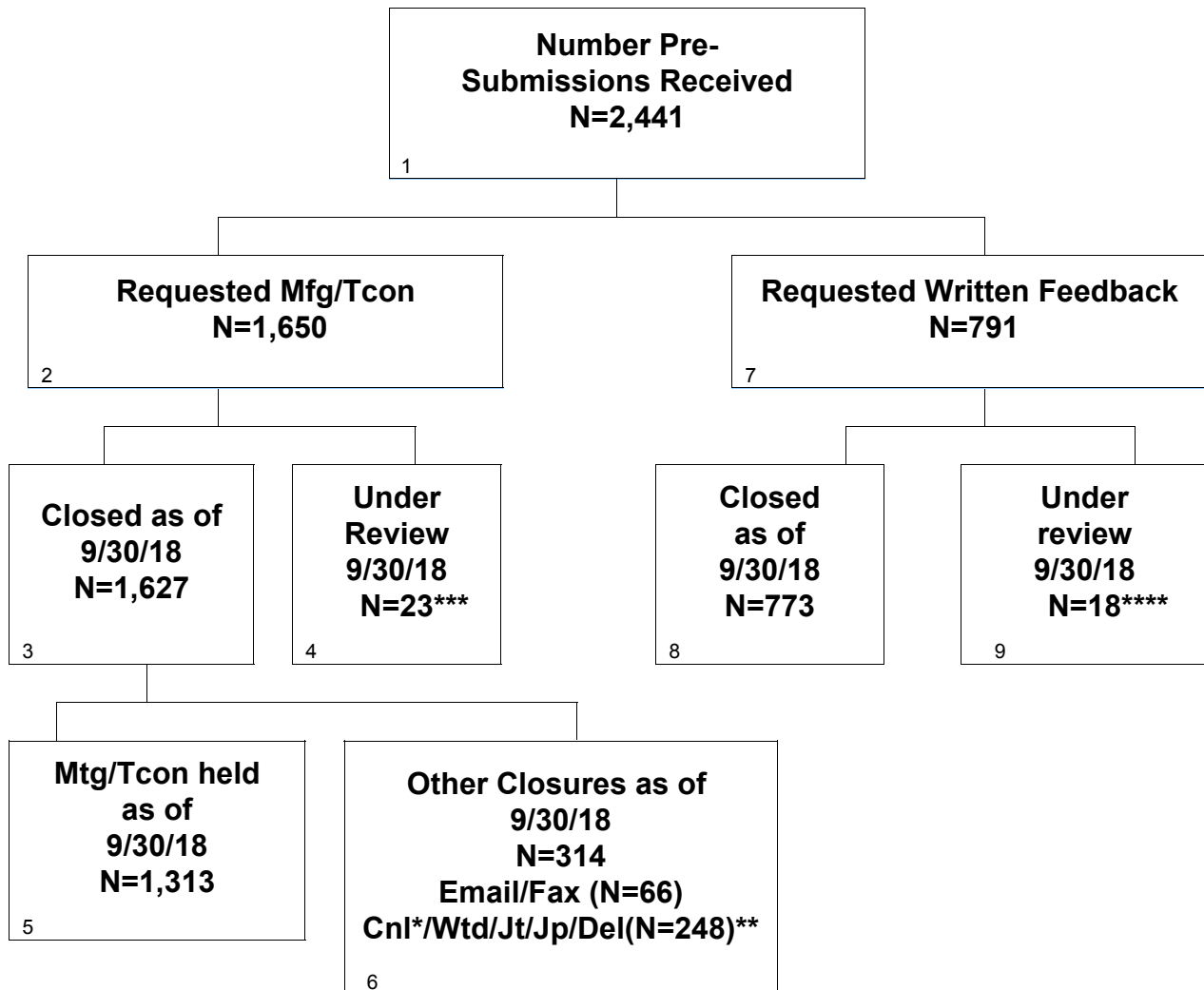
**Cnl/Wtd/Jt/Jp/Del= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending / Deleted Due to No RTA Response

***Includes 2 Pre-Submissions on RTA Hold as of 09/30/2018

****Includes 5 Pre-Submissions on RTA Hold as of 09/30/2018

CDRH Pre-Submissions - FY 2017

As of 9/30/18



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

**Cnl/Wtd/Jt/Jp/Del= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending / Deleted Due to No RTA Response

***Includes 17 Pre-Submissions on RTA Hold as of 09/30/2018

****Includes 14 Pre-Submissions on RTA Hold as of 09/30/2018

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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	2,313	2,441
Number requesting a meeting or teleconference	971	1,043	1,306	1,433	1,650
Number with meetings or teleconferences held	755	839	1,080	1,166	1,313
Average days to meeting	59.24	64.99	65.78	69.07	69.46
20th Percentile days to meeting	38	48	51	55	56
40th Percentile days to meeting	55	62	64	66	66
60th Percentile days to meeting	66	70	70	72	72
80th Percentile days to meeting	77	78	78	82	81
Maximum days to meeting	183	243	249	221	250

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	1,138	1,347	1,473	1,592
Number requesting a meeting or teleconference	611	696	858	944	1,089
Number with meetings or teleconferences held	455	554	693	761	862
Average days to meeting	61.77	67.79	68.88	71.27	71.44
20th Percentile days to meeting	40	49	52	54	56
40th Percentile days to meeting	57	63	66	67	68
60th Percentile days to meeting	67	72	73	74	74
80th Percentile days to meeting	79	83	82	84	84
Maximum days to meeting	183	243	249	221	250

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	720	807	840	849
Number requesting a meeting or teleconference	360	347	448	489	561
Number with meetings or teleconferences held	300	285	387	405	451
Average days to meeting	55.43	59.55	60.24	64.90	65.69
20th Percentile days to meeting	37	46	51	56	56
40th Percentile days to meeting	53	60	62	65	65
60th Percentile days to meeting	63	68	68	70	70
80th Percentile days to meeting	71	72	71	75	74
Maximum days to meeting	138	115	112	203	146

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	159	205	229	306	312
Number requesting a meeting or teleconference	85	109	134	177	197
Number with meetings or teleconferences held	59	82	103	143	149
Average days to meeting	68.40	70.68	74.74	79.52	77.17
20th Percentile days to meeting	52	55	64	66	62
40th Percentile days to meeting	66	65	70	74	72
60th Percentile days to meeting	75	75	77	82	79
80th Percentile days to meeting	83	85	86	92	88
Maximum days to meeting	121	149	179	200	181

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	306	375	390	446	463
Number requesting a meeting or teleconference	212	237	264	290	295
Number with meetings or teleconferences held	172	201	224	229	244
Average days to meeting	55.86	59.47	57.55	59.86	61.91
20th Percentile days to meeting	35	44	43	44	44
40th Percentile days to meeting	49	54	52	54	56
60th Percentile days to meeting	62	66	63	63	64
80th Percentile days to meeting	74	74	71	73	78
Maximum days to meeting	134	140	218	221	191

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	116	149	131	165
Number requesting a meeting or teleconference	50	71	105	106	133
Number with meetings or teleconferences held	31	48	90	80	107
Average days to meeting	72.48	88.75	82.22	83.15	85.41
20th Percentile days to meeting	47	67	67	64	69
40th Percentile days to meeting	65	78	76	74	76
60th Percentile days to meeting	77	90	84	83	85
80th Percentile days to meeting	92	113	95	96	103
Maximum days to meeting	163	243	249	179	250

