

Agenda for Quarterly Meeting on MDUFA III (FY 2013-2017) Performance

November 3, 2017, 10:00 – 12:00

WebEx

Welcome

Guidance Development

FDA MDUFA Performance — Actions through September 30, 2017

- Report on decision goals for 4th Quarter FY 2017.

Qualitative Update on Finances – 4th Quarter FY 2017

- User fee receipts through the 4th Quarter FY 2017.

CDRH Registration and Listing

- Report on registration and listing

CDRH Training update

M4 Implementation

M4 Audit plan

Reminder: Set date for 1st Quarter 2018 meeting

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Medical Device Guidance Documents

(Issued in FY 2017)

(July 1, 2017 thru September 30, 2017) (Quarter 4)

34. Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions - Guidance for Industry and Food and Drug Administration Staff
(09/29/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073680>
33. Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A - Guidance for Industry and Food and Drug Administration Staff
(09/29/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254>
32. Display Devices for Diagnostic Radiology - Guidance for Industry and Food and Drug Administration Staff
(09/29/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM484914>
31. Administrative Procedures for CLIA Categorization - Guidance for Industry and Food and Drug Administration Staff
(09/29/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070889>
30. Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses - Guidance for Industry and Food and Drug Administration Staff
(09/15/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM458179>
29. Regulatory Considerations for Microneedling Devices - Draft Guidance for Industry and Food and Drug Administration Staff
(09/15/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM575923>
28. Utilizing Animal Studies to Evaluate Organ Preservation Devices - Draft Guidance for Industry and Food and Drug Administration Staff
(09/15/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM575922>
27. Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies - Guidance for Industry and Food and Drug Administration Staff
(09/12/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM507278>
26. Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff
(09/06/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482649>
25. Procedures for Meetings of the Medical Devices Advisory Committee - Guidance for Industry and Food and Drug Administration Staff

- (09/01/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM440348>
24. Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices - Guidance for Industry and Food and Drug Administration Staff
(08/31/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027>
23. Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices - Draft Guidance for Industry and Food and Drug Administration Staff
(08/31/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM573663>
22. FY 2018 Medical Device User Fee Small Business Qualification and Certification - Guidance for Industry, Food and Drug Administration Staff and Foreign Governments
(08/29/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM456779>
21. Qualification of Medical Device Development Tools - Guidance for Industry, Tool Developers, and Food and Drug Administration Staff
(08/10/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM374432>

(April 1, 2017 thru June 30, 2017) (Quarter 3)

20. Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 –
(06/20/2017) <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM563785>

(January 1, 2017 thru March 31, 2017) (Quarter 2)

19. Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers Guidance for Industry and Review Staff
(01/18/2017) <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537347>
18. Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers Guidance for Industry
(01/17/2017) <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537130>
17. Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions - Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators and Food and Drug Administration Staff
(01/13/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM451440>
16. Current Good Manufacturing Practice Requirements for Combination Products - Guidance for Industry and Food and Drug Administration Staff
(01/10/2017) <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126198.htm>

15. Premarket Notification (510(k)) Submissions for Bone Anchors - Draft Guidance for Industry and Food and Drug Administration Staff
(01/3/2017) <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080264>

(October 1, 2016 thru December 31, 2016) (Quarter 1)

14. Medical Device Accessories - Describing Accessories and Classification Pathway for New Accessory Types - Guidance for Industry and Food and Drug Administration Staff
(12/30/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672>
13. Postmarket Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
(12/28/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022>
12. Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions - Guidance for Industry and Food and Drug Administration Staff
(12/27/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM506679>
11. Public Notification of Emerging Postmarket Medical Device Signals (Emerging Signals) - Guidance for Industry and Food and Drug Administration Staff
(12/14/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM479248>
10. Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids - Guidance for Industry and Food and Drug Administration Staff
(12/12/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM531995>
9. Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes - Guidance for Industry and Food and Drug Administration Staff
(11/29/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM430550>
8. Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices - Guidance for Industry and Food and Drug Administration Staff
(11/18/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM454613>
7. Product Labeling for Certain Ultrasonic Surgical Aspirator Devices - Draft Guidance for Industry and Food and Drug Administration Staff
(11/10/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM528182>
6. Medical Device Reporting for Manufacturers - Guidance for Industry and Food and Drug Administration Staff
(11/08/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM359566>

5. Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes - Guidance for Industry and Food and Drug Administration Staff
(11/07/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM489111>
4. Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization - Guidance for Industry and Food and Drug Administration Staff
(10/31/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020>
3. Software as a Medical Device (SaMD): Clinical Evaluation
(10/14/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904>
2. Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use - Guidance for Industry and Food and Drug Administration Staff
(10/11/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380325>
1. Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Guidance for Industry and Food and Drug Administration Staff
(10/11/2016) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380327>

**Quarterly Update on
Medical Device Performance Goals
----MDUFA III CDRH Performance Data ----
Action through 30 September 2017**

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Acronyms and Abbreviations

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

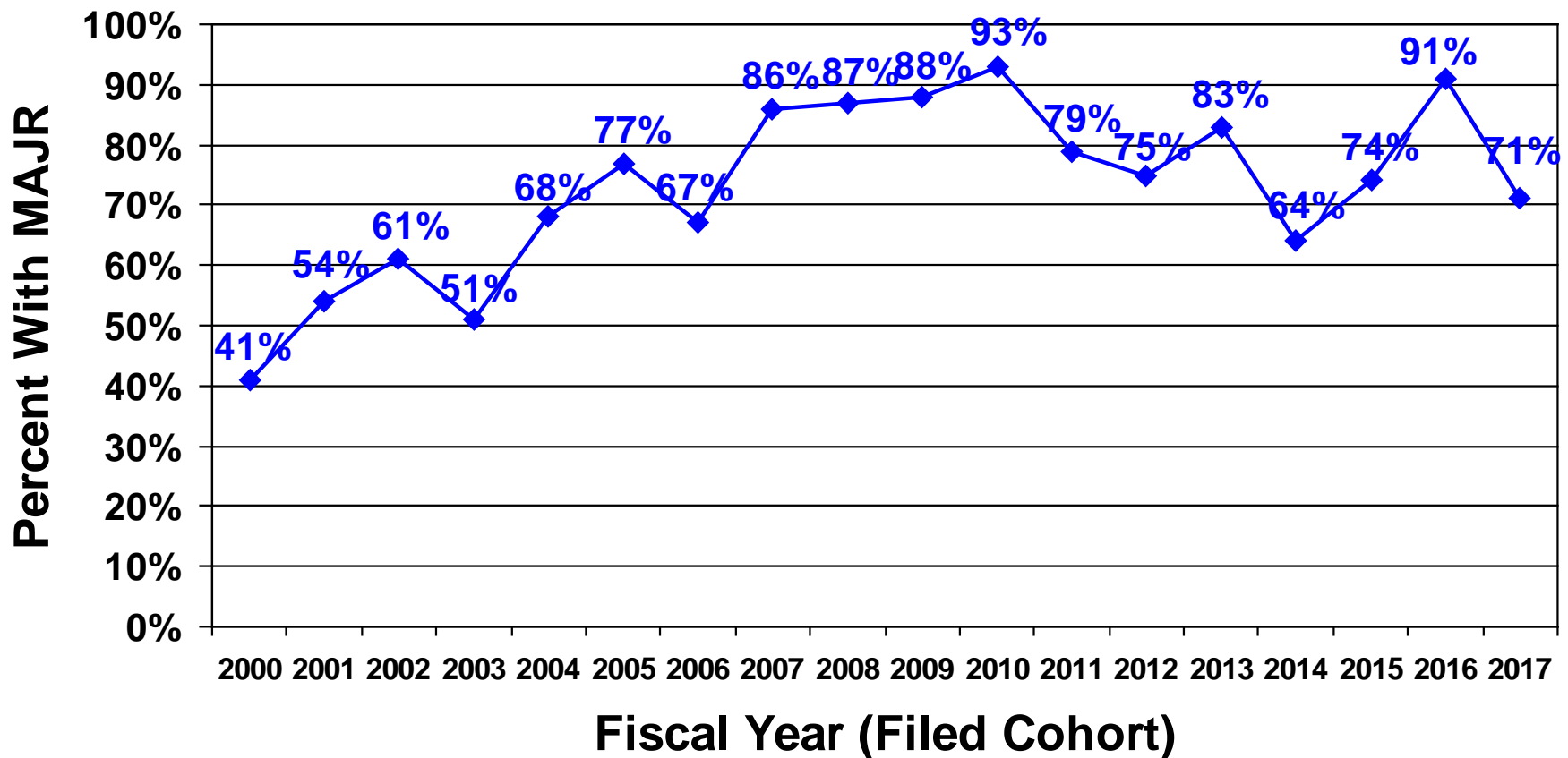
Note: Data may change in subsequent quarterly and annual reports.

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PMA's

Q4 FY17

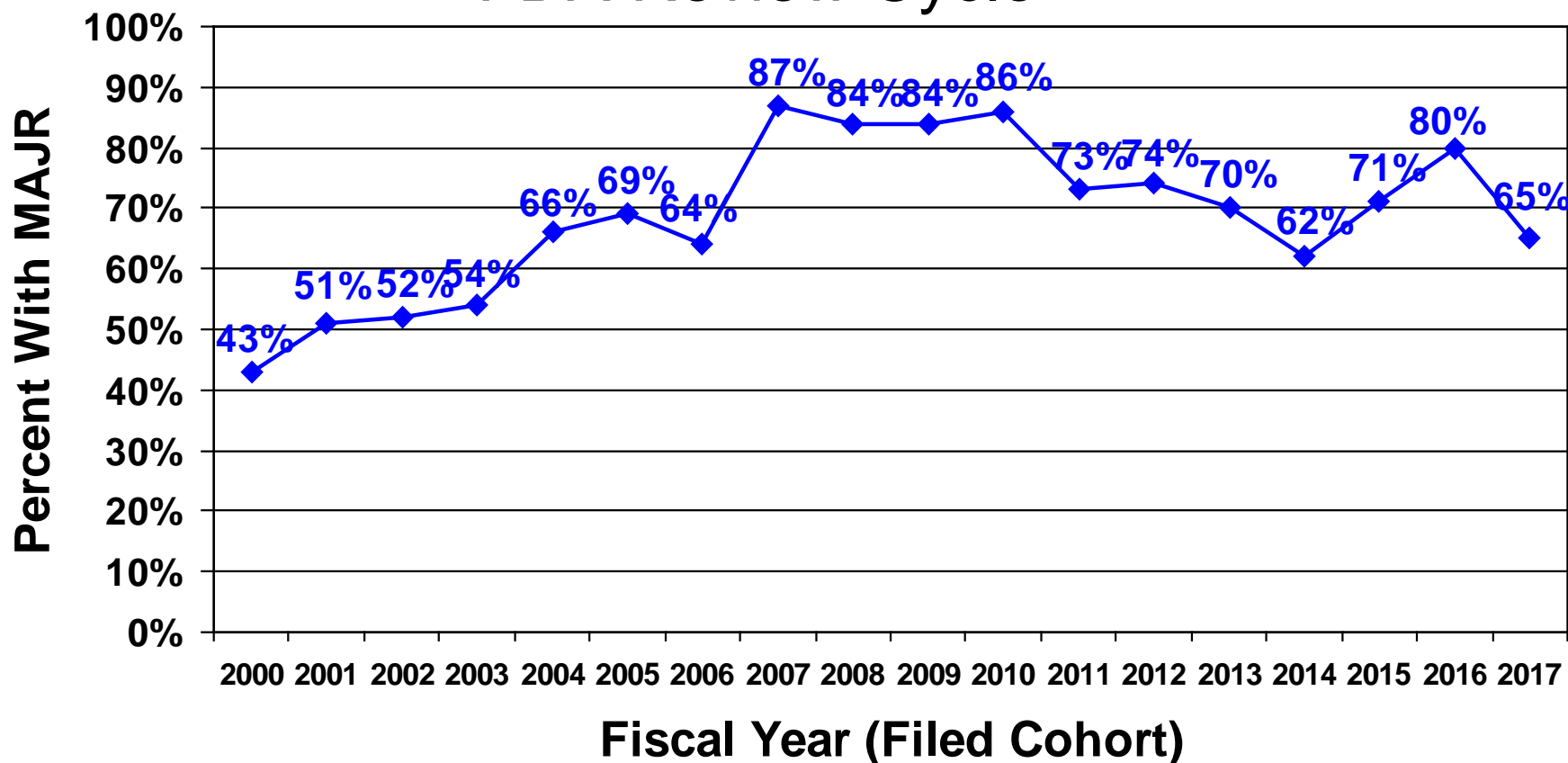
Percent of PMA Originals With Major Deficiency Letter on 1st* FDA Review Cycle*



- Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle.

*Includes original PMAs filed as of 6/30/2017. Note that for the latest FY cohort, a Substantive Interaction of “Proceed Interactively” was considered to be a first cycle outcome.

Percent of PMA Originals and Panel Track Supplements With Major Deficiency Letter on 1st* FDA Review Cycle**

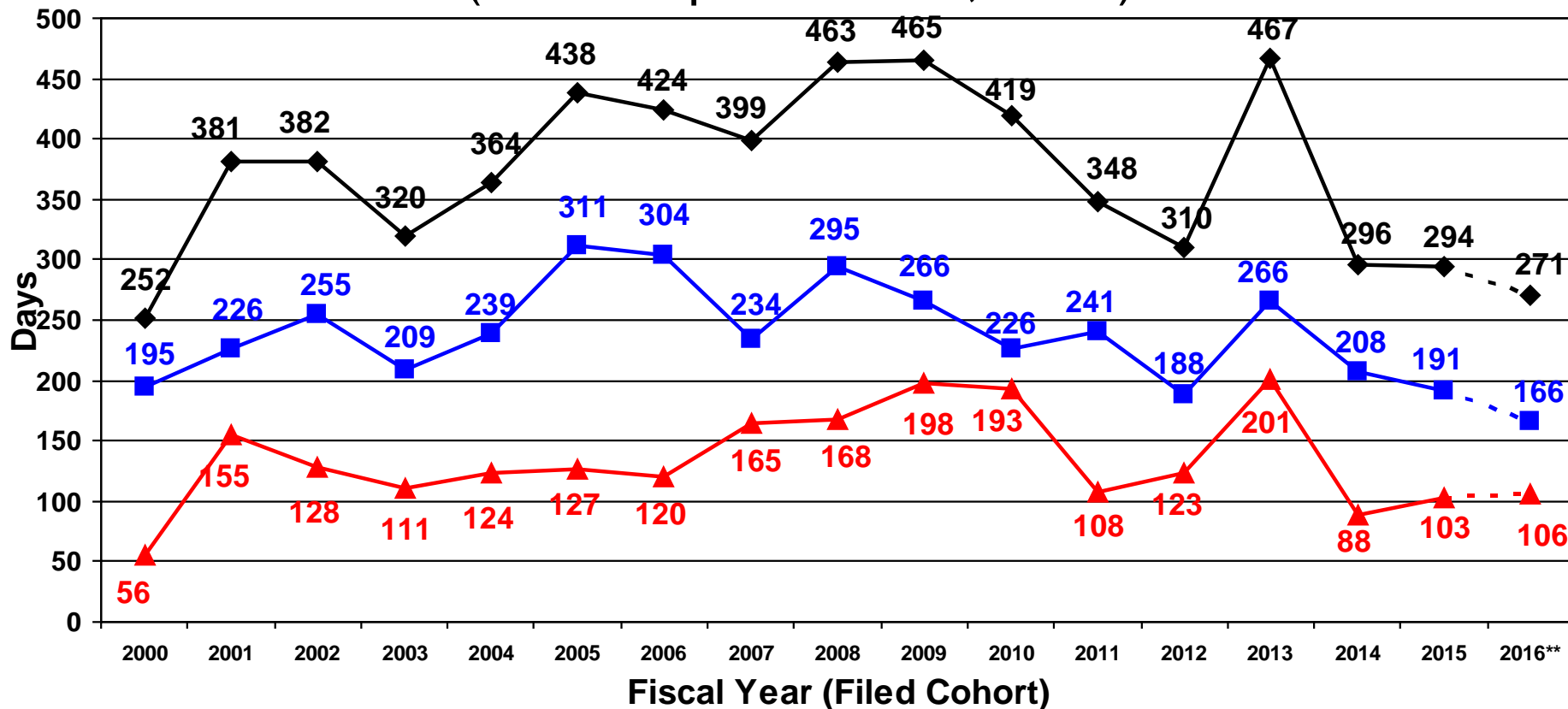


*Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle as of the date specified.