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	101	103	127	113	121
Number requesting a meeting or teleconference	64	71	84	81	80
Number with meetings or teleconferences held	41	62	67	68	55
Average days to meeting	60.51	75.44	70.72	71.47	74.09
20th Percentile days to meeting	45	62	59	58	66
40th Percentile days to meeting	57	71	69	69	70
60th Percentile days to meeting	68	77	77	75	73
80th Percentile days to meeting	77	90	82	83	85
Maximum days to meeting	129	158	126	173	149

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	85	70	110	115	140
Number requesting a meeting or teleconference	47	45	77	74	109
Number with meetings or teleconferences held	34	33	56	63	91
Average days to meeting	66.85	75.61	74.45	77.73	73.99
20th Percentile days to meeting	54	66	65	70	67
40th Percentile days to meeting	65	69	73	75	70
60th Percentile days to meeting	71	73	77	83	76
80th Percentile days to meeting	83	86	83	87	84
Maximum days to meeting	118	146	99	125	146

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	128	137	159	170	185
Number requesting a meeting or teleconference	75	85	89	95	125
Number with meetings or teleconferences held	59	68	71	78	99
Average days to meeting	60.52	60.93	71.46	67.85	68.42
20th Percentile days to meeting	47	45	56	55	58
40th Percentile days to meeting	60	59	69	67	67
60th Percentile days to meeting	67	69	73	73	71
80th Percentile days to meeting	72	75	85	77	78
Maximum days to meeting	132	119	129	127	158

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	132	183	192	206
Number requesting a meeting or teleconference	78	78	105	121	150
Number with meetings or teleconferences held	59	60	82	100	117
Average days to meeting	65.77	70.63	70.27	74.68	70.40
20th Percentile days to meeting	41	62	59	61	62
40th Percentile days to meeting	63	69	67	69	69
60th Percentile days to meeting	71	76	70	73	72
80th Percentile days to meeting	80	87	78	84	80
Maximum days to meeting	183	111	189	162	132

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	180	232	225	231
Number requesting a meeting or teleconference	108	101	151	143	170
Number with meetings or teleconferences held	91	89	137	125	150
Average days to meeting	51.30	57.64	55.36	62.37	64.65
20th Percentile days to meeting	36	42	38	52	54
40th Percentile days to meeting	49	55	57	61	65
60th Percentile days to meeting	59	65	65	67	70
80th Percentile days to meeting	68	70	70	72	73
Maximum days to meeting	90	113	97	203	105

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	128	119	137	126
Number requesting a meeting or teleconference	66	71	66	87	91
Number with meetings or teleconferences held	54	66	66	76	74
Average days to meeting	61.11	64.28	67.35	72.17	75.18
20th Percentile days to meeting	41	56	61	64	66
40th Percentile days to meeting	64	66	66	71	71
60th Percentile days to meeting	70	71	70	74	73
80th Percentile days to meeting	81	73	73	80	81
Maximum days to meeting	99	87	111	113	143

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	233	204	213	214	212
Number requesting a meeting or teleconference	58	48	63	80	95
Number with meetings or teleconferences held	49	28	44	59	59
Average days to meeting	52.57	60.39	61.11	63.84	65.58
20th Percentile days to meeting	42	43	53	56	62
40th Percentile days to meeting	51	56	63	67	67
60th Percentile days to meeting	61	68	67	71	71
80th Percentile days to meeting	67	77	72	74	74
Maximum days to meeting	81	91	112	104	95

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	146	154	171	188	199
Number requesting a meeting or teleconference	83	90	118	122	147
Number with meetings or teleconferences held	70	70	102	102	117
Average days to meeting	63.01	58.14	61.58	65.69	65.62
20th Percentile days to meeting	44	41	50	57	57
40th Percentile days to meeting	56	60	63	66	64
60th Percentile days to meeting	66	68	69	70	71
80th Percentile days to meeting	83	72	72	75	74
Maximum days to meeting	138	115	94	121	146

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	72	76	81
Number requesting a meeting or teleconference	45	37	50	57	58
Number with meetings or teleconferences held	36	32	38	43	51
Average days to meeting	46.72	57.53	60.89	58.98	55.29
20th Percentile days to meeting	31	47	55	47	47
40th Percentile days to meeting	43	59	61	56	54
60th Percentile days to meeting	57	68	65	65	60
80th Percentile days to meeting	63	72	70	70	65
Maximum days to meeting	98	107	91	89	87

Section 10 CLIA Waiver Annual Metrics

Table 10.1.CDRH – CLIA Waiver Substantive Interaction Performance Goals

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	3	14	11	9	7
Withdrawn prior to SI	0	1	1	0	3
SI within 90 FDA days	2	13	10	9	4
SI over 90 FDA days	0	0	0	0	0
SI pending within 90 FDA days	0	0	0	0	0
SI pending over 90 FDA days	0	0	0	0	0
Denial without SI	1	0	0	0	0
Current SI Performance Percent within 90 FDA days	67%	100%	100%	100%	100%

Table 10.2.CDRH – CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2	13	10	9	4
Average number of FDA days to Substantive Interaction	73.5	69.9	77.5	81.9	89.0
20th Percentile FDA days to Substantive Interaction	73	56	79	82	88
40th Percentile FDA days to Substantive Interaction	73	78	87	87	89
60th Percentile FDA days to Substantive Interaction	74	83	88	87	90
80th Percentile FDA days to Substantive Interaction	74	86	89	89	90
Maximum FDA days to Substantive Interaction	74	90	90	90	90

Table 10.3.CDRH – CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
CLIA Waiver Applications accepted	3	14	11	9	7
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	3	14	11	9	7
MDUFA III Decisions within 180 FDA Days	3	14	11	9	7
CLIA Waiver Applications pending MDUFA III Decision	0	0	0	0	0
CLIA Waiver Applications pending MDUFA III Decision over 180 FDA days	0	0	0	0	0
Current Performance Percent within 180 FDA Days	100%	100%	100%	100%	100%

Table 10.4.CDRH – CLIA Waiver with Panel Review MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
CLIA Waiver Applications accepted	0	0	0	0	0
Non-MDUFA III Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA III Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA III Decisions within 330 FDA Days	N/A	N/A	N/A	N/A	N/A
CLIA Waiver Applications pending MDUFA III Decision	N/A	N/A	N/A	N/A	N/A
CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent within 330 FDA Days	N/A	N/A	N/A	N/A	N/A

Table 10.5.CDRH – CLIA Waiver (without Panel Review) Time to MDUFA Decision

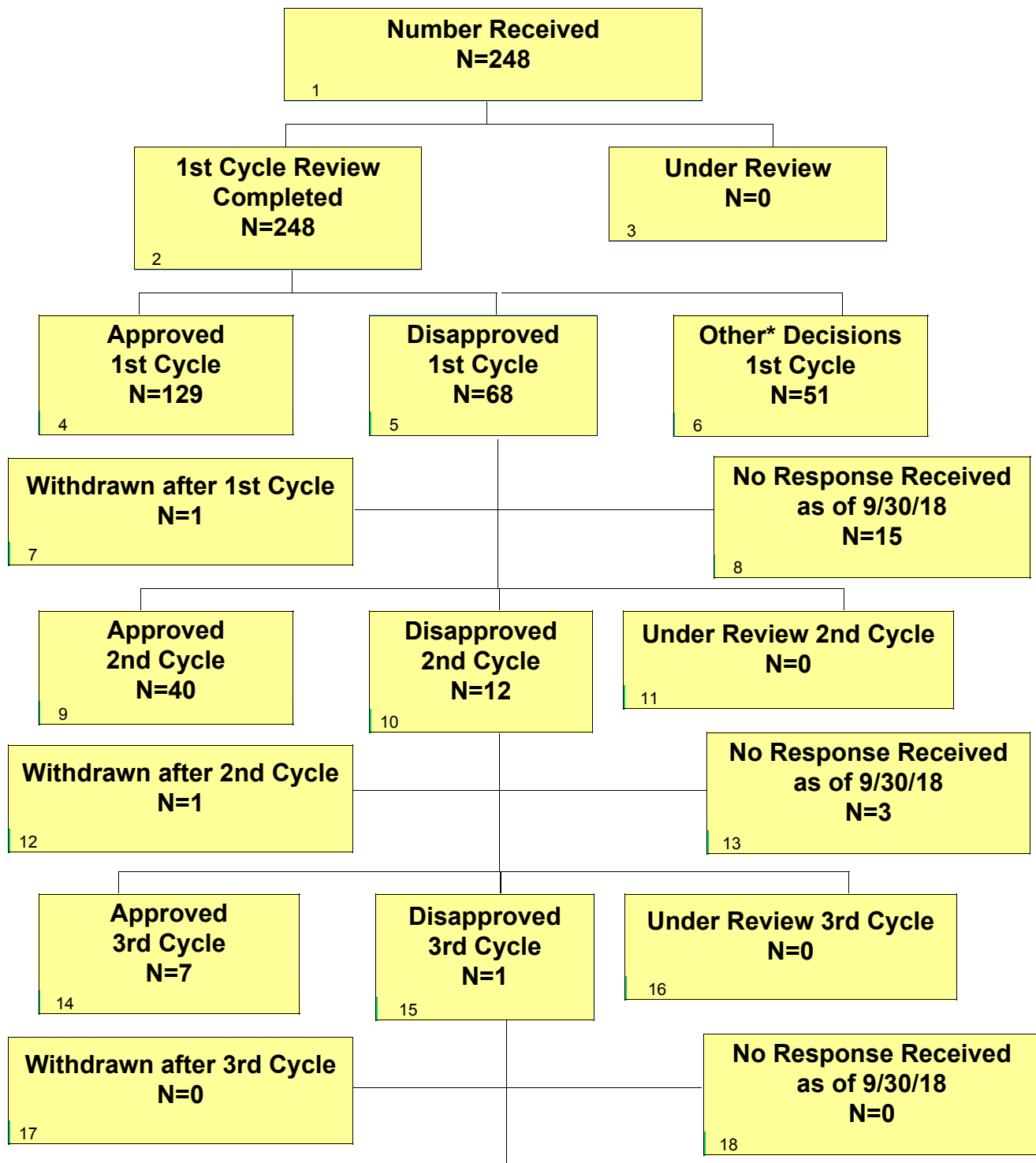
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	3	14	11	9	7
Average FDA days to MDUFA III decision	102.7	118.6	122.4	118.4	113.9
20th Percentile FDA days to MDUFA III decision	66	80	58	83	76
40th Percentile FDA days to MDUFA III decision	71	104	104	88	106
60th Percentile FDA days to MDUFA III decision	94	135	171	121	139
80th Percentile FDA days to MDUFA III decision	133	177	173	180	159
Maximum FDA days to MDUFA III decision	173	179	180	180	171
Average Industry days to MDUFA III decision	59.0	46.1	88.1	64.0	9.1
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	0	0	0	0
60th Percentile Industry days to MDUFA III decision	35	21	98	58.4	0
80th Percentile Industry days to MDUFA III decision	106	60	180	157.8	0
Maximum Industry days to MDUFA III decision	177	274	317	180	64
Average Total days to MDUFA III decision	161.7	164.7	210.5	182.4	123.0
20th Percentile Total days to MDUFA III decision	66	80	104	83	76
40th Percentile Total days to MDUFA III decision	71	131	171	139	112
60th Percentile Total days to MDUFA III decision	129	177	238	238	156
80th Percentile Total days to MDUFA III decision	240	197	278	268	169
Maximum Total days to MDUFA III decision	350	453	489	323	193