**Includes original PMAs/PTS filed as of 6/30/2017. Note that for the latest FY cohort, a Substantive Interaction of “Proceed Interactively” was considered to be a first cycle outcome.

Average Time to MDUFA Decision: PMA Originals*

(As of September 30, 2017)



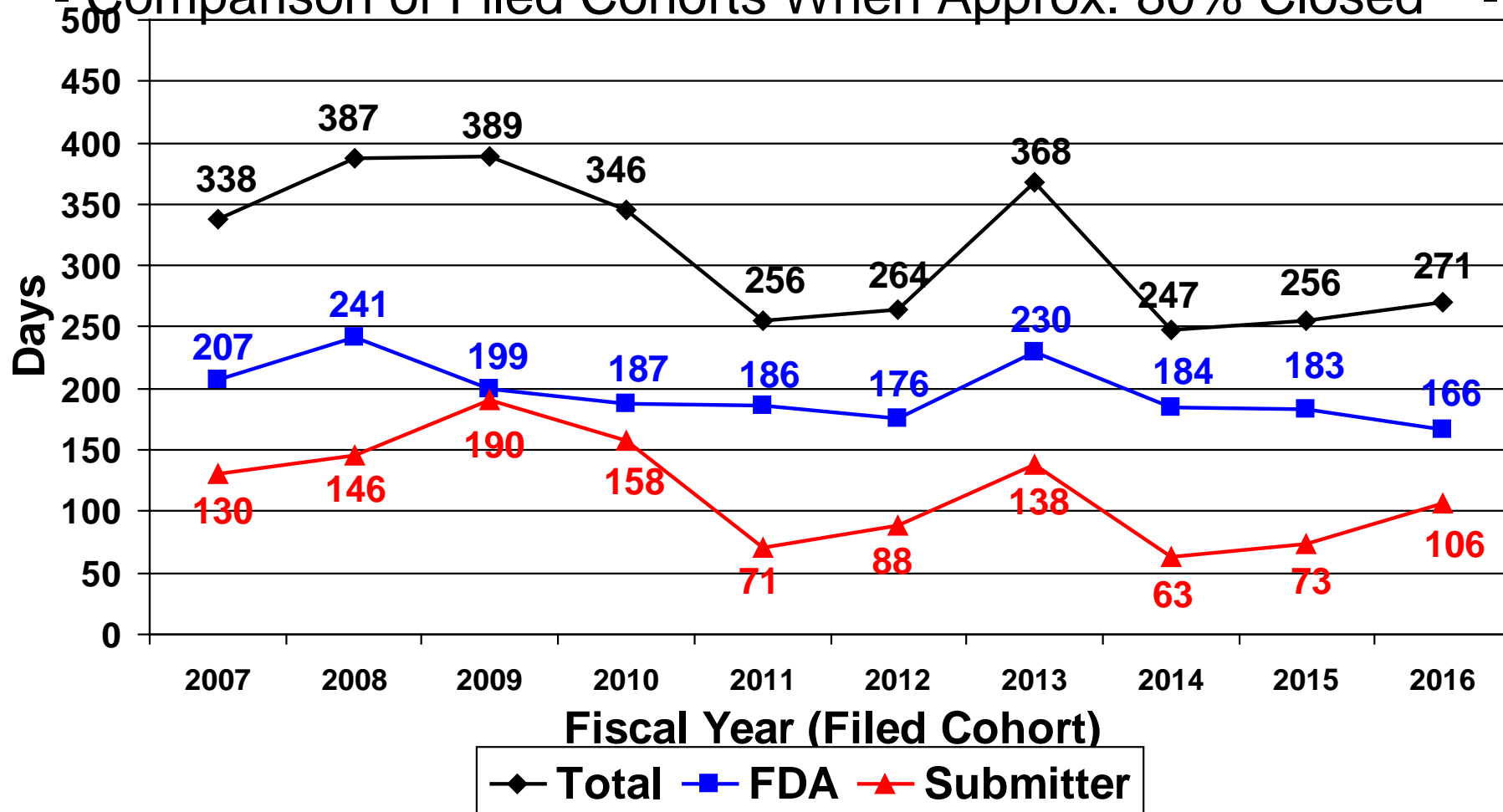
◆ Total ■ FDA ▲ Submitter

*Includes original PMAs filed as of 9/30/2017; times may not add to total due to rounding

** Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY16 = 80% (44/55)

Average Time to MDUFA Decision: PMA Originals*

- Comparison of Filed Cohorts When Approx. 80% Closed** -

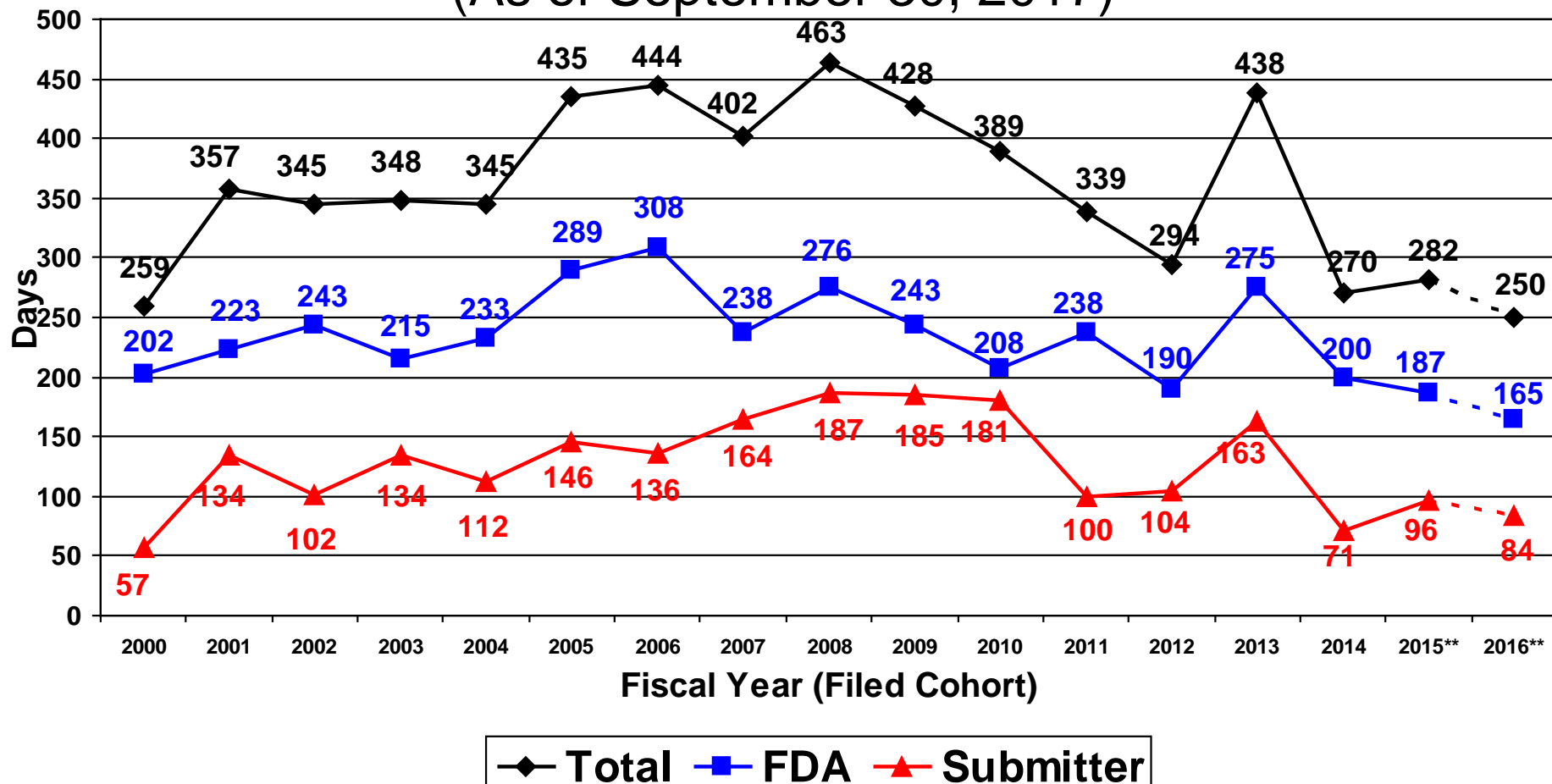


*Includes original PMAs only; times may not add to total due to rounding

**Proportion of cohort closed (MDUFA decision) in this comparison: FY16: 44/55; FY15: 34/42; FY14: 22/28; FY13: 23/29; FY12: 19/24; FY11: 34/43; FY10: 34/43; FY09: 26/32; FY08: 24/30; FY07: 28/35

Average Time to MDUFA Decision: PMA Originals and Panel Track Supplements*

(As of September 30, 2017)

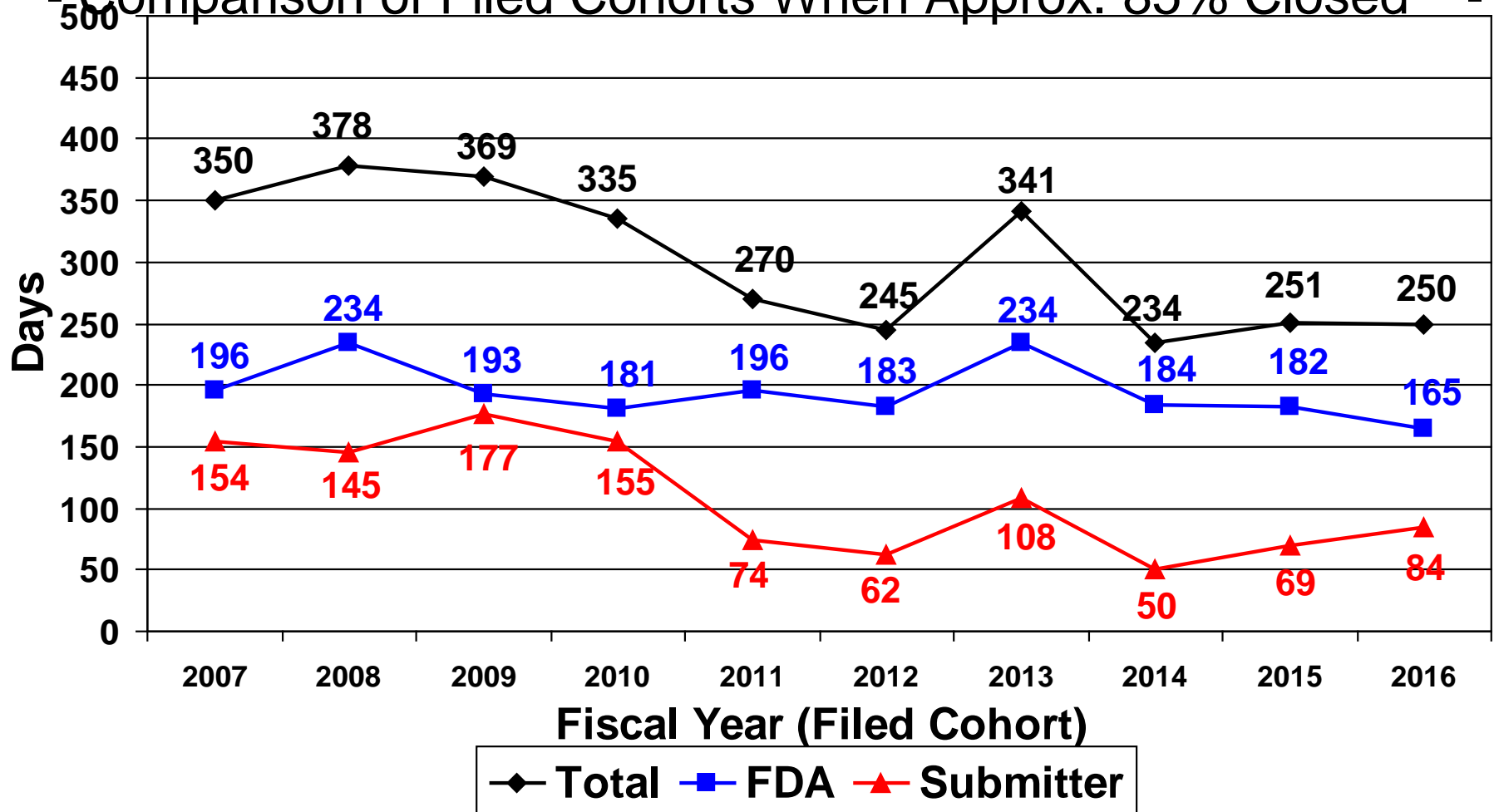


*Includes original PMAs/PTS filed as of 9/30/2017; times may not add to total due to rounding

** Cohort still open, average times will increase; percent of cohort with MDUFA decision:
FY16 = 85% (60/71)

Average Time to MDUFA Decision: PMA Originals and Panel Track Supplements*

- Comparison of Filed Cohorts When Approx. 85% Closed** -

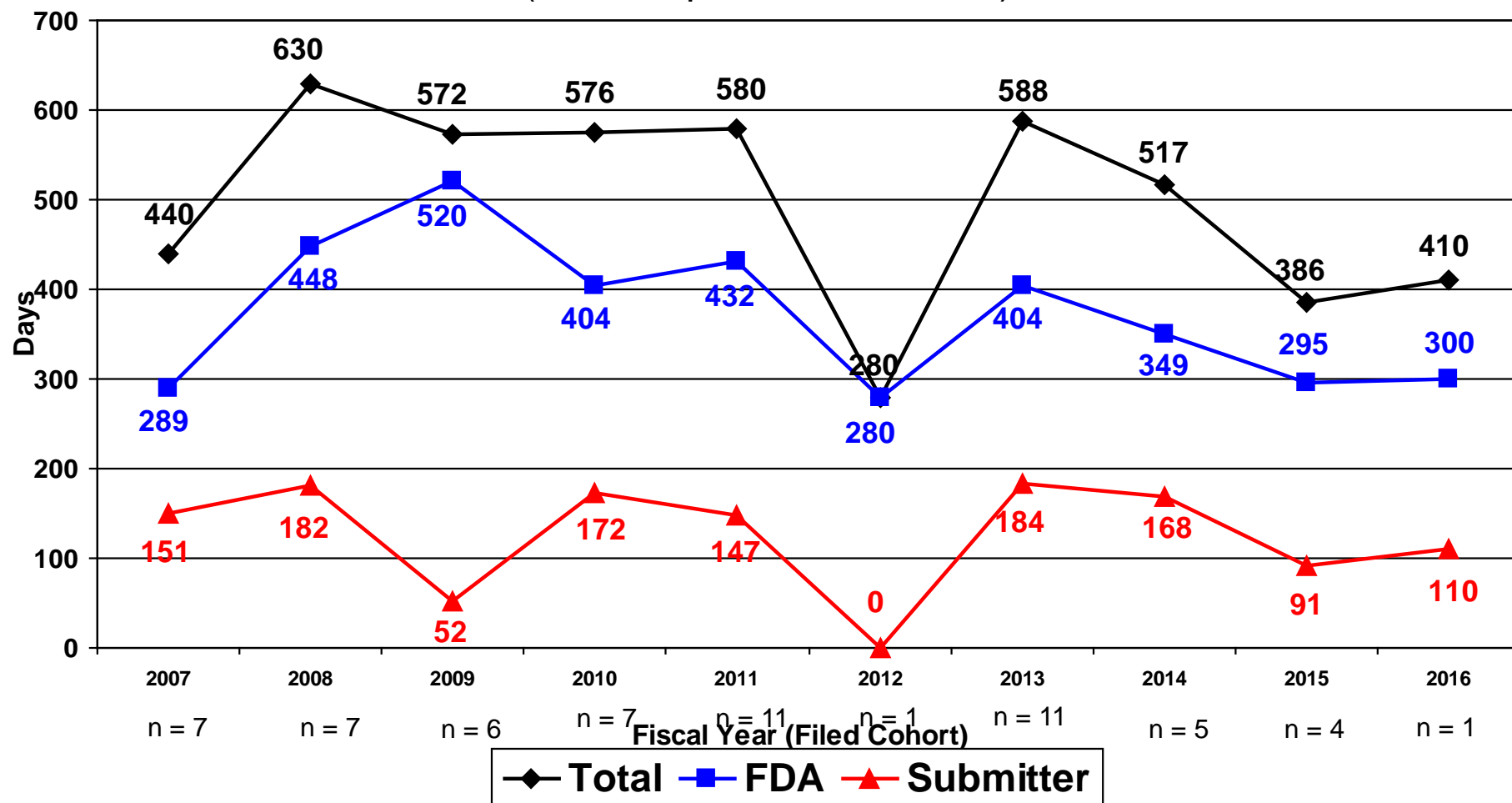


*Includes original PMAs and Panel Track Supplements; times may not add to total due to rounding

**Proportion of cohort closed (MDUFA decision) in this comparison: FY16: 60/71; FY15: 58/68; FY14: 36/42; FY13: 37/44 ; FY12: 29/34; FY11: 43/51; FY10: 50/59; FY09: 37/43; FY08: 31/37; FY07: 33/39

Average Time to MDUFA Decision: PMA Originals With Panel Review*

(As of September 30, 2017)

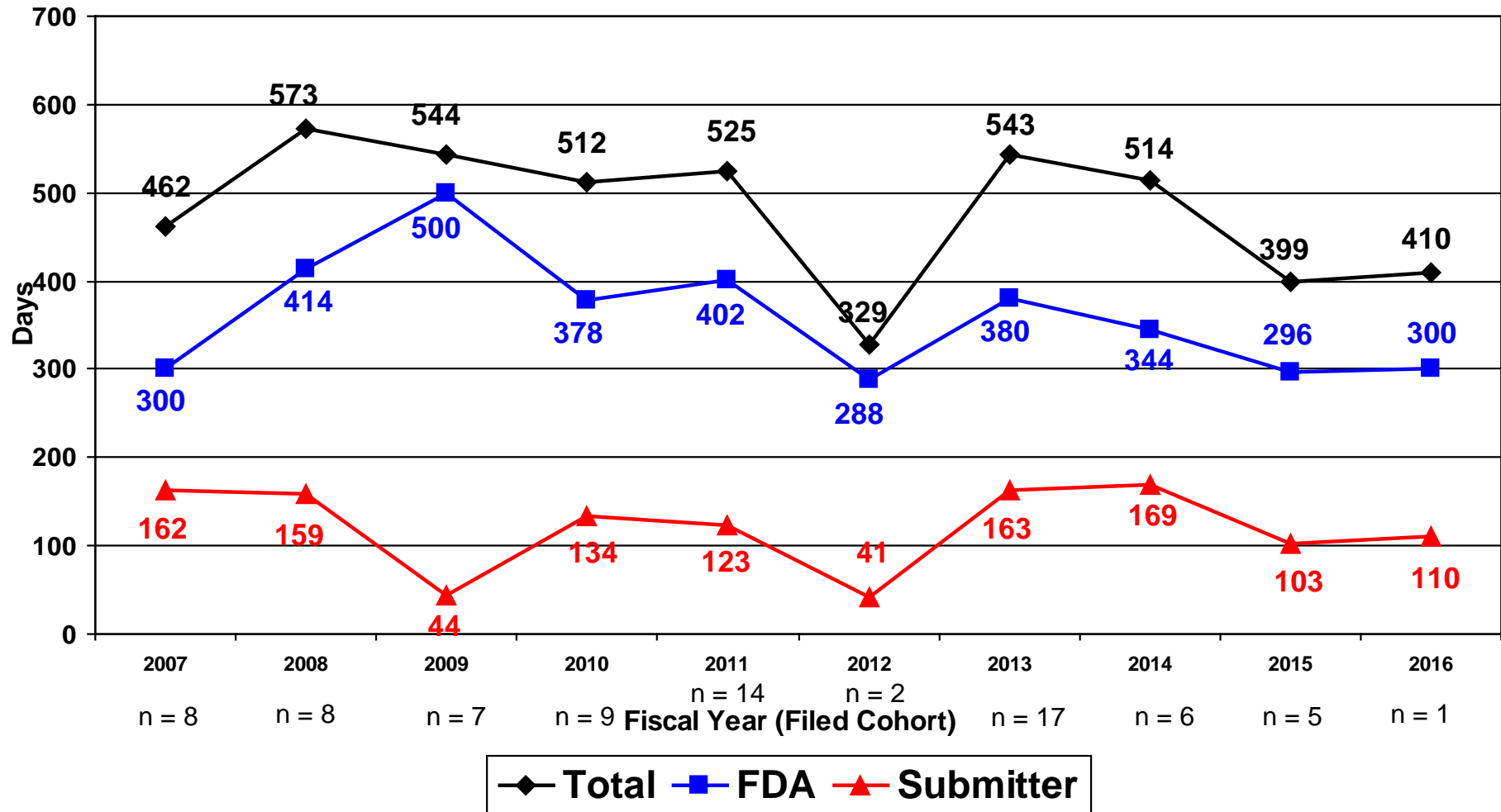


*Includes original PMAs filed as of 9/30/2017; times may not add to total due to rounding.

**Cohort still open

Average Time to MDUFA Decision: PMA Originals & Panel Track Supplements With Panel Review*

(As of September 30, 2017)



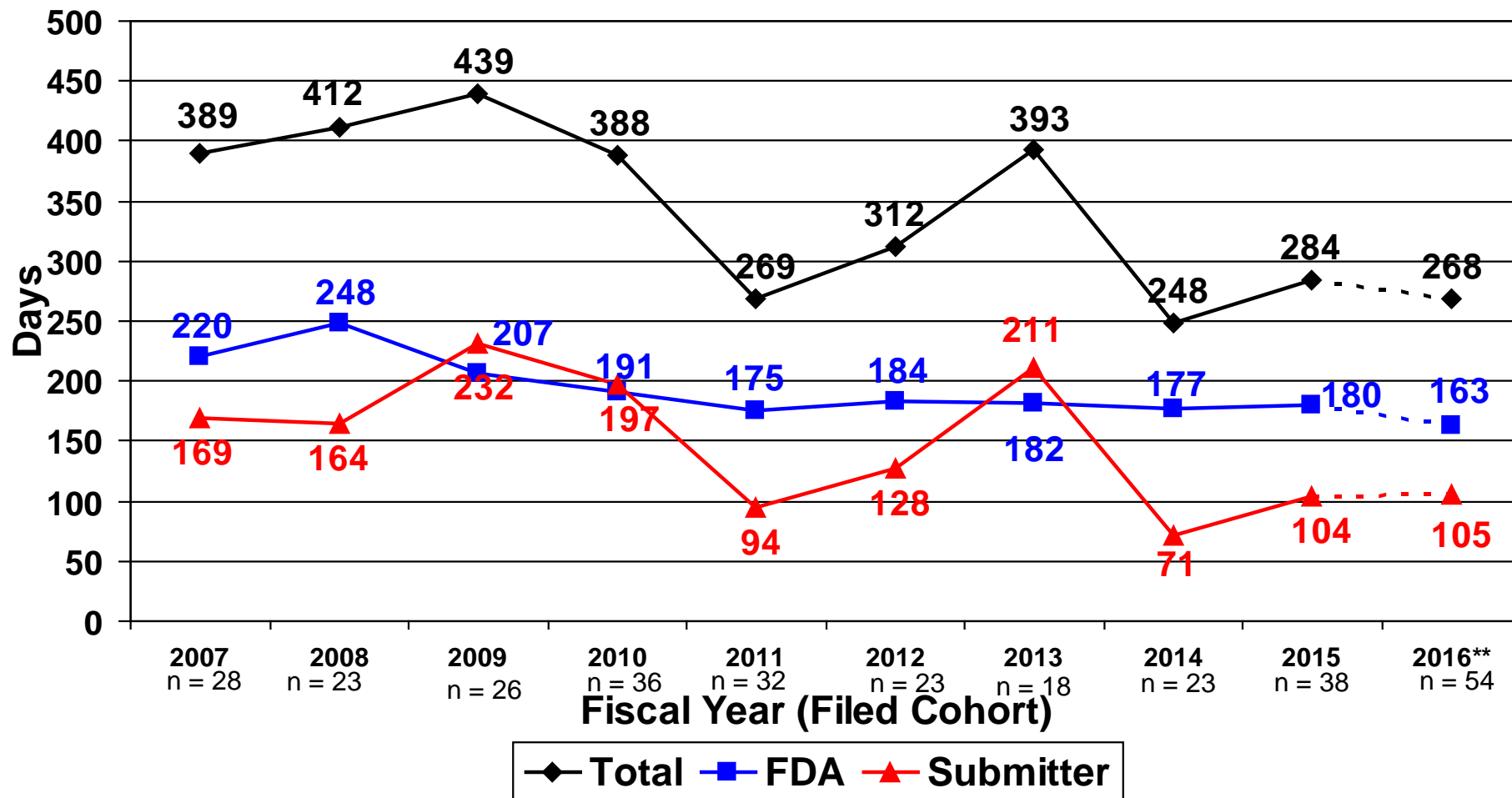
*Includes original PMAs/PTS filed as of 9/30/2017, prior cohorts are filed cohorts; times may not add to total due to rounding.

**Cohort still open

- Performance data (from FY13 onward) map Table 1.8 in the CDRH MDUFA III performance report. Numbers filed map to table 1.6.

Average Time to MDUFA Decision: PMA Originals Without Panel Review*

(As of September 30, 2017)

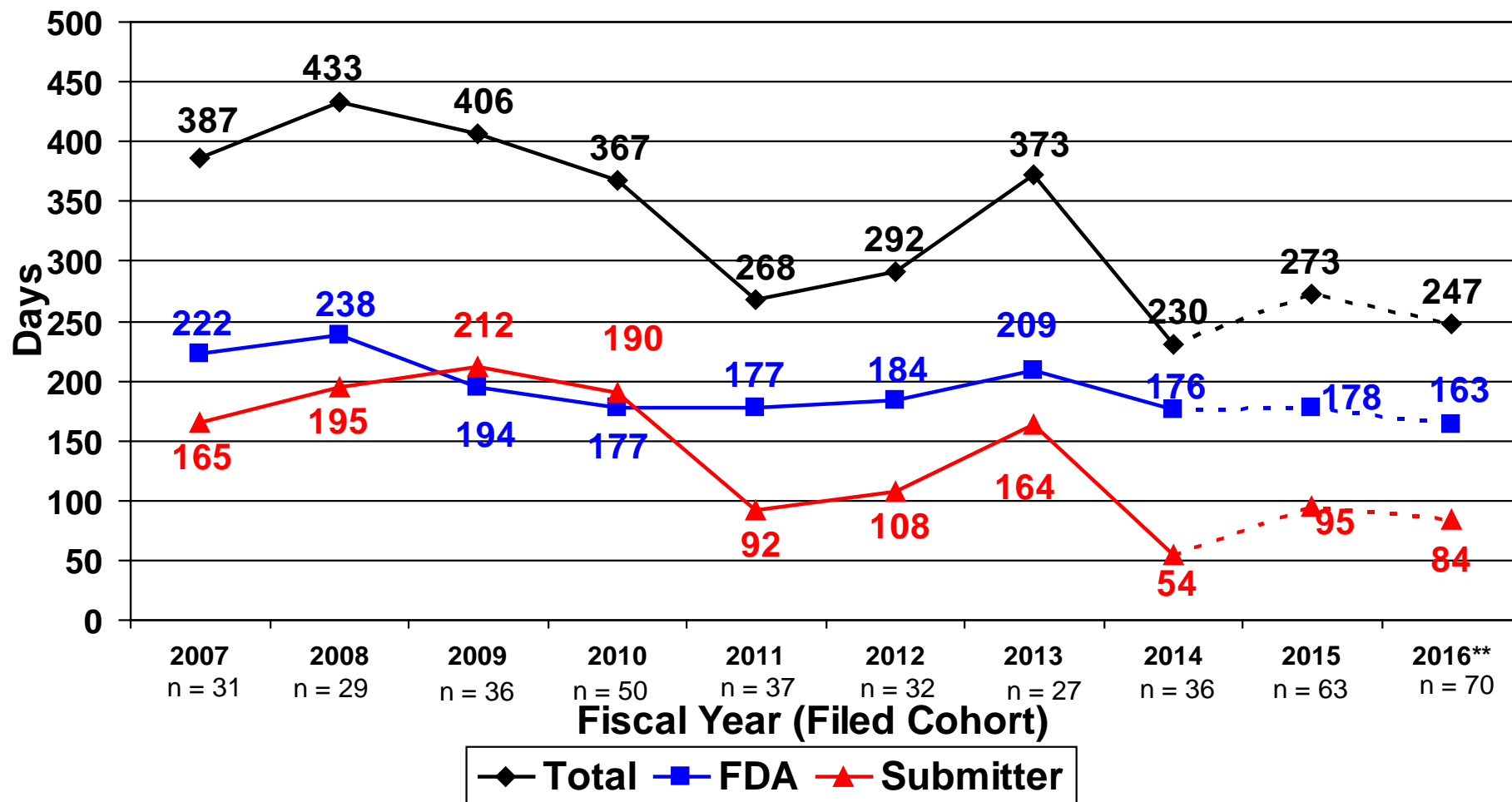


*Includes original PMAs filed as of 9/30/2017; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision:
FY16 = 80% (43/54)

Average Time to MDUFA Decision: PMA Original & Panel Track Supplements Without Panel Review*

(As of September 30, 2017)

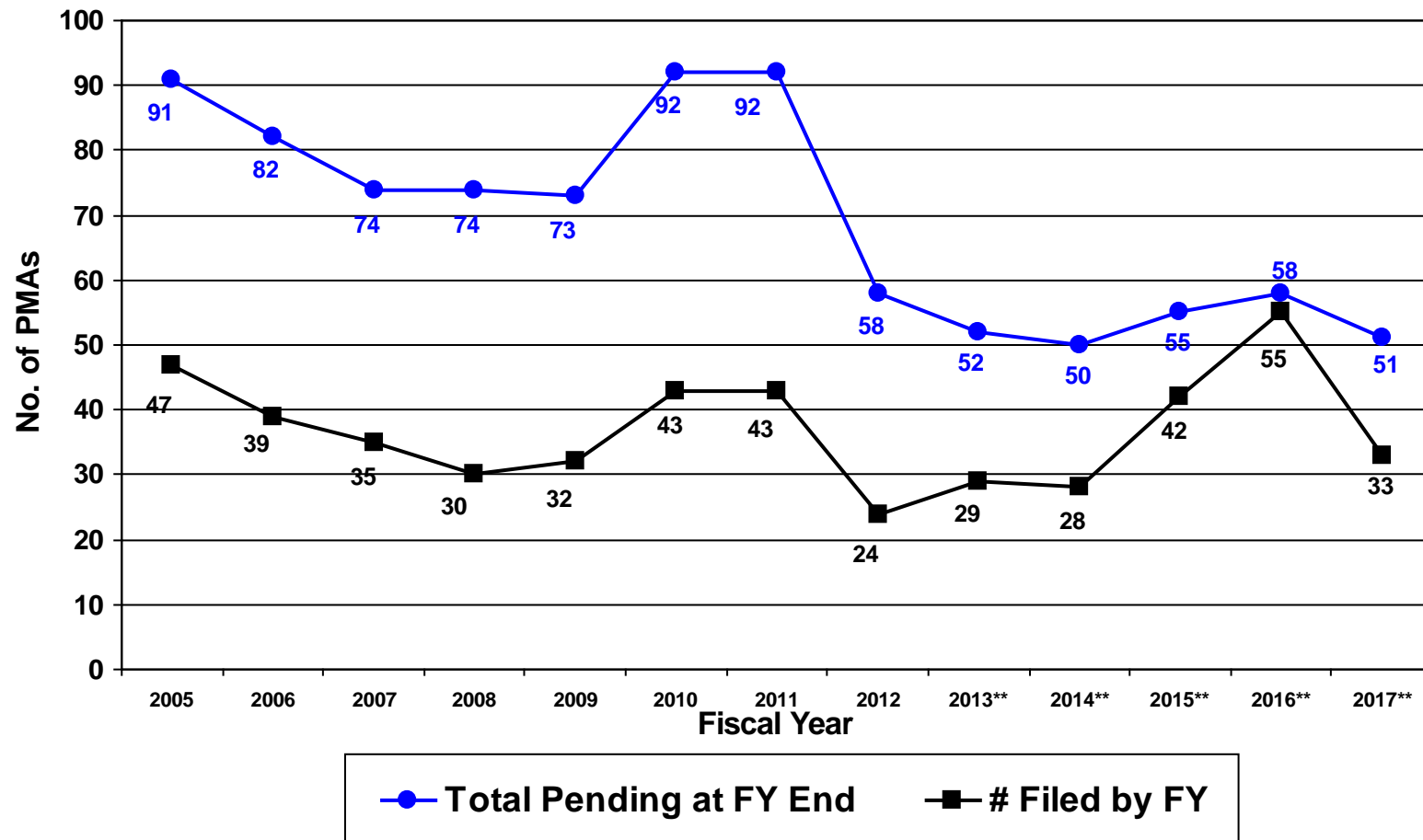


*Includes original PMAs/PTS filed as of 9/30/2017; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY16 = 84% (59/70)

- Performance data (from FY13 onward) map to Table 1.7 in the CDRH MDUFA III performance report. Numbers filed map to table 1.5.