Table 10.6.CDRH – CLIA Waiver (with Panel Review) Time to MDUFA Decision

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

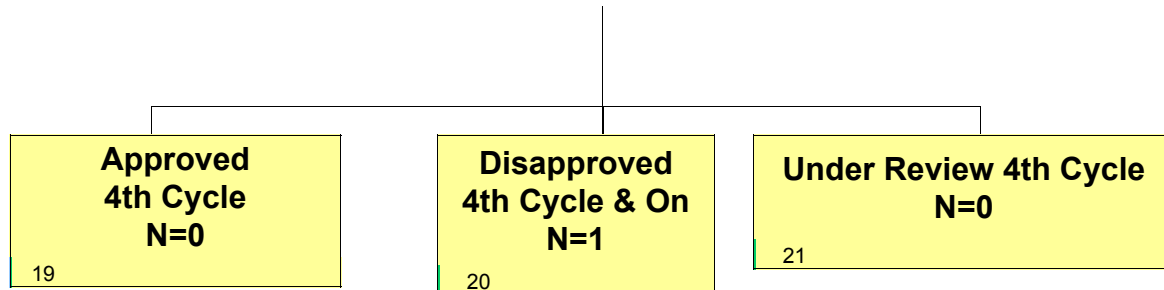
CDRH IDEs - FY 2014

As of 9/30/18



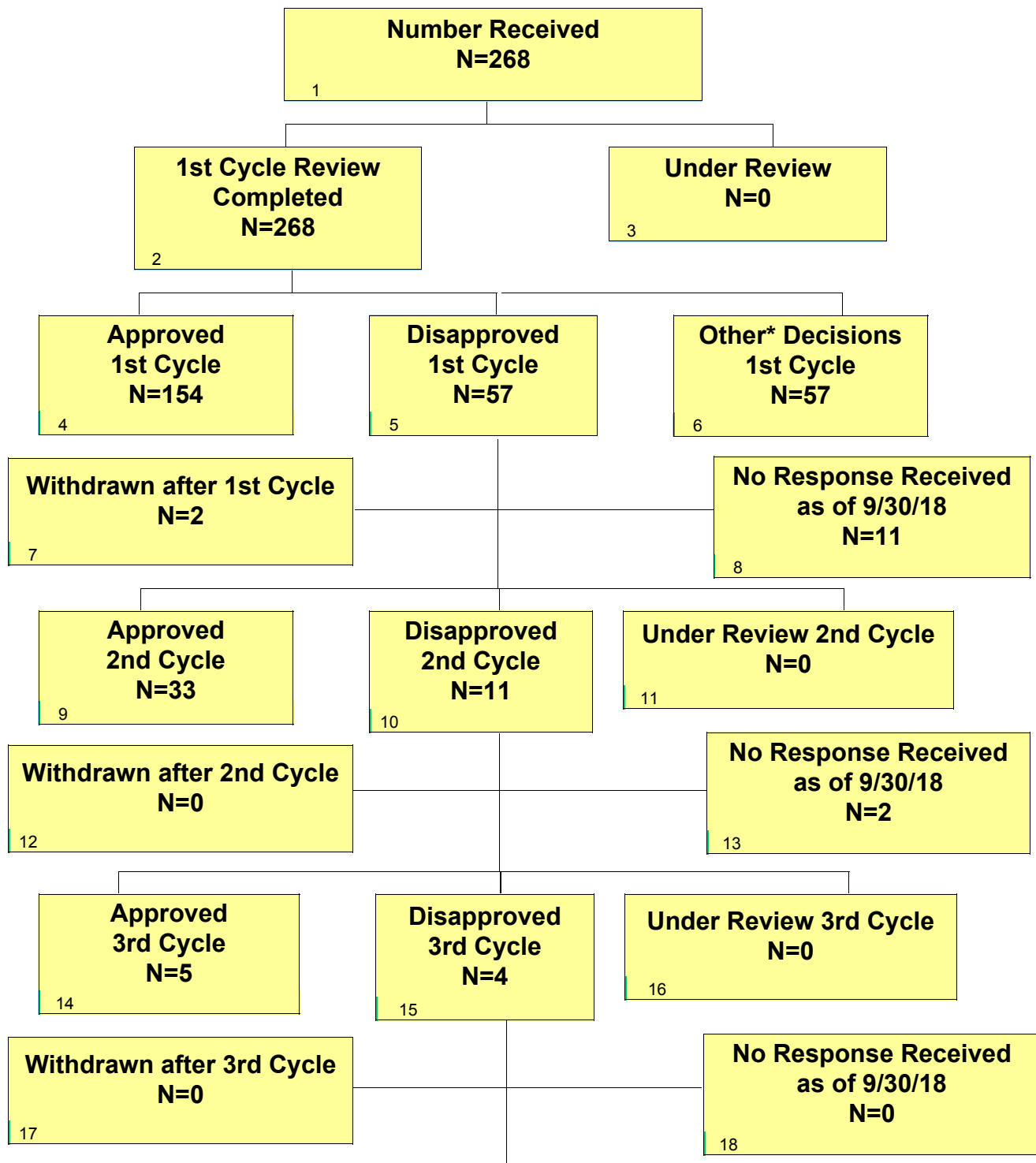
* Other decisions include withdrawn (N=34), RTA (N=2), nonsignificant risk device (N=9), exempt (N=3), product jurisdiction pending (N=0), or product jurisdiction transferred (N=3), Basic Physiological Research (N=0).

CDRH IDEs - FY 2014 As of 9/30/18 Continued



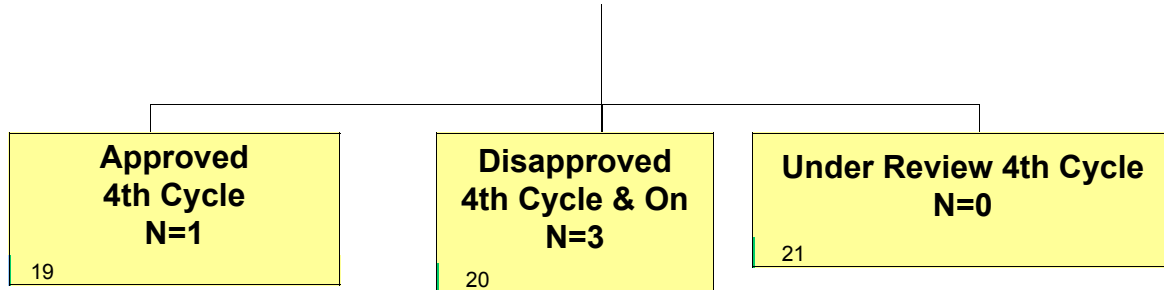
CDRH IDEs - FY 2015

As of 9/30/18



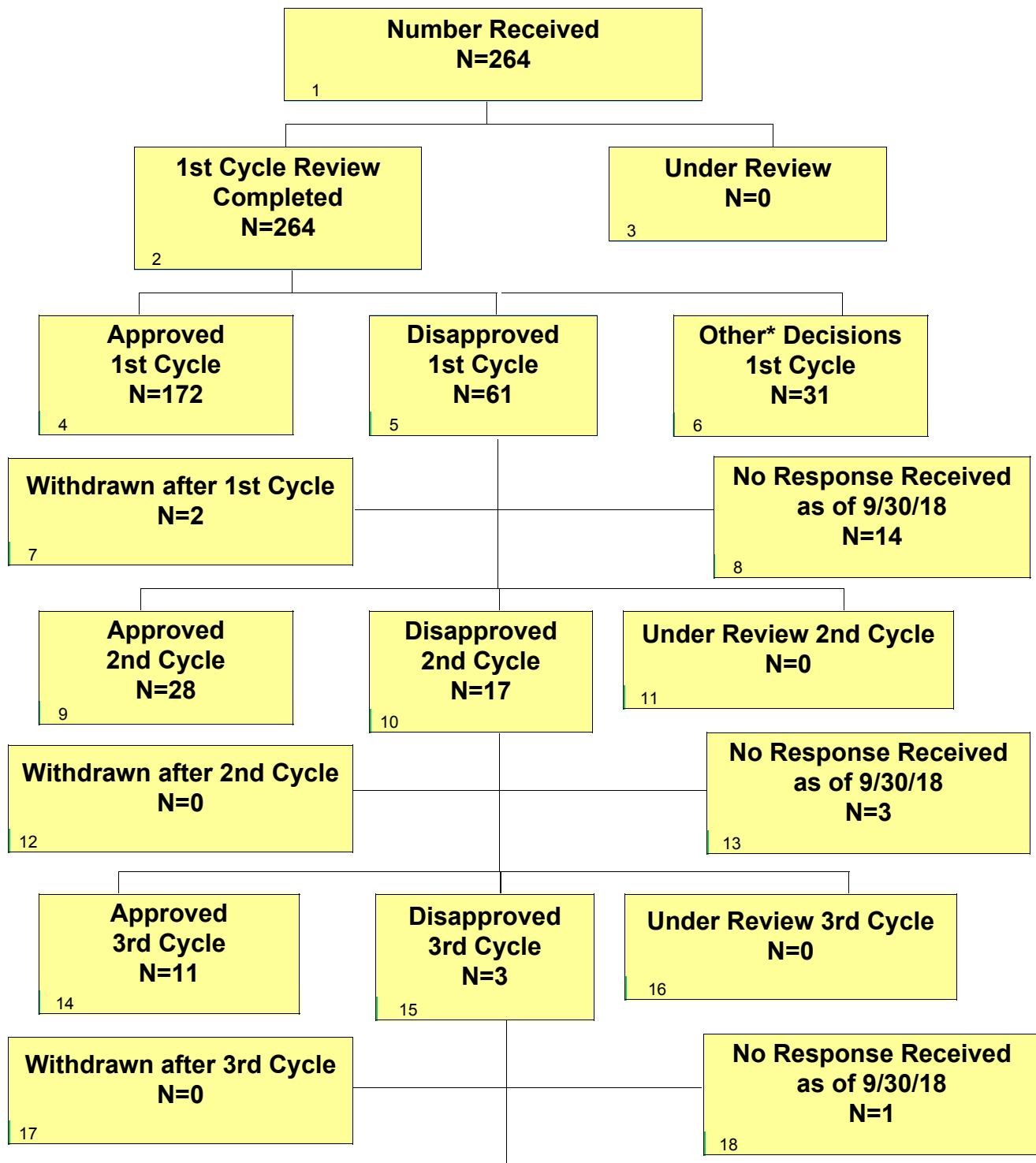
* Other decisions include withdrawn (N=38), RTA (N=0), nonsignificant risk device (N=13), exempt (N=5), product jurisdiction pending (N=0), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).