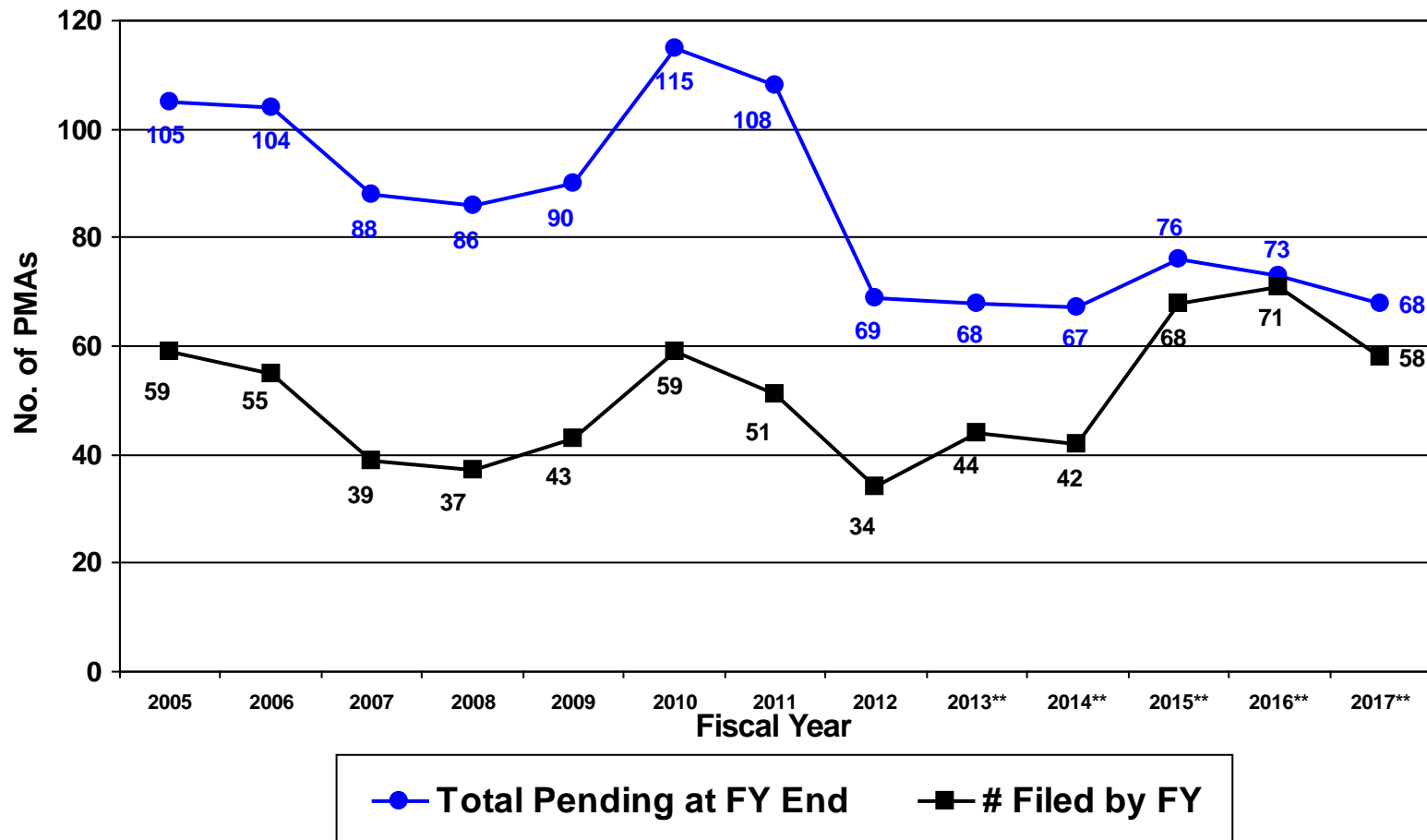
PMA Originals Pending* at End of Year



*Original PMAs under review or on hold

**Excludes FY 2013 - FY 2017 receipts that were not accepted for review at quarter end

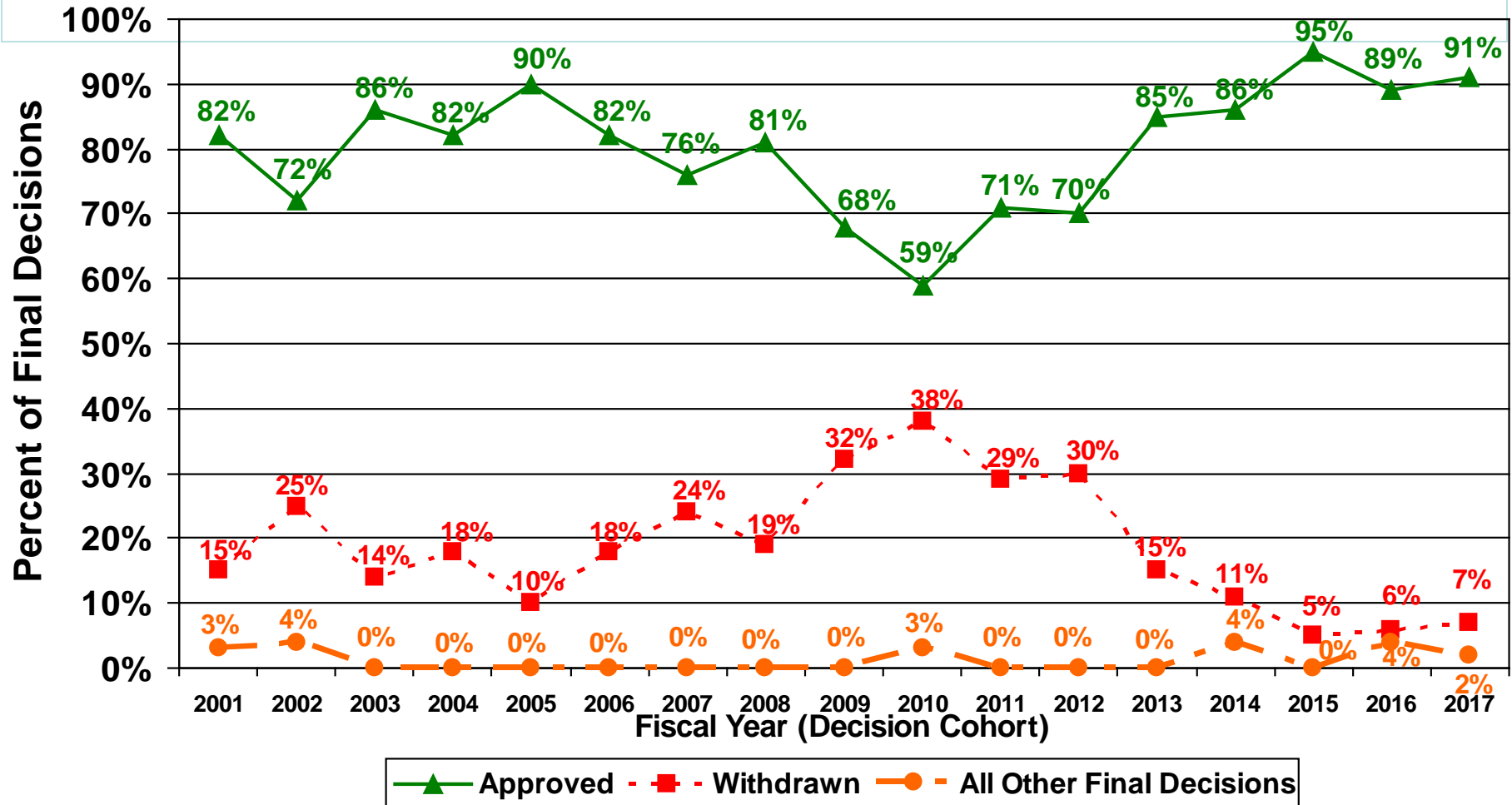
PMA Original and Panel Track Supplements Pending* at End of Year



*Original PMAs/PTS under review or on hold

**Excludes FY 2013 - FY 2017 receipts that were not accepted for review at quarter end

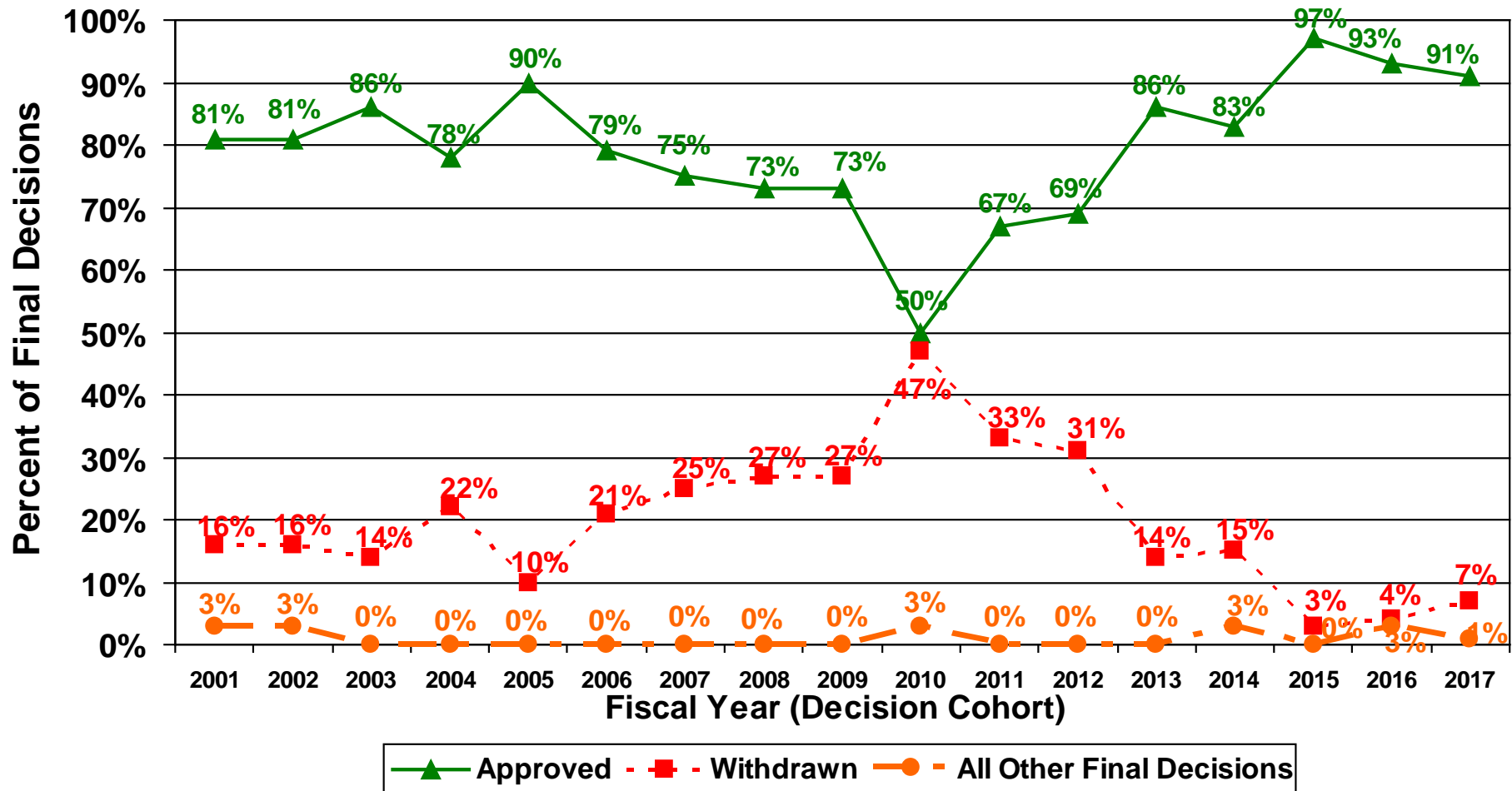
Percent of PMA Originals Approved*



*Based on final decisions on original PMAs that were accepted for filing as of 9/30/2017; percentages may not add to 100% due to rounding.

Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions from FY16 onward

Percent of PMA Originals and Panel Track Supplements Approved*

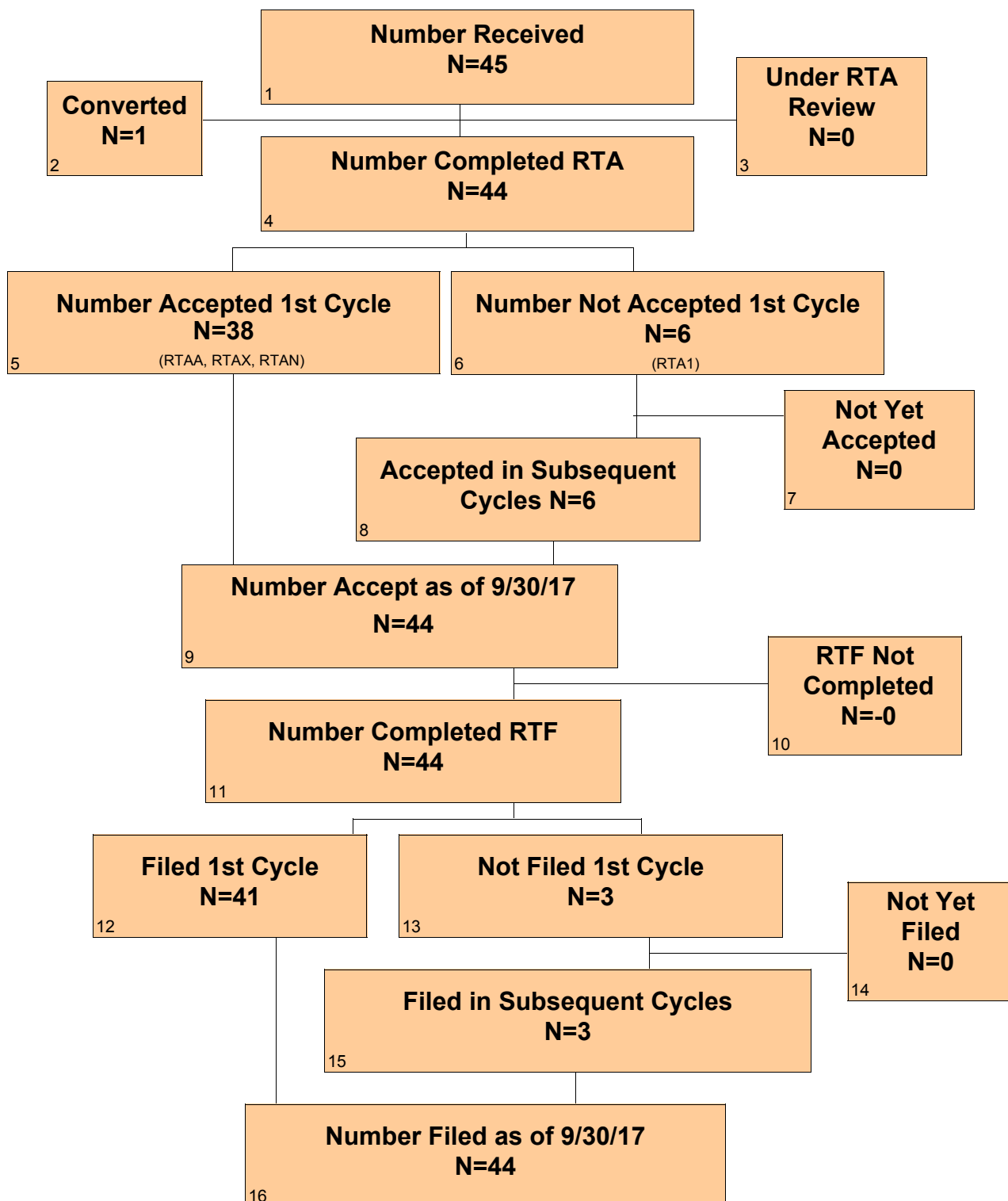


*Based on original PMAs/PTS that were accepted for filing as of 9/30/2017; percentages may not add to 100% due to rounding.

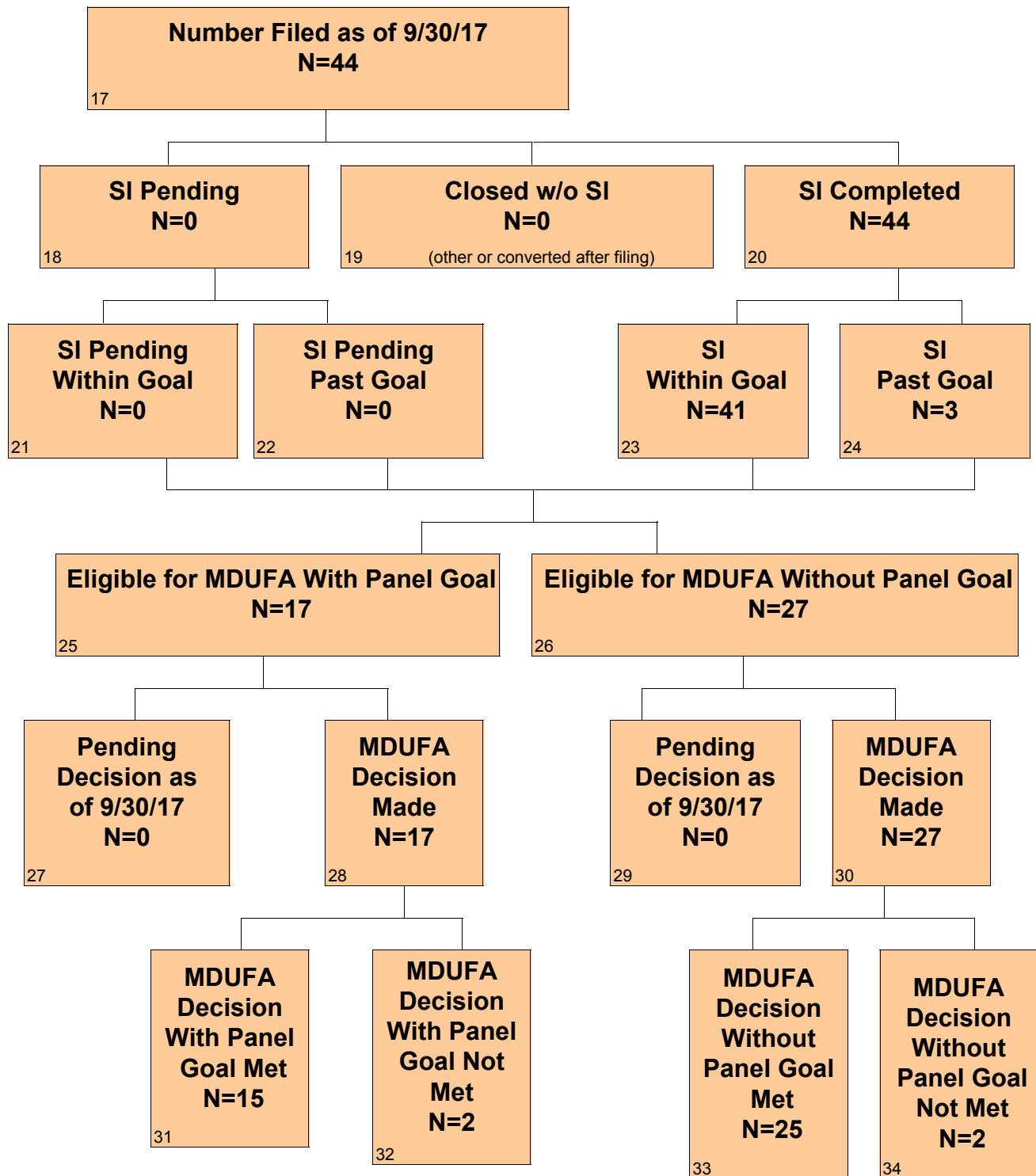
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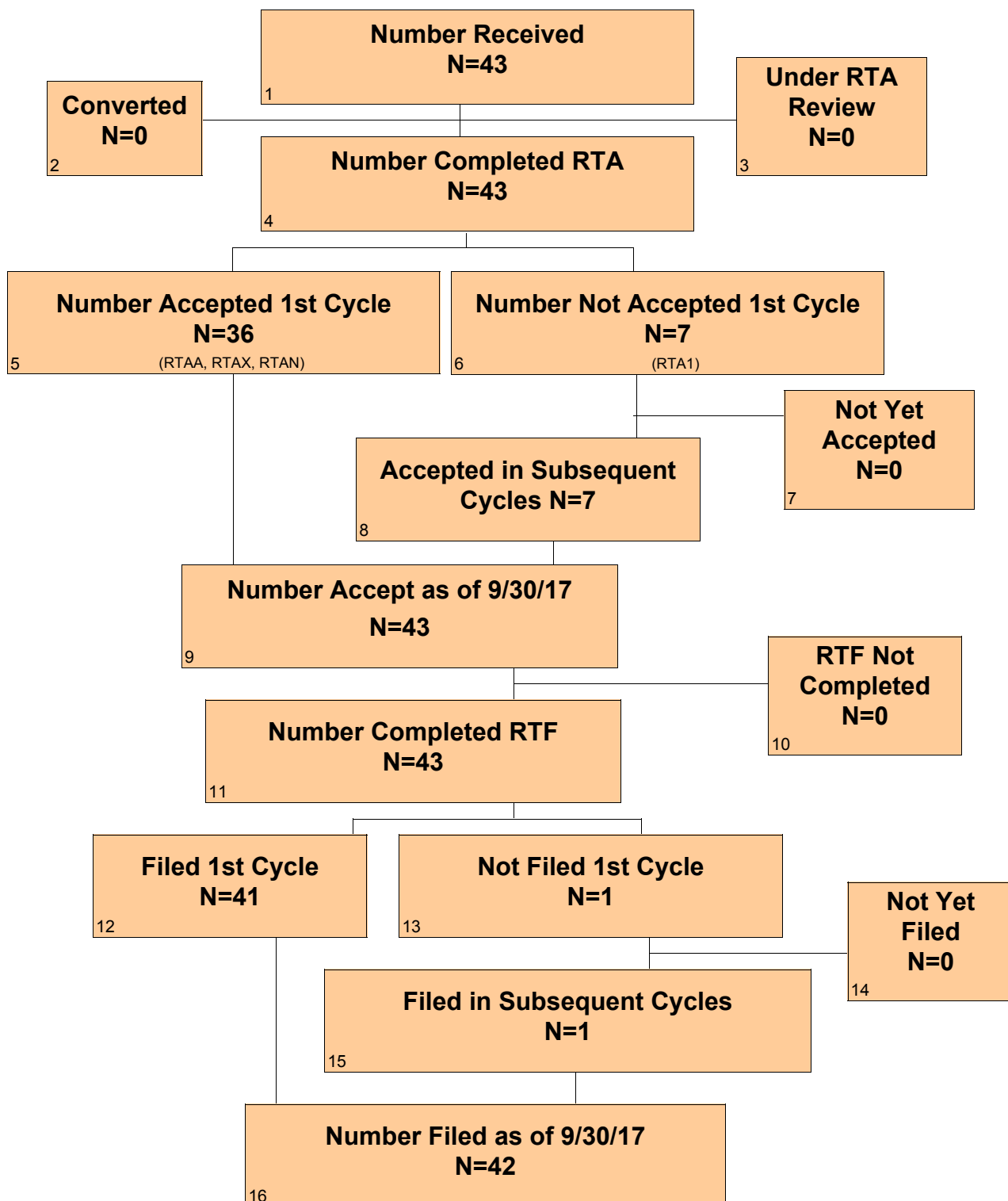
CDRH PMA Original and Panel Track Supplements - FY 2013 As of 9/30/17



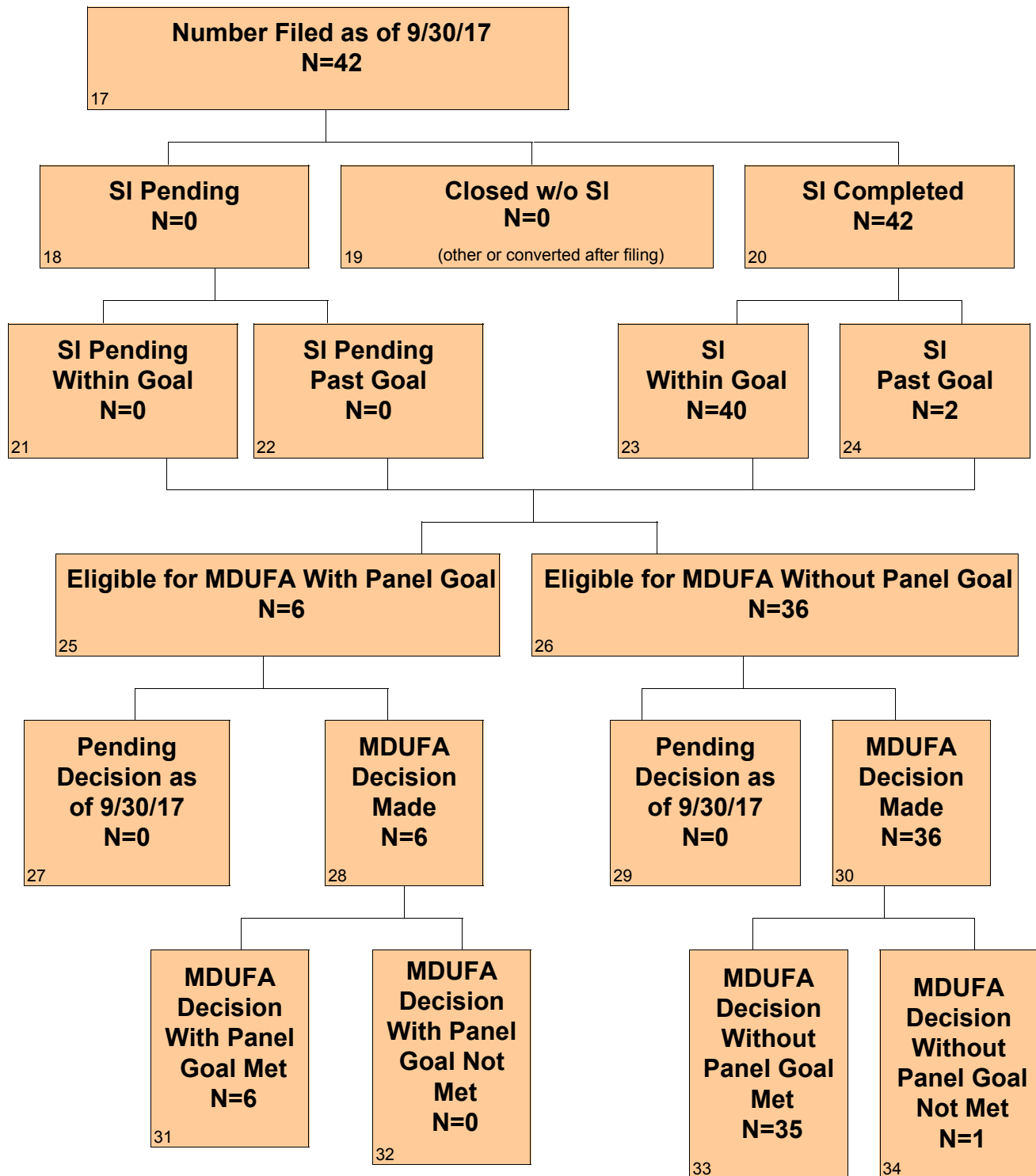
CDRH PMA Original and Panel Track Supplements - FY 2013 As of 9/30/17 Continued



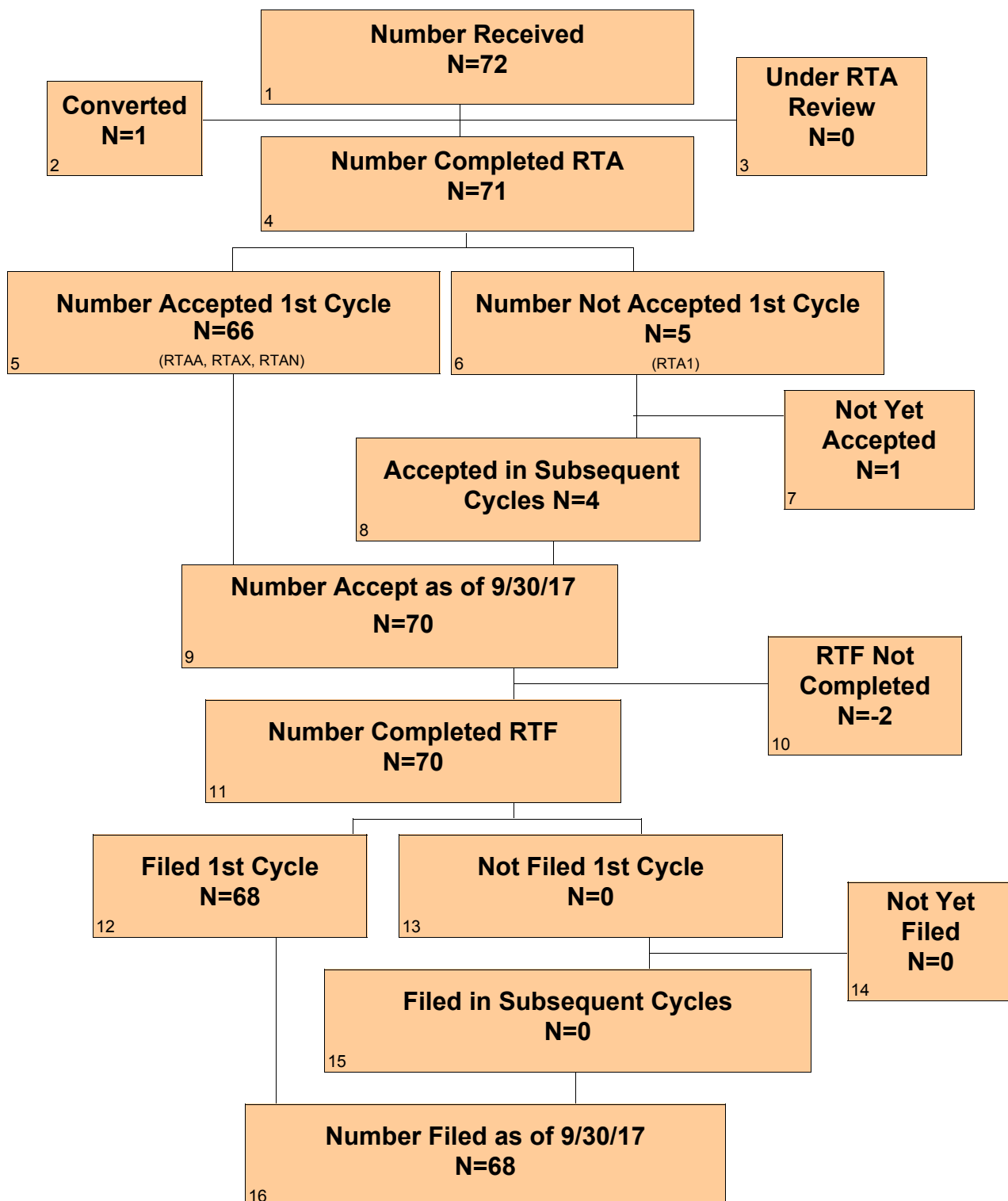
CDRH PMA Original and Panel Track Supplements - FY 2014 As of 9/30/17