CDRH IDEs - FY 2015 As of 9/30/18 Continued



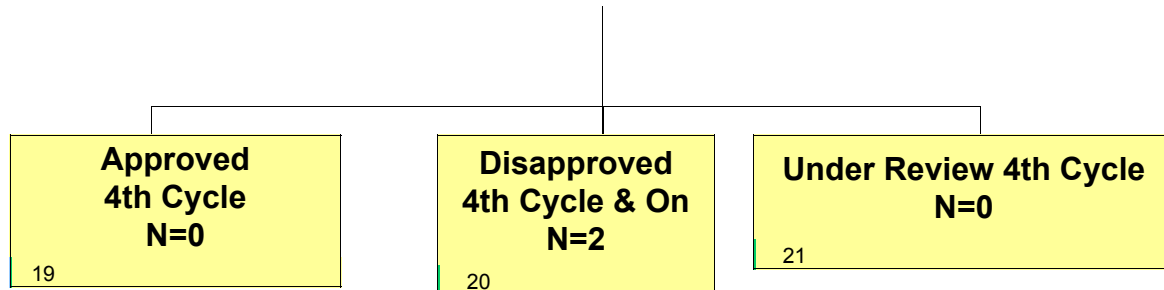
CDRH IDEs - FY 2016

As of 9/30/18



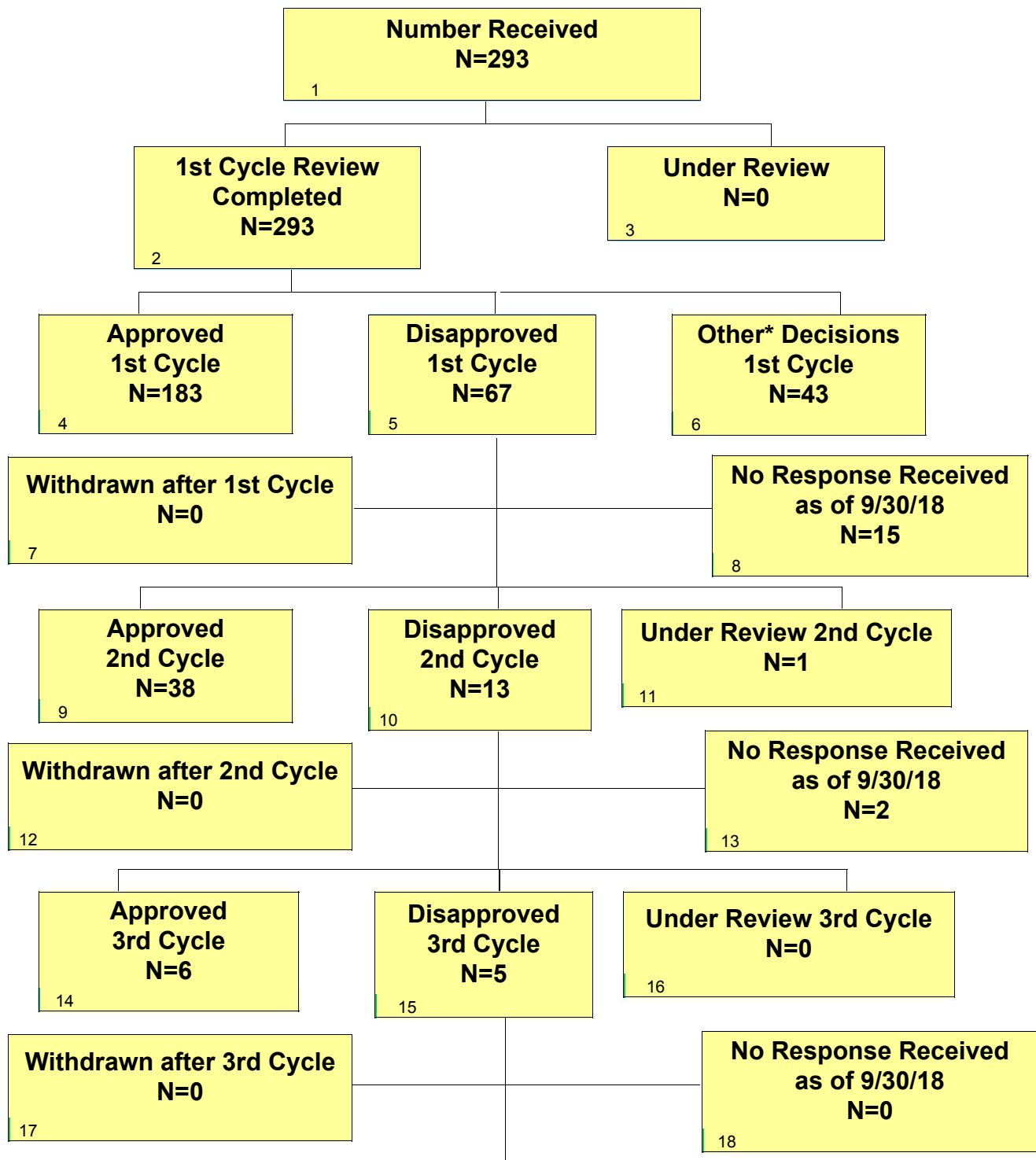
* Other decisions include withdrawn (N=21), RTA (N=0), nonsignificant risk device (N=4), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).

CDRH IDEs - FY 2016 As of 9/30/18 Continued



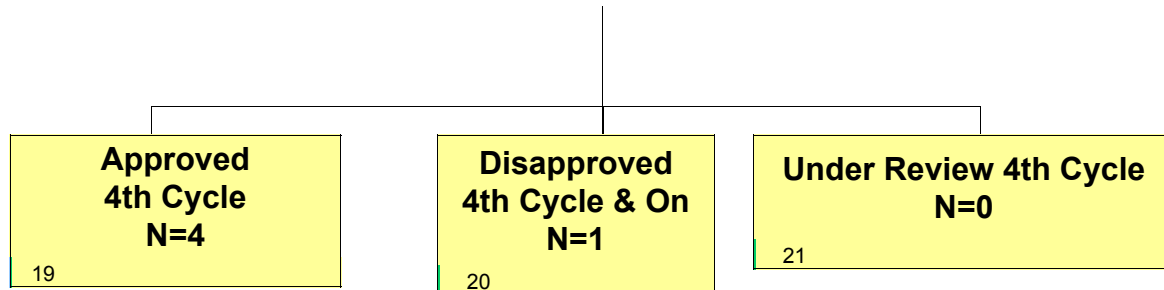
CDRH IDEs - FY 2017

As of 9/30/18



* Other decisions include withdrawn (N=8), withdrawn and converted (N=26), RTA (N=0), nonsignificant risk device (N=6), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=1), Basic Physiological Research (N=1).