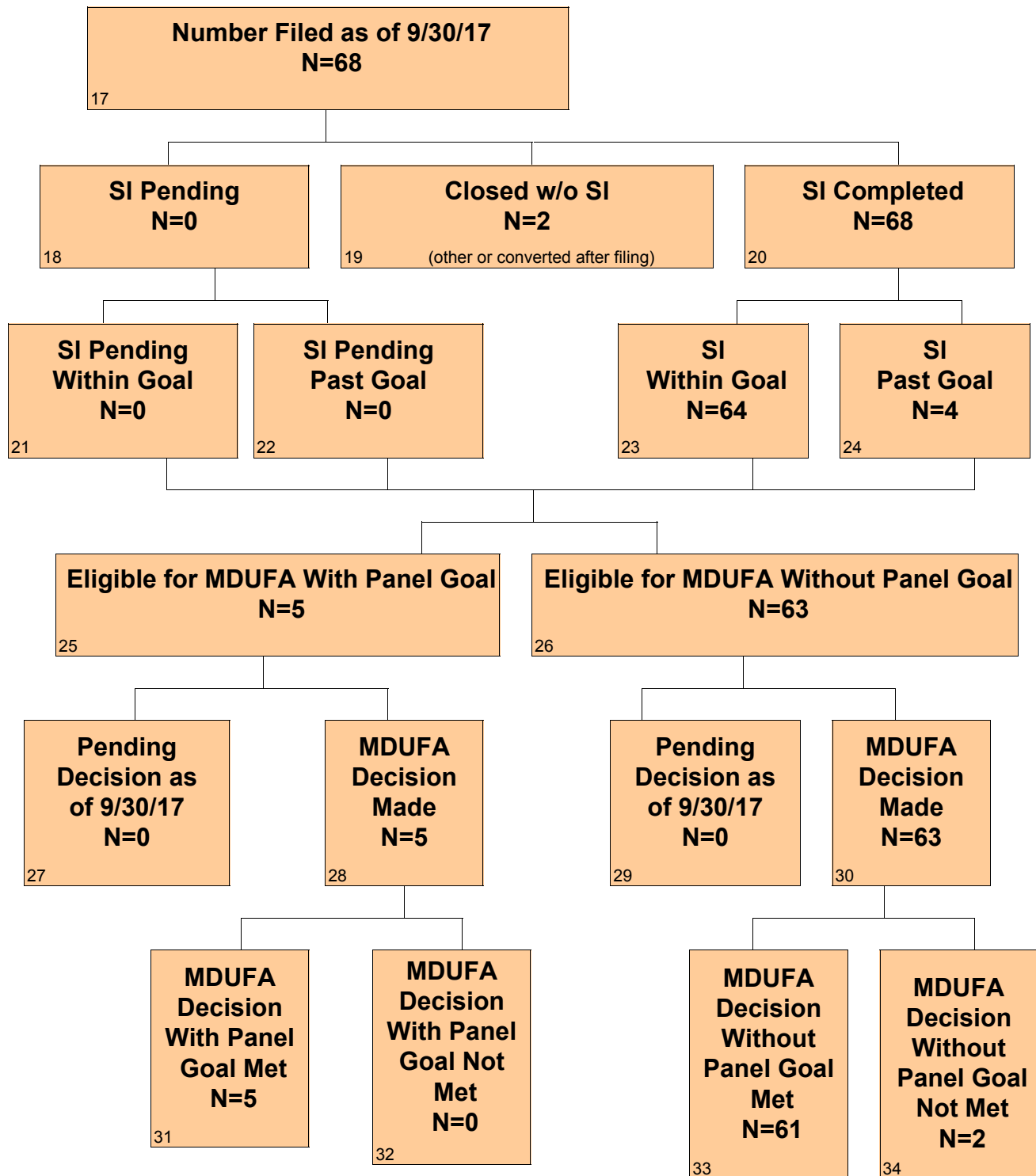
CDRH PMA Original and Panel Track Supplements - FY 2014 As of 9/30/17 Continued



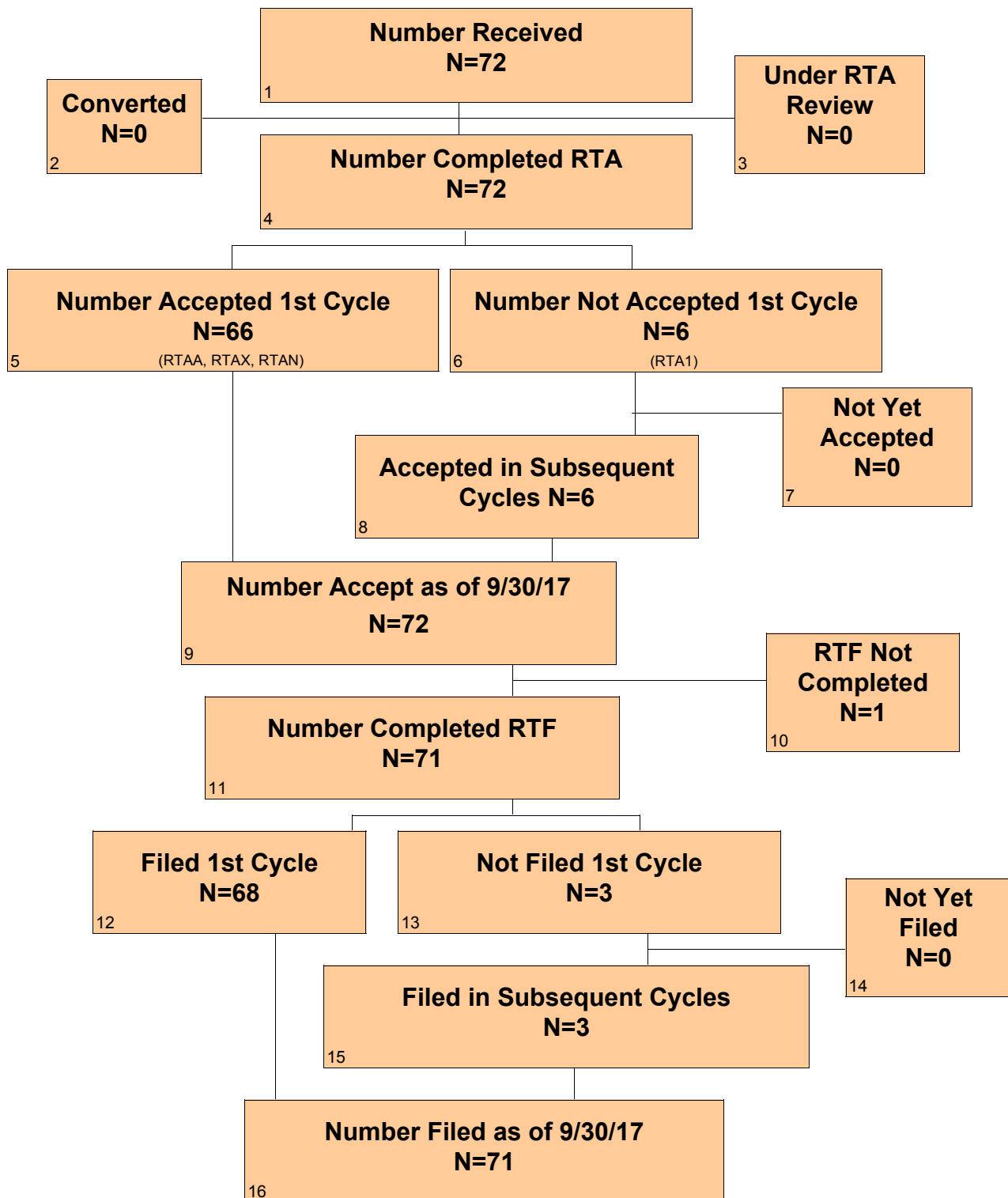
CDRH PMA Original and Panel Track Supplements - FY 2015 As of 9/30/17



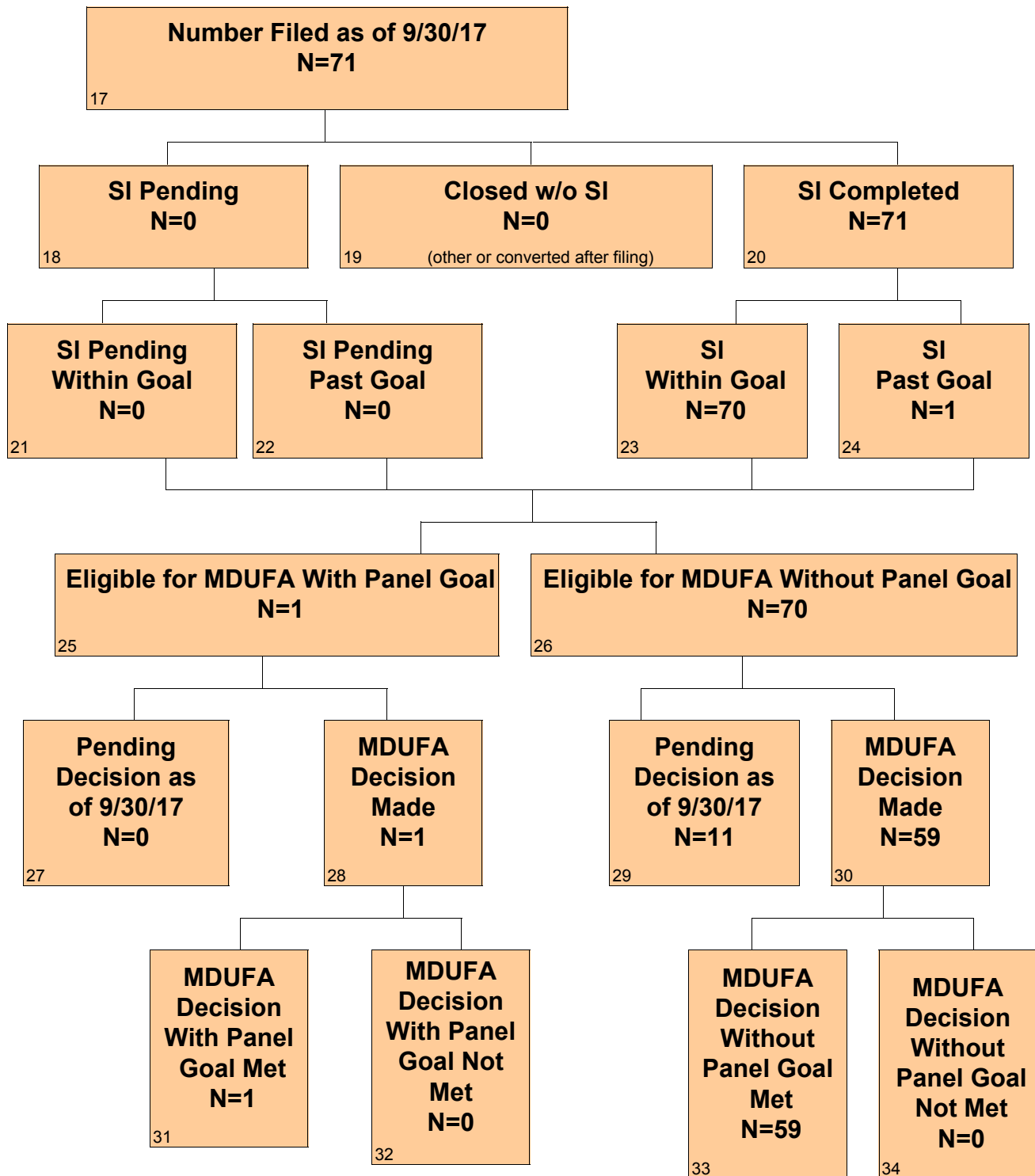
CDRH PMA Original and Panel Track Supplements - FY 2015 As of 9/30/17 Continued



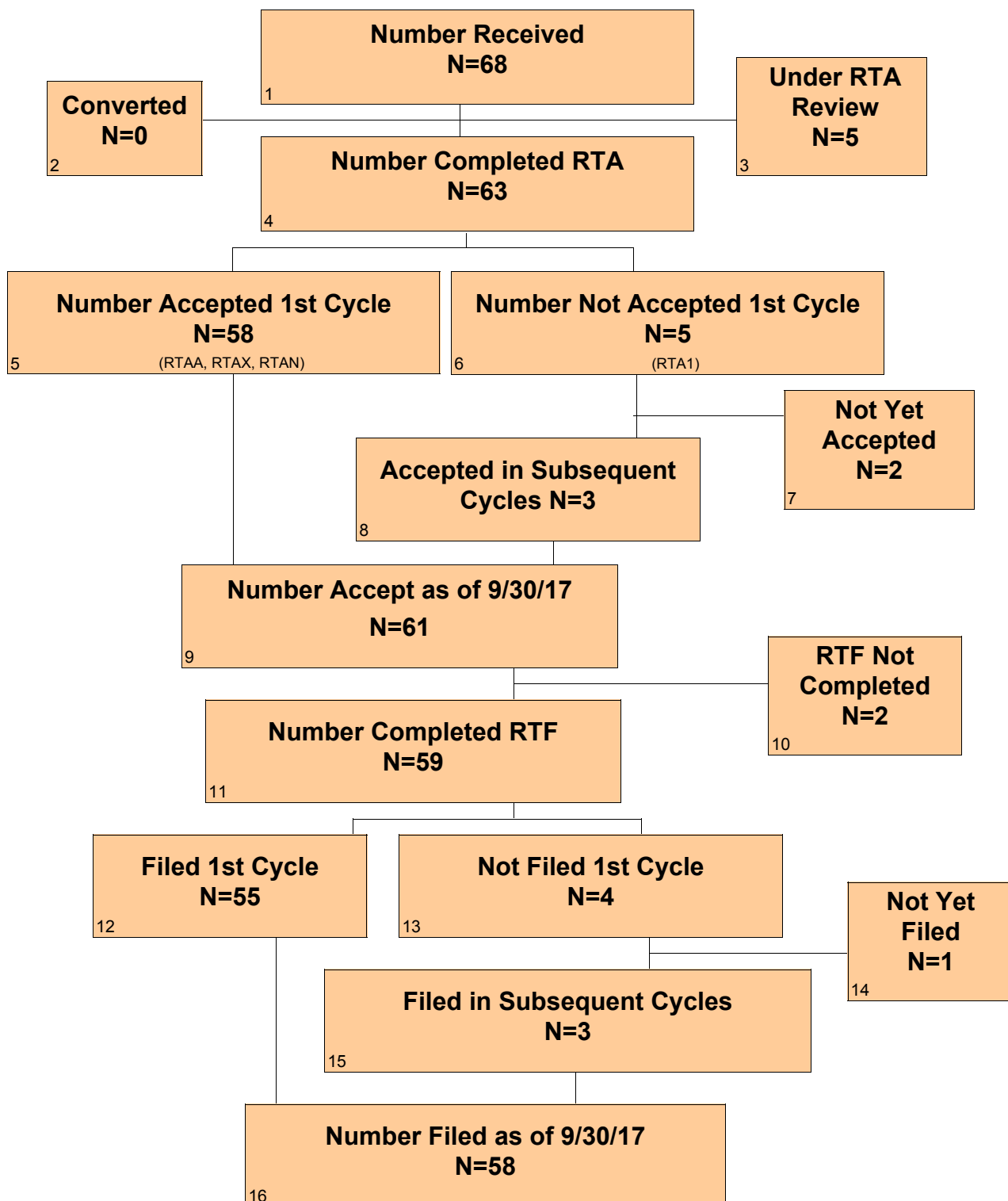
CDRH PMA Original and Panel Track Supplements - FY 2016 As of 9/30/17



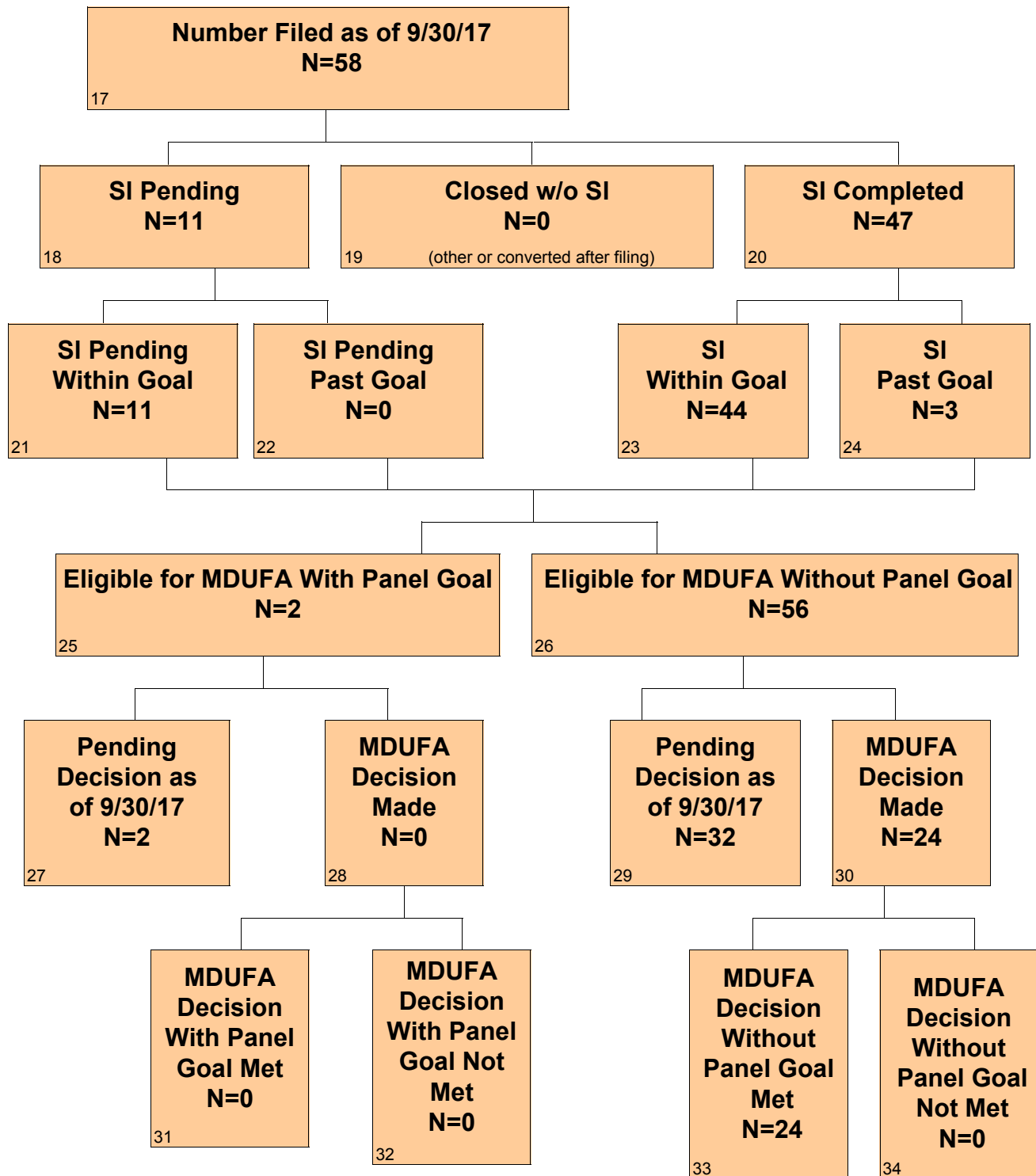
CDRH PMA Original and Panel Track Supplements - FY 2016 As of 9/30/17 Continued



CDRH PMA Original and Panel Track Supplements - FY 2017 As of 9/30/17



CDRH PMA Original and Panel Track Supplements - FY 2017 As of 9/30/17 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	57
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	5
Number Not Accepted for Filing Review	6	7	5	6	5
Rate of submissions not accepted for filing review	17.6%	16.3%	7.0%	8.3%	7.9%

*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	58
Completed RTF	44	42	68	71	59
Number Not Filed	3	1	0	3	4
Rate of submissions Not Filed	6.8%	2.4%	0%	4.2%	6.8%

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	44	42	68	71	58
SI Goal Met	41	40	64	70	44
SI Goal Not Met	3	2	4	1	3
SI Pending Within Goal	0	0	0	0	11
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	93.2%	95.2%	94.1%	98.6%	93.6%

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	47
Average number of FDA days to Substantive Interaction	109.73	90.02	91.74	87.52	88.51
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	1031	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	63	70	56
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	27	36	63	59	24
MDUFA III Decisions Goal Met	25	35	61	59	24
PMAs pending MDUFA III Decision	0	0	0	11	32
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	92.6%	97.2%	96.8%	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	5	1	2
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	17	6	5	1	0
MDUFA III Decisions Goal Met	15	6	5	1	0
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	88.2%	100%	100%	100%	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	27	36	63	59	24
Average FDA days to MDUFA III decision	208.81	175.81	177.87	163.10	172.46
20th Percentile FDA days to MDUFA III decision	175	176	174	138	162
40th Percentile FDA days to MDUFA III decision	178	179	178	176	177
60th Percentile FDA days to MDUFA III decision	180	179	180	178	179
80th Percentile FDA days to MDUFA III decision	180	180	180	180	180
Maximum FDA days to MDUFA III decision	1031	359	256	256	258
Average Industry days to MDUFA III decision	163.81	54.08	95.33	83.69	33.96
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	80	0	44	37	0
60th Percentile Industry days to MDUFA III decision	116	48	83	74	34
80th Percentile Industry days to MDUFA III decision	337	106	176	134	56
Maximum Industry days to MDUFA III decision	563	238	361	368	170
Average Total days to MDUFA III decision	372.63	229.89	273.21	246.80	206.42
20th Percentile Total days to MDUFA III decision	181	179	178	177	178
40th Percentile Total days to MDUFA III decision	253	180	220	212	180
60th Percentile Total days to MDUFA III decision	345	244	263	243	217
80th Percentile Total days to MDUFA III decision	538	283	361	302	246
Maximum Total days to MDUFA III decision	1031	418	607	548	266

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	5	1	0
Average FDA days to MDUFA III decision	380.2	344.3	296.0	300	0
20th Percentile FDA days to MDUFA III decision	291	318	280	300	0
40th Percentile FDA days to MDUFA III decision	315	320	310	300	0
60th Percentile FDA days to MDUFA III decision	318	359	318	300	0
80th Percentile FDA days to MDUFA III decision	510	376	323	300	0
Maximum FDA days to MDUFA III decision	700	379	339	300	0
Average Industry days to MDUFA III decision	162.8	169.3	103.2	411.0	0
20th Percentile Industry days to MDUFA III decision	0	20	89	411	0
40th Percentile Industry days to MDUFA III decision	44	101	107	411	0
60th Percentile Industry days to MDUFA III decision	163	178	114	411	0
80th Percentile Industry days to MDUFA III decision	272	358	126	411	0
Maximum Industry days to MDUFA III decision	728	359	153	411	0
Average Total days to MDUFA III decision	543.0	513.7	399.2	711.0	0
20th Percentile Total days to MDUFA III decision	316	399	361	711	0
40th Percentile Total days to MDUFA III decision	371	415	401	711	0
60th Percentile Total days to MDUFA III decision	498	498	424	711	0
80th Percentile Total days to MDUFA III decision	656	717	432	711	0
Maximum Total days to MDUFA III decision	1428	735	452	711	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	27	36	63	70	56
Number with MDUFA decision	27	36	63	59	24
Number of Withdrawals	1	1	0	3	2
Number of Not Approvable	4	2	11	3	0
Rate of Withdrawals	3.7%	2.8%	0%	5.1%	8.3%
Rate of Not Approvable	14.8%	5.6%	17.5%	5.1%	0%

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	5	1	2
Number with MDUFA decision	17	6	5	1	0
Number of Withdrawals	1	1	1	0	0
Number of Not Approvable	3	1	1	0	0
Rate of Withdrawals	5.9%	16.7%	20.0%	0%	N/A
Rate of Not Approvable	17.6%	16.7%	20.0%	0%	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	1	2	0	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

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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	37
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	2
Number Not Accepted for Filing Review	6	6	5	5	3
Rate of submissions not accepted for filing review	22.2%	16.2%	9.3%	10.9%	7.3%

*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	38
Completed RTF	34	36	51	46	40
Number Not Filed	3	1	0	3	2
Rate of submissions Not Filed	8.8%	2.8%	0%	6.5%	5.0%

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	40
SI Goal Met	31	34	48	46	31
SI Goal Not Met	3	2	3	0	2
SI Pending Within Goal	0	0	0	0	7
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	91.2%	94.4%	94.1%	100%	93.9%

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	33
Average number of FDA days to Substantive Interaction	115.9	90.6	94.3	90.3	87.2
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	1031	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	47	45	39
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	21	30	47	35	15
MDUFA III Decisions Goal Met	19	29	45	35	15
PMAs pending MDUFA III Decision	0	0	0	10	24
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	90.5%	96.7%	95.7%	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	4	1	1
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	13	6	4	1	0
MDUFA III Decisions Goal Met	11	6	4	1	0
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	84.6%	100%	100%	100%	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	21	30	47	35	15
Average FDA days to MDUFA III decision	225.1	178.3	185.0	173.3	179.8
20th Percentile FDA days to MDUFA III decision	177	175	178	177	177
40th Percentile FDA days to MDUFA III decision	180	179	179	178	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	1031	359	256	256	258
Average Industry days to MDUFA III decision	167.3	49.4	106.4	76.3	20.8
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	68	11	46	35	0
60th Percentile Industry days to MDUFA III decision	113	46	97	59	13
80th Percentile Industry days to MDUFA III decision	356	82	182	109	42
Maximum Industry days to MDUFA III decision	563	193	361	368	96
Average Total days to MDUFA III decision	392.3	227.7	291.4	249.6	200.6
20th Percentile Total days to MDUFA III decision	180	179	180	179	178
40th Percentile Total days to MDUFA III decision	260	190	235	214	180
60th Percentile Total days to MDUFA III decision	397	238	283	240	212
80th Percentile Total days to MDUFA III decision	540	267	385	295	233
Maximum Total days to MDUFA III decision	1031	392	607	548	266

**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	4	1	0
Average FDA days to MDUFA III decision	409.2	344.3	295.3	300	0
20th Percentile FDA days to MDUFA III decision	299	318	273	300	0
40th Percentile FDA days to MDUFA III decision	316	320	317	300	0
60th Percentile FDA days to MDUFA III decision	356	359	319	300	0
80th Percentile FDA days to MDUFA III decision	606	376	327	300	0
Maximum FDA days to MDUFA III decision	700	379	339	300	0
Average Industry days to MDUFA III decision	190.3	169.3	90.8	110.0	0
20th Percentile Industry days to MDUFA III decision	0	20	74	110	0
40th Percentile Industry days to MDUFA III decision	60	101	104	110	0
60th Percentile Industry days to MDUFA III decision	180	178	109	110	0
80th Percentile Industry days to MDUFA III decision	294	358	114	110	0
Maximum Industry days to MDUFA III decision	728	359	119	110	0
Average Total days to MDUFA III decision	599.5	513.7	386.0	410.0	0
20th Percentile Total days to MDUFA III decision	319	399	352	410	0
40th Percentile Total days to MDUFA III decision	394	415	380	410	0
60th Percentile Total days to MDUFA III decision	577	498	412	410	0
80th Percentile Total days to MDUFA III decision	750	717	424	410	0
Maximum Total days to MDUFA III decision	1428	735	427	410	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	21	30	47	45	39
Number with MDUFA decision	21	30	47	35	15
Number of Withdrawals	1	1	0	2	0
Number of Not Approvable	3	2	10	0	0
Rate of Withdrawals	4.8%	3.3%	0%	5.7%	0%
Rate of Not Approvable	14.3%	6.7%	21.3%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	13	6	4	1	1
Number with MDUFA decision	13	6	4	1	0
Number of Withdrawals	1	1	1	0	0
Number of Not Approvable	2	1	1	0	0
Rate of Withdrawals	7.7%	16.7%	25.0%	0%	N/A
Rate of Not Approvable	15.4%	16.7%	25.0%	0%	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	1	2	0	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	20
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	3
Number Not Accepted for Filing Review	0	1	0	1	2
Rate of submissions not accepted for filing review	0%	16.7%	0%	3.8%	9.1%

*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	20
Completed RTF	10	6	17	25	19
Number Not Filed	0	0	0	0	2
Rate of submissions Not Filed	0%	0%	0%	0%	10.5%

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	18
SI Goal Met	10	6	16	24	13
SI Goal Not Met	0	0	1	1	1
SI Pending Within Goal	0	0	0	0	4
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%	94.1%	96.0%	92.9%

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	14
Average number of FDA days to Substantive Interaction	88.8	86.3	84.1	82.4	91.6
20th Percentile FDA days to Substantive Interaction	86	85	84	82	88
40th Percentile FDA days to Substantive Interaction	90	86	87	85	90
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	17
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	6	6	16	24	9
MDUFA III Decisions Goal Met	6	6	16	24	9
PMAs pending MDUFA III Decision	0	0	0	1	8
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	0
MDUFA III Decisions Goal Met	4	0	1	0	0
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%	N/A	100%	N/A	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	6	6	16	24	9
Average FDA days to MDUFA III decision	152.0	163.3	156.9	148.3	160.22
20th Percentile FDA days to MDUFA III decision	116	177	133	115	132
40th Percentile FDA days to MDUFA III decision	167	179	170	142	158
60th Percentile FDA days to MDUFA III decision	174	179	175	172	169
80th Percentile FDA days to MDUFA III decision	177	179	177	177	178
Maximum FDA days to MDUFA III decision	179	180	180	179	245
Average Industry days to MDUFA III decision	151.7	77.3	62.8	94.5	55.89
20th Percentile Industry days to MDUFA III decision	81	0	0	16	0
40th Percentile Industry days to MDUFA III decision	107	0	21	46	28
60th Percentile Industry days to MDUFA III decision	118	106	63	117	52
80th Percentile Industry days to MDUFA III decision	133	120	105	155	102
Maximum Industry days to MDUFA III decision	400	238	283	267	170
Average Total days to MDUFA III decision	303.7	240.7	219.8	242.8	216.11
20th Percentile Total days to MDUFA III decision	217	179	172	174	179
40th Percentile Total days to MDUFA III decision	248	179	179	196	199
60th Percentile Total days to MDUFA III decision	284	283	197	250	241
80th Percentile Total days to MDUFA III decision	307	299	284	308	253
Maximum Total days to MDUFA III decision	579	418	459	443	261

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	0
Average FDA days to MDUFA III decision	285.8	0	299.0	0	0
20th Percentile FDA days to MDUFA III decision	261	0	299	0	0
40th Percentile FDA days to MDUFA III decision	301	0	299	0	0
60th Percentile FDA days to MDUFA III decision	311	0	299	0	0
80th Percentile FDA days to MDUFA III decision	319	0	299	0	0
Maximum FDA days to MDUFA III decision	325	0	299	0	0
Average Industry days to MDUFA III decision	73.5	0	153.0	0	0
20th Percentile Industry days to MDUFA III decision	0	0	153	0	0
40th Percentile Industry days to MDUFA III decision	21	0	153	0	0
60th Percentile Industry days to MDUFA III decision	84	0	153	0	0
80th Percentile Industry days to MDUFA III decision	139	0	153	0	0
Maximum Industry days to MDUFA III decision	189	0	153	0	0
Average Total days to MDUFA III decision	359.3	0	452.0	0	0
20th Percentile Total days to MDUFA III decision	261	0	452	0	0
40th Percentile Total days to MDUFA III decision	324	0	452	0	0
60th Percentile Total days to MDUFA III decision	403	0	452	0	0
80th Percentile Total days to MDUFA III decision	460	0	452	0	0
Maximum Total days to MDUFA III decision	504	0	452	0	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	6	6	16	25	17
Number with MDUFA decision	6	6	16	24	9
Number of Withdrawals	0	0	0	1	2
Number of Not Approvable	1	0	1	3	0
Rate of Withdrawals	0%	0%	0%	4.2%	22.2%
Rate of Not Approvable	16.7%	0%	6.3%	12.5%	0.0%

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	0
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	N/A
Rate of Not Approvable	25.0%	N/A	0%	N/A	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	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	85.0	87.0	128.0	90.0	90.0
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	1
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	1
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	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.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	180.0	179.0	218.0	180.0	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	360.0	0	271.5	17.0	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	540.0	179.0	489.5	197.0	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	0
Average FDA days to MDUFA III decision	320.0	0	0	0	0
20th Percentile FDA days to MDUFA III decision	320	0	0	0	0
40th Percentile FDA days to MDUFA III decision	320	0	0	0	0
60th Percentile FDA days to MDUFA III decision	320	0	0	0	0
80th Percentile FDA days to MDUFA III decision	320	0	0	0	0
Maximum FDA days to MDUFA III decision	320	0	0	0	0
Average Industry days to MDUFA III decision	28.0	0	0	0	0
20th Percentile Industry days to MDUFA III decision	28	0	0	0	0
40th Percentile Industry days to MDUFA III decision	28	0	0	0	0
60th Percentile Industry days to MDUFA III decision	28	0	0	0	0
80th Percentile Industry days to MDUFA III decision	28	0	0	0	0
Maximum Industry days to MDUFA III decision	28	0	0	0	0
Average Total days to MDUFA III decision	348.0	0	0	0	0
20th Percentile Total days to MDUFA III decision	348	0	0	0	0
40th Percentile Total days to MDUFA III decision	348	0	0	0	0
60th Percentile Total days to MDUFA III decision	348	0	0	0	0
80th Percentile Total days to MDUFA III decision	348	0	0	0	0
Maximum Total days to MDUFA III decision	348	0	0	0	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1	2	1	1
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	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.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	21
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	1
Number Not Accepted for Filing Review	0	1	2	2	0
Rate of submissions not accepted for filing review	0%	5.9%	7.4%	6.1%	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	21
Number Accepted	19	16	25	31	20
Completed RTF	19	17	27	33	19
Number Not Filed	0	0	0	3	1
Rate of submissions Not Filed	0%	0%	0%	9.1%	5.3%