CDRH IDEs - FY 2017 As of 9/30/18 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	264	293
Average number of cycles to approval or conditional approval of the IDE	N/A	1.31	1.30	1.32	1.28
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.31	0.30	0.32	0.28

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	215	250
Average number of cycles to approval or conditional approval of the IDE	N/A	1.38	1.34	1.38	1.33
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.38	0.34	0.38	0.33

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	49	43
Average number of cycles to approval or conditional approval of the IDE	N/A	1.07	1.08	1.08	1.03
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.07	0.08	0.08	0.03

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	20	13	19
Average number of cycles to approval or conditional approval of the IDE	N/A	1.67	1.14	1.33	1.00
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.67	0.14	0.33	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	57	58	70	77
Average number of cycles to approval or conditional approval of the IDE	N/A	1.48	1.43	1.53	1.52
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.48	0.43	0.53	0.52

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	34	38	48	55
Average number of cycles to approval or conditional approval of the IDE	N/A	1.29	1.15	1.19	1.20
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.29	0.15	0.19	0.20

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	15	14	13	10
Average number of cycles to approval or conditional approval of the IDE	N/A	1.18	1.15	1.09	1.00
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.18	0.15	0.09	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	25	14	23
Average number of cycles to approval or conditional approval of the IDE	N/A	1.21	1.13	1.55	1.24
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.21	0.13	0.55	0.24

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	30	43	36	35
Average number of cycles to approval or conditional approval of the IDE	N/A	1.57	1.64	1.50	1.45
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.57	0.64	0.50	0.45

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	26	33	21	31
Average number of cycles to approval or conditional approval of the IDE	N/A	1.28	1.29	1.12	1.20
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.28	0.29	0.12	0.20

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	24	16
Average number of cycles to approval or conditional approval of the IDE	N/A	1.00	1.08	1.05	1.00
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0.08	0.05	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	2
Average number of cycles to approval or conditional approval of the IDE	N/A	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	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	1	3
Average number of cycles to approval or conditional approval of the IDE	N/A	1.00	1.00	1.00	1.00
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0	0	0

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	16	18
Average number of cycles to approval or conditional approval of the IDE	N/A	1.00	1.00	1.00	1.00
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	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	8	4
Average number of cycles to approval or conditional approval of the IDE	N/A	1.60	1.50	1.40	1.25
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.60	0.50	0.40	0.25

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Section 12 DUAL (510(k) and CLIA Waiver) Annual Metrics

Table 12.1 CDRH – DUAL (510(k) and CLIA Waiver) Substantive Interaction Performance Goals

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	0	1	3	1	6
Withdrawn prior to SI	N/A	0	0	0	0
SI within 90 FDA days	N/A	1	3	1	6
SI over 90 FDA days	N/A	0	0	0	0
SI pending within 90 FDA days	N/A	0	0	0	0
SI pending over 90 FDA days	N/A	0	0	0	0
Denial without SI	N/A	0	0	0	0
Current SI Performance Percent within 90 FDA days	N/A	100%	100%	100%	100%

Table 12.2.CDRH –DUAL (510(k) and CLIA Waiver)Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	0	1	3	1	6
Average number of FDA days to Substantive Interaction	N/A	87.0	87.0	77.0	84.3
20th Percentile FDA days to Substantive Interaction	N/A	N/A	86	N/A	84
40th Percentile FDA days to Substantive Interaction	N/A	N/A	87	N/A	87
60th Percentile FDA days to Substantive Interaction	N/A	N/A	88	N/A	87
80th Percentile FDA days to Substantive Interaction	N/A	N/A	89	N/A	90
Maximum FDA days to Substantive Interaction	N/A	87	89	77	90

Table 12.3.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
CLIA Waiver Applications accepted	0	1	3	1	6
Non-MDUFA III Decisions	N/A	0	0	0	0
MDUFA III Decisions	N/A	1	3	1	6
MDUFA III Decisions within 210 FDA Days	N/A	1	3	1	6
CLIA Waiver Applications pending MDUFA III Decision	N/A	0	0	0	0
CLIA Waiver Applications pending MDUFA III Decision over 210 FDA days	N/A	0	0	0	0
Current Performance Percent within 210 FDA Days	N/A	100%	100%	100%	100%

Table 12.4.CDRH – DUAL (510(k) and CLIA Waiver) (with panel review) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
CLIA Waiver Applications accepted	0	0	0	0	0
Non-MDUFA III Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA III Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA III Decisions with in 330 FDA Days	N/A	N/A	N/A	N/A	N/A
CLIA Waiver Applications pending MDUFA III Decision	N/A	N/A	N/A	N/A	N/A
CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent within 330 FDA Days	N/A	N/A	N/A	N/A	N/A

Table 12.5.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0	1	3	1	6
Average FDA days to MDUFA III decision	N/A	169.0	167.7	131.0	153.2
20th Percentile FDA days to MDUFA III decision	N/A	N/A	134	N/A	87
40th Percentile FDA days to MDUFA III decision	N/A	N/A	184	N/A	174
60th Percentile FDA days to MDUFA III decision	N/A	N/A	209	N/A	174
80th Percentile FDA days to MDUFA III decision	N/A	N/A	210	N/A	207
Maximum FDA days to MDUFA III decision	N/A	169	210	131	209
Average Industry days to MDUFA III decision	N/A	0.0	119.7	96.0	57.5
20th Percentile Industry days to MDUFA III decision	N/A	N/A	72	N/A	0
40th Percentile Industry days to MDUFA III decision	N/A	N/A	143	N/A	0
60th Percentile Industry days to MDUFA III decision	N/A	N/A	179	N/A	40
80th Percentile Industry days to MDUFA III decision	N/A	N/A	180	N/A	146
Maximum Industry days to MDUFA III decision	N/A	0	180	96	159
Average Total days to MDUFA III decision	N/A	169.0	287.3	227.0	210.7
20th Percentile Total days to MDUFA III decision	N/A	N/A	231	N/A	174
40th Percentile Total days to MDUFA III decision	N/A	N/A	253	N/A	207
60th Percentile Total days to MDUFA III decision	N/A	N/A	289	N/A	233
80th Percentile Total days to MDUFA III decision	N/A	N/A	339	N/A	249
Maximum Total days to MDUFA III decision	N/A	169	389	227	333

Table 12.6.CDRH – DUAL (510(k) and CLIA Waiver) (with Panel Review) Time to MDUFA Decision

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

**Quarterly Update on
Medical Device Performance Goals
----MDUFA III CBER Performance Data ----
Action through 30 Sep 2018**

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	2	2
Closed before RTA action	0	0	0	0	0
Number Accepted	1	6	3	2	2
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	0	0	0	0
Rate of submissions not accepted for filing review	0.0%	0.0%	0.0%	0.0%	0.0%
Completed RTF	0	0	0	0	0
Number Not Filed	0	0	0	0	0
Rate of submissions Not Filed	0.0%	0.0%	0.0%	0.0%	0.0%

Table 1.2 CBER – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	1	6	3	2	2
SI within 90 FDA days	0	6	3	2	2
SI over 90 FDA days	1	0	0	0	0
SI pending within 90 FDA days	0	0	0	0	0
SI pending over 90 FDA days	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent within 90 FDA days	0.0%	100.0%	100.0%	100.0%	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	2	2
Average number of FDA days to Substantive Interaction	101	88	87	87.5	86
20th Percentile FDA days to Substantive Interaction	101	87	85	87	87
40th Percentile FDA days to Substantive Interaction	101	88	86	87	85
60th Percentile FDA days to Substantive Interaction	101	88	86	88	87
80th Percentile FDA days to Substantive Interaction	101	90	90	88	87
Maximum FDA days to Substantive Interaction	101	90	90	88	87

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	2	2
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	0	6	3	2	2
MDUFA III Decisions within 180 FDA Days	0	6	3	2	2
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision over 180 FDA days	0	0	0	0	0
Current Performance Percent within 180 FDA Days	0.0%	100.0%	100.0%	100.0%	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	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	1	0	0	0	0
MDUFA III Decisions within 320 FDA Days	1	0	0	0	0
PMAs pending MDUFA III Decision	0	0	0	0	0
PMAs pending MDUFA III Decision over 320 FDA days	0	0	0	0	0
Current Performance Percent within 320 FDA Days	100.0%	0.0%	0.0%	0.0%	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	3	2	2
Average FDA days to MDUFA III decision	0	173	165	165	180
20th Percentile FDA days to MDUFA III decision	0	170	159	152	179
40th Percentile FDA days to MDUFA III decision	0	172	165	152	179
60th Percentile FDA days to MDUFA III decision	0	176	165	177	180
80th Percentile FDA days to MDUFA III decision	0	177	171	177	180
Maximum FDA days to MDUFA III decision	0	180	171	177	180
Average Industry days to MDUFA III decision	0	137	120	207	179
20th Percentile Industry days to MDUFA III decision	0	0	0	0	178
40th Percentile Industry days to MDUFA III decision	0	41	56	0	178
60th Percentile Industry days to MDUFA III decision	0	178	56	207	179
80th Percentile Industry days to MDUFA III decision	0	284	305	207	179
Maximum Industry days to MDUFA III decision	0	317	305	207	179
Average Total days to MDUFA III decision	0	310	285	268	358
20th Percentile Total days to MDUFA III decision	0	172	171	152	357
40th Percentile Total days to MDUFA III decision	0	218	221	152	357
60th Percentile Total days to MDUFA III decision	0	358	221	384	359
80th Percentile Total days to MDUFA III decision	0	460	464	384	359
Maximum Total days to MDUFA III decision	0	479	464	384	359

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	0
Average FDA days to MDUFA III decision	303	0	0	0	0
20th Percentile FDA days to MDUFA III decision	303	0	0	0	0
40th Percentile FDA days to MDUFA III decision	303	0	0	0	0
60th Percentile FDA days to MDUFA III decision	303	0	0	0	0
80th Percentile FDA days to MDUFA III decision	303	0	0	0	0
Maximum FDA days to MDUFA III decision	303	0	0	0	0
Average Industry days to MDUFA III decision	41	0	0	0	0
20th Percentile Industry days to MDUFA III decision	41	0	0	0	0
40th Percentile Industry days to MDUFA III decision	41	0	0	0	0
60th Percentile Industry days to MDUFA III decision	41	0	0	0	0
80th Percentile Industry days to MDUFA III decision	41	0	0	0	0
Maximum Industry days to MDUFA III decision	41	0	0	0	0
Average Total days to MDUFA III decision	344	0	0	0	0
20th Percentile Total days to MDUFA III decision	344	0	0	0	0
40th Percentile Total days to MDUFA III decision	344	0	0	0	0
60th Percentile Total days to MDUFA III decision	344	0	0	0	0
80th Percentile Total days to MDUFA III decision	344	0	0	0	0
Maximum Total days to MDUFA III decision	344	0	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	2	2
Number with MDUFA decision	0	6	3	2	2
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	0.0%	0.0%	0.0%	0.0%	0.0%
Rate of Not Approvable	0.0%	0.0%	0.0%	0.0%	0.0%

Table 1.9 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0	0	0	0
Number with MDUFA decision	1	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	0.0%	0.0%	0.0%	0.0%	0.0%
Rate of Not Approvable	0.0%	0.0%	0.0%	0.0%	0.0%

**Table 1.10 CBER – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	0
Mean FDA days for submissions that missed goal	0	0	0	0	0
Mean industry days for submissions that missed goal	0	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	4	5	5
SI within 90 FDA days	2	1	3	3	5
SI over 90 FDA days	0	0	1	1	0
SI pending within 90 FDA days	0	0	0	0	0
SI pending over 90 FDA days	0	0	0	0	0
Closed without SI	1	0	0	1	0
Current SI Performance Percent within 90 FDA days	100.0%	100.0%	75.0%	75.0%	100.0%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	3	1	5	5	5
Non-MDUFA III Decisions	1	0	1	1	0
MDUFA III Decisions	2	1	4	4	5
MDUFA III Decisions within 180 FDA Days	2	1	4	4	3
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision over 180 FDA days	0	0	0	0	0
Current Performance Percent within 180 FDA Days	100.0%	100.0%	100.0%	100.0%	60.0%

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	5	5
Number with MDUFA decision	2	1	4	4	5
Number of Not Approvable	0	0	0	1	0
Rate of Not Approvable	0.0%	0.0%	0.0%	25.0%	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	2
Mean FDA days for submissions that missed goal	0	0	0	0	319
Mean Industry days for submissions that missed goal	0	0	0	0	126

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	4
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	3	2	5	3	4
MDUFA III Decisions within 90 FDA Days	3	2	5	3	4
Supplements pending MDUFA III Decision	0	0	0	0	0
Supplements pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	100.0%	100.0%	100.0%	100.0%	100.0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	2	5	3	4
Number with MDUFA decision	3	2	5	3	4
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0.0%	0.0%	0.0%	0.0%	0.0%

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

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

Section 5 PMA Annual Metrics and Goals

Table 5.1 CBER – PMAs (All Review Tracks) Annual General Metrics – PMAs Received by Type

PMA Submissions Received	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Premarket Report Submissions	0	0	0	0	0
Original PMAs (Panel) – Priority	0	0	0	0	0
Original PMAs (No Panel) – Priority	0	0	0	0	0
Original PMAs (Panel) – Non-Priority	1	0	0	0	0
Original PMAs (No Panel) – Non-Priority	0	5	2	1	2
Panel-Tracked Supplements (Panel) – Priority	0	0	0	0	0
Panel-Tracked Supplements (No Panel) – Priority	0	0	0	0	0
Panel-Tracked Supplements (Panel) – Non-Priority	0	0	0	0	0
Panel-Tracked Supplements (No Panel) – Non-Priority	0	1	1	1	0
PMA Modules	7	1	4	2	2
180-Day Supplements	3	1	5	5	5
Real-Time Supplements	3	2	5	3	4

Table 5.2 CBER – PMA Originals and Panel Tracked Supplements Annual Shared Outcome Goal – Percent Cohorts Closed

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	6	3	2	2
Number with a decision (MDUFA or Non-MDUFA)	1	6	3	2	2
% of FY closed	100.0%	100.0%	100.0%	100.0%	100.0%

Section 6 510(k) Center Level Metrics

Table 6.1 CBER – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	57	56	44	53
Closed before RTA action	1	1	0	1	3
Number Accepted	40	35	37	31	43
Number without a RTA Review and > 15 Days since Date Received	0	0	0	0	1
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	0
Number Not Accepted	19	21	19	12	6
Rate of submissions not accepted for review	32.20%	37.50%	33.90%	27.90%	12.00%

Table 6.2 CBER – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	47	51	52	42	50
SI within 60 FDA days	41	49	49	42	50
SI over 60 FDA days	6	2	1	0	0
SI pending within 60 FDA days	0	0	0	0	0
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	0	0
Current SI Performance Percent within 60 FDA days	87.20%	96.10%	98.00%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	47	51	50	42	50
Average number of FDA days to Substantive Interaction	49	50	49	48	50
20th Percentile FDA days to Substantive Interaction	30	34	30	30	29
40th Percentile FDA days to Substantive Interaction	46	54	52	51	55
60th Percentile FDA days to Substantive Interaction	58	57	58	56	57
80th Percentile FDA days to Substantive Interaction	59	60	59	59	59
Maximum FDA days to Substantive Interaction	90	90	62	60	60

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	47	51	52	42	50
Non-MDUFA III Decisions	8	5	11	6	9
MDUFA III Decisions (SE/NSE)	39	46	41	36	40
MDUFA III Decisions within 90 FDA Days	37	46	41	36	40
510(k)s pending MDUFA III Decision	0	0	0	0	1
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	94.9%	100%	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	1.61	1.51	1.64	1.60
Number with MDUFA III decision	39	46	41	36	40
Average FDA days to MDUFA III decision	71	113	80	78	73
20th Percentile FDA days to MDUFA III decision	30	37	30	56	30
40th Percentile FDA days to MDUFA III decision	81	67	76	76	85
60th Percentile FDA days to MDUFA III decision	87	88	84	84	88
80th Percentile FDA days to MDUFA III decision	89	90	88	87	89
Maximum FDA days to MDUFA III decision	94	588	308	388	90
Average Industry days to MDUFA III decision	76	87	65	73	44
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	19	0	0	0	0
60th Percentile Industry days to MDUFA III decision	83	44	29	65	24
80th Percentile Industry days to MDUFA III decision	150	182	123	133	177
Maximum Industry days to MDUFA III decision	370	381	399	392	209
Average Total days to MDUFA III decision	147	201	145	152	117
20th Percentile Total days to MDUFA III decision	30	40	58	74	30
40th Percentile Total days to MDUFA III decision	108	81	79	80	89
60th Percentile Total days to MDUFA III decision	171	126	110	126	111
80th Percentile Total days to MDUFA III decision	244	272	207	219	182
Maximum Total days to MDUFA III decision	460	958	707	532	294

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	47	51	52	42	50
Number with MDUFA decision	39	46	41	36	40
Number of SE decisions	36	43	37	32	38
Number of NSE decisions	3	3	4	4	2
Number of Withdrawals	8	5	11	5	9
Number deleted	0	0	0	0	0
Rate of SE decisions	92.30%	93.50%	90.20%	88.89%	95.00%
Rate of NSE decisions	7.70%	6.50%	9.80%	11.11%	5.00%
Rate of Withdrawals	17.00%	9.80%	21.20%	11.90%	18.00%
Rate of Deleted	0%	0%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0	0	0
Mean FDA days for submissions that missed goal	94	0	0	0	0
Mean industry days for submissions that missed goal	150	0	0	0	0

Section 7 510(k) Annual General Metrics

Table 7.1 CBER – 510(k) Annual General Metrics – 510(k)s Received by Type

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	47	51	52	42	50
Number of Traditional submissions	34	42	40	35	38
Number of Special submissions	9	9	12	7	11
Number of Abbreviated submissions	4	0	0	0	1
Average number of days to Accept / Refuse to Accept	13	13	12	12	12
Number of Third Party submissions	0	0	0	0	0

Table 7.2 CBER - 510(k) Annual Shared Outcome Goal

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	47	51	52	42	50
Currently Under Review	0	0	0	0	1
Number with Non-MDUFA Decision	8	5	11	6	9
Number with MDUFA III Decision	39	46	41	36	40
Percent of cohort closed	100%	100%	100%	100%	97.5%
Number with MDUFA III decision after trimming the upper and lower 2%	37	44	39	34	38
Average Total Time to MDUFA III decision	147	201	145	152	117

Section 8 De Novo Petitions

Table 8.1 CBER – Annual General Metric Report for De Novo Classification Petitions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of De Novo Petitions Received	2	0	1	0	2
Number of De Novo Petitions with Decision	2	0	1	0	2
Number of De Novo Petitions with Decision Pending	0	0	0	0	0
Average Number of Days to Decision	577	0	314	0	225

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	55	58
Number requesting a meeting or teleconference	34	46	48	41	47
Number with meetings or teleconferences granted	29	41	45	39	47
Number with meeting granted and industry cancelled	13	7	12	13	15
Number with meeting granted and FDA cancelled	0	1	1	1	0
Number with meeting granted and pending within timeframe	0	0	0	0	0
Number with meeting granted and pending outside timeframe	0	0	0	0	0
Number with meetings or teleconferences held	15	33	32	25	32
Average days to meeting	65	68	68	77	77
20th Percentile days to meeting	55	44	58	62	68
40th Percentile days to meeting	58	62	68	79	74
60th Percentile days to meeting	61	78	76	83	78
80th Percentile days to meeting	70	92	83	86	84
Maximum days to meeting	122	132	101	105	120

CBER – Annual General Metric Report for BLAs

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard BLAs Filed	9	10	2	26	5
Number of Standard BLA First Actions less than or equal to 10 months	9	10	2	26	3
Number of Standard BLA First Actions greater than 10 months	0	0	0	0	0
Number of Standard BLAs Pending	0	0	0	0	2
Number of Priority BLA Filed	0	0	2	1	1
Number of Priority BLA First Actions less than or equal to 10 months	0	0	2	1	1
Number of Priority BLA First Actions greater than 10 months	0	0	0	0	0
Number of Priority BLAs Pending	0	0	0	0	0

BLA Efficacy Supplements

CBER – Annual General Metric Report for BLA Efficacy Supplements

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard Efficacy Supplements Filed	0	17	1	1	1
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0	17	1	1	1
Number of Standard Efficacy Supplements First Actions greater than 10 months	0	0	0	0	0
Number of Standard Efficacy Supplements Pending	0	0	0	0	0
Number of Priority Efficacy Supplements Filed	0	0	0	0	0
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0	0	0	0	0
Number of Priority Efficacy Supplements First Actions greater than 10 months	0	0	0	0	0
Number of Priority Efficacy Supplements Pending	0	0	0	0	0

BLA Prior Approval Manufacturing Supplements
CBER – Annual General Metric Report for BLA PAS Supplements

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard PAS Supplements Filed	20	6	19	47	38
Number of Standard PAS Supplements First Actions less than or equal to 4months	20	6	19	47	38
Number of Standard PAS Supplements First Actions greater than 4 months	0	0	0	0	0
Number of Standard PAS Supplements Pending	0	0	0	0	0

BLA/BLA Resubmissions
CBER – Annual General Metric Report for BLA/BLA Resubmissions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Class 1 Resubmissions Received	10	6	1	2	1
Number of Class 1 Resubmission Actions less than or equal to 2 months	10	6	1	2	1
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0	0	0
Number of Class 1 Resbumssions Pending	0	0	0	0	0
Number of Class 2 Resubmissions Received	0	2	16	28	40
Number of Class 2 Resubmission Actions less than or equal to 6 months	0	2	16	28	40
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0	0	0
Number of Class 2 Resubmissions Pending	0	0	0	0	0

IDEs
CBER – Annual General Metric Report for IDEs

#	Measure	Description	FY13	FY14	FY15	FY16	FY17
1	Number of IDEs received	Number of IDEs received in the fiscal year.	14*	23	17	20	19
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.	1.42 (17/12)	1.04	1.6 (24/15)	1.2 14/12	1.21 (17/14)
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.	0.5 (6/12)	0.04	0.33 (5/15)	0.17 (2/12)	0.35 (5/14)