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	19
SI Goal Met	17	16	26	33	16
SI Goal Not Met	2	1	1	0	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	89.5%	94.1%	96.3%	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	16
Average number of FDA days to Substantive Interaction	138.0	87.7	91.7	90.8	82.4
20th Percentile FDA days to Substantive Interaction	85	87	85	88	85
40th Percentile FDA days to Substantive Interaction	88	88	88	88	87
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	1031	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	25	33	19
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	15	16	25	24	9
MDUFA III Decisions Goal Met	13	15	23	24	9
PMAs pending MDUFA III Decision	0	0	0	9	10
PMAs pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	86.7%	93.8%	92.0%	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	2	0	0
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	4	1	2	0	0
MDUFA III Decisions Goal Met	2	1	2	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	50.0%	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	25	24	9
Average FDA days to MDUFA III decision	243.6	174.3	179.9	170.6	180.3
20th Percentile FDA days to MDUFA III decision	177	177	178	174	172
40th Percentile FDA days to MDUFA III decision	180	178	179	178	178
60th Percentile FDA days to MDUFA III decision	180	179	180	179	179
80th Percentile FDA days to MDUFA III decision	200	180	180	180	179
Maximum FDA days to MDUFA III decision	1031	201	232	256	258
Average Industry days to MDUFA III decision	154.7	29.3	66.9	72.4	20.9
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	55	0	44	34	0
60th Percentile Industry days to MDUFA III decision	99	0	61	56	0
80th Percentile Industry days to MDUFA III decision	262	43	129	110	44
Maximum Industry days to MDUFA III decision	563	161	263	368	96
Average Total days to MDUFA III decision	398.3	203.6	246.8	243.0	201.2
20th Percentile Total days to MDUFA III decision	180	179	180	177	176
40th Percentile Total days to MDUFA III decision	255	179	230	213	179
60th Percentile Total days to MDUFA III decision	319	180	241	237	207
80th Percentile Total days to MDUFA III decision	713	244	309	296	245
Maximum Total days to MDUFA III decision	1031	338	442	548	266

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	2	0	0
Average FDA days to MDUFA III decision	500.0	318.0	329.0	0	0
20th Percentile FDA days to MDUFA III decision	316	318	323	0	0
40th Percentile FDA days to MDUFA III decision	386	318	327	0	0
60th Percentile FDA days to MDUFA III decision	598	318	331	0	0
80th Percentile FDA days to MDUFA III decision	681	318	335	0	0
Maximum FDA days to MDUFA III decision	700	318	339	0	0
Average Industry days to MDUFA III decision	182.0	0	67.0	0	0
20th Percentile Industry days to MDUFA III decision	0	0	45	0	0
40th Percentile Industry days to MDUFA III decision	0	0	60	0	0
60th Percentile Industry days to MDUFA III decision	0	0	74	0	0
80th Percentile Industry days to MDUFA III decision	291	0	89	0	0
Maximum Industry days to MDUFA III decision	728	0	103	0	0
Average Total days to MDUFA III decision	682.0	318.0	396.0	0	0
20th Percentile Total days to MDUFA III decision	316	318	380	0	0
40th Percentile Total days to MDUFA III decision	386	318	391	0	0
60th Percentile Total days to MDUFA III decision	598	318	401	0	0
80th Percentile Total days to MDUFA III decision	972	318	412	0	0
Maximum Total days to MDUFA III decision	1428	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	25	33	19
Number with MDUFA decision	15	16	25	24	9
Number of Withdrawals	1	0	0	2	0
Number of Not Approvable	2	0	4	0	0
Rate of Withdrawals	6.7%	0%	0%	8.3%	0%
Rate of Not Approvable	13.3%	0%	16.0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4	1	2	0	0
Number with MDUFA decision	4	1	2	0	0
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	0	0	1	0	0
Rate of Withdrawals	0%	0%	0%	N/A	N/A
Rate of Not Approvable	0%	0%	50.0%	N/A	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	1	2	0	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	4
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	1
Number Not Accepted for Filing Review	1	1	0	0	0
Rate of submissions not accepted for filing review	100%	33.3%	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	5
Completed RTF	1	3	4	1	5
Number Not Filed	0	1	0	0	0
Rate of submissions Not Filed	0%	33.3%	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	5
SI Goal Met	0	2	4	1	4
SI Goal Not Met	1	1	0	0	0
SI Pending Within Goal	0	0	0	0	1
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	0%	66.7%	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	4
Average number of FDA days to Substantive Interaction	92.0	90.3	108.3	90.0	90.0
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	5
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	1	3	4	1	2
MDUFA III Decisions Goal Met	1	3	4	1	2
PMAs pending MDUFA III Decision	0	0	0	0	3
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	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.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	2
Average FDA days to MDUFA III decision	180.0	182.3	211.3	180.0	178.0
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	178
Maximum FDA days to MDUFA III decision	180	190	256	180	178
Average Industry days to MDUFA III decision	0	91.7	124.0	84.0	20.0
20th Percentile Industry days to MDUFA III decision	0	48	8	84	8
40th Percentile Industry days to MDUFA III decision	0	69	36	84	16
60th Percentile Industry days to MDUFA III decision	0	97	100	84	24
80th Percentile Industry days to MDUFA III decision	0	132	217	84	32
Maximum Industry days to MDUFA III decision	0	168	360	84	40
Average Total days to MDUFA III decision	180.0	274.0	335.3	264.0	198.0
20th Percentile Total days to MDUFA III decision	180	227	178	264	186
40th Percentile Total days to MDUFA III decision	180	246	218	264	194
60th Percentile Total days to MDUFA III decision	180	276	338	264	202
80th Percentile Total days to MDUFA III decision	180	317	470	264	210
Maximum Total days to MDUFA III decision	180	358	607	264	218

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	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.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	5
Number with MDUFA decision	1	3	4	1	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%	25.0%	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	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.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	1	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%	28.6%	0%	20.0%

*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.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%	83.3%	100%	60.0%

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	86.0	100.0	89.3	89.0	97.0
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	1	1
MDUFA III Decisions Goal Met	1	2	5	1	1
PMAs pending MDUFA III Decision	0	0	0	1	3
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	0
MDUFA III Decisions Goal Met	1	2	1	0	0
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%	N/A	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	2	5	1	1
Average FDA days to MDUFA III decision	175.0	179.5	174.8	179.0	180.0
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	179	180
80th Percentile FDA days to MDUFA III decision	175	180	179	179	180
Maximum FDA days to MDUFA III decision	175	180	179	179	180
Average Industry days to MDUFA III decision	356.0	79.0	165.0	0	0
20th Percentile Industry days to MDUFA III decision	356	78	0	0	0
40th Percentile Industry days to MDUFA III decision	356	79	133	0	0
60th Percentile Industry days to MDUFA III decision	356	79	231	0	0
80th Percentile Industry days to MDUFA III decision	356	80	268	0	0
Maximum Industry days to MDUFA III decision	356	81	358	0	0
Average Total days to MDUFA III decision	531.0	258.5	339.8	179.0	180.0
20th Percentile Total days to MDUFA III decision	531	258	176	179	180
40th Percentile Total days to MDUFA III decision	531	258	312	179	180
60th Percentile Total days to MDUFA III decision	531	259	410	179	180
80th Percentile Total days to MDUFA III decision	531	259	446	179	180
Maximum Total days to MDUFA III decision	531	260	532	179	180

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	0
Average FDA days to MDUFA III decision	219.0	345.0	317.0	0	0
20th Percentile FDA days to MDUFA III decision	219	326	317	0	0
40th Percentile FDA days to MDUFA III decision	219	339	317	0	0
60th Percentile FDA days to MDUFA III decision	219	351	317	0	0
80th Percentile FDA days to MDUFA III decision	219	364	317	0	0
Maximum FDA days to MDUFA III decision	219	376	317	0	0
Average Industry days to MDUFA III decision	186.0	230.0	110.0	0	0
20th Percentile Industry days to MDUFA III decision	186	153	110	0	0
40th Percentile Industry days to MDUFA III decision	186	204	110	0	0
60th Percentile Industry days to MDUFA III decision	186	256	110	0	0
80th Percentile Industry days to MDUFA III decision	186	307	110	0	0
Maximum Industry days to MDUFA III decision	186	359	110	0	0
Average Total days to MDUFA III decision	405.0	575.0	427.0	0	0
20th Percentile Total days to MDUFA III decision	405	479	427	0	0
40th Percentile Total days to MDUFA III decision	405	543	427	0	0
60th Percentile Total days to MDUFA III decision	405	607	427	0	0
80th Percentile Total days to MDUFA III decision	405	671	427	0	0
Maximum Total days to MDUFA III decision	405	735	427	0	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	2	5	2	4
Number with MDUFA decision	1	2	5	1	1
Number of Withdrawals	0	0	0	0	0
Number of Not Approvable	1	1	1	0	0
Rate of Withdrawals	0%	0%	0%	0%	0%
Rate of Not Approvable	100%	50.0%	20.0%	0%	0%

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	0
Number of Withdrawals	1	0	0	0	0
Number of Not Approvable	0	1	0	0	0
Rate of Withdrawals	100%	0%	0%	N/A	N/A
Rate of Not Approvable	0%	50.0%	0%	N/A	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	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	20.0%	0%	0%	0%	50.0%

*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.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	16.7%	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%	80.0%	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	88.5	81.0	87.4	89.0	90.0
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	1
MDUFA III Decisions Goal Met	2	1	5	5	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	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	1
Average FDA days to MDUFA III decision	178.5	170.0	179.4	179.2	178.0
20th Percentile FDA days to MDUFA III decision	178	170	179	178	178
40th Percentile FDA days to MDUFA III decision	178	170	180	179	178
60th Percentile FDA days to MDUFA III decision	179	170	180	180	178
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	108.5	0	126.0	71.2	32.0
20th Percentile Industry days to MDUFA III decision	43	0	0	21	32
40th Percentile Industry days to MDUFA III decision	87	0	59	63	32
60th Percentile Industry days to MDUFA III decision	130	0	131	94	32
80th Percentile Industry days to MDUFA III decision	174	0	214	111	32
Maximum Industry days to MDUFA III decision	217	0	351	139	32
Average Total days to MDUFA III decision	287.0	170.0	305.4	250.4	210.0
20th Percentile Total days to MDUFA III decision	221	170	179	200	210
40th Percentile Total days to MDUFA III decision	265	170	239	243	210
60th Percentile Total days to MDUFA III decision	309	170	311	273	210
80th Percentile Total days to MDUFA III decision	353	170	394	289	210
Maximum Total days to MDUFA III decision	397	170	531	319	210

Table 1.8.DOE - 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	413.3	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	247.8	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	661.0	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	1226	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	1
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%	20.0%	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	75.0%	40.0%	0%	50.0%	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.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	50.0%	0%	0%	0%	25.0%

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Substantive Interaction (SI) Goals:	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	4	5	2	2	4
SI Goal Met	4	5	2	2	2
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	2
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	2
Average number of FDA days to Substantive Interaction	88.5	97.8	122.0	88.5	88.5
20th Percentile FDA days to Substantive Interaction	88	88	100	88	88
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	89
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	1
MDUFA III Decisions Goal Met	1	4	1	1	1
PMAs pending MDUFA III Decision	0	0	0	0	3
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	1
Average FDA days to MDUFA III decision	180.0	193.5	250.0	177.0	180.0
20th Percentile FDA days to MDUFA III decision	180	124	250	177	180
40th Percentile FDA days to MDUFA III decision	180	154	250	177	180
60th Percentile FDA days to MDUFA III decision	180	174	250	177	180
80th Percentile FDA days to MDUFA III decision	180	252	250	177	180
Maximum FDA days to MDUFA III decision	180	359	250	177	180
Average Industry days to MDUFA III decision	260.0	108.5	36.0	68.0	52.0
20th Percentile Industry days to MDUFA III decision	260	54	36	68	52
40th Percentile Industry days to MDUFA III decision	260	82	36	68	52
60th Percentile Industry days to MDUFA III decision	260	126	36	68	52
80th Percentile Industry days to MDUFA III decision	260	161	36	68	52
Maximum Industry days to MDUFA III decision	260	193	36	68	52
Average Total days to MDUFA III decision	440.0	302.0	286.0	245.0	232.0
20th Percentile Total days to MDUFA III decision	440	267	286	245	232
40th Percentile Total days to MDUFA III decision	440	282	286	245	232
60th Percentile Total days to MDUFA III decision	440	286	286	245	232
80th Percentile Total days to MDUFA III decision	440	330	286	245	232
Maximum Total days to MDUFA III decision	440	392	286	245	232

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	376.0	359.0	206.0	300.0	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	180.3	358.0	119.0	110.0	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	556.3	717.0	325.0	410.0	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	1
Number of Withdrawals	0	1	0	0	0
Number of Not Approvable	0	1	0	0	0
Rate of Withdrawals	0%	25.0%	0%	0%	0%
Rate of Not Approvable	0%	25.0%	0%	0%	0%

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	66.7%	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	4
Closed before RTA action	0	0	0	0	0
Number with accepted RTA review	0	4	4	0	3
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	33.3%	16.7%	100%	25.0%

*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.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	4
Number Accepted	0	4	5	0	3
Completed RTF	0	5	5	2	4
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	4
SI Goal Met	0	5	5	2	3
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	1
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	3
Average number of FDA days to Substantive Interaction	0	88.8	85.6	88.5	89.3
20th Percentile FDA days to Substantive Interaction	0	88	82	88	89
40th Percentile FDA days to Substantive Interaction	0	90	85	88	90
60th Percentile FDA days to Substantive Interaction	0	90	87	89	90
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	4
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	0	3	5	2	1
MDUFA III Decisions Goal Met	0	3	5	2	1
PMAs pending MDUFA III Decision	0	0	0	0	3
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	1
Average FDA days to MDUFA III decision	0	177.3	179.0	179.0	180.0
20th Percentile FDA days to MDUFA III decision	0	175	178	179	180
40th Percentile FDA days to MDUFA III decision	0	178	179	179	180
60th Percentile FDA days to MDUFA III decision	0	179	180	179	180
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	49.0	159.8	203.5	0
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	0
80th Percentile Industry days to MDUFA III decision	0	52	201	297	0
Maximum Industry days to MDUFA III decision	0	55	356	359	0
Average Total days to MDUFA III decision	0	226.3	338.8	382.5	180.0
20th Percentile Total days to MDUFA III decision	0	222	268	289	180
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	180
80th Percentile Total days to MDUFA III decision	0	230	378	476	180
Maximum Total days to MDUFA III decision	0	234	534	538	180

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	349.5	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	99.0	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	448.5	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	4
Number with MDUFA decision	0	3	5	2	1
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%	20.0%	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	7
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	1
Number Not Accepted for Filing Review	0	0	0	0	1
Rate of submissions not accepted for filing review	0%	0%	0%	0%	12.5%

*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	7
Completed RTF	2	2	8	4	6
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	6
SI Goal Met	2	2	8	4	3
SI Goal Not Met	0	0	0	0	1
SI Pending Within Goal	0	0	0	0	2
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%	75.0%

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	4
Average number of FDA days to Substantive Interaction	90.0	88.0	80.3	86.5	83.8
20th Percentile FDA days to Substantive Interaction	90	87	71	85	80
40th Percentile FDA days to Substantive Interaction	90	88	85	85	90
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	5
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	2	2	7	4	2
MDUFA III Decisions Goal Met	2	2	7	4	2
PMAs pending MDUFA III Decision	0	0	0	0	3
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	0
MDUFA III Decisions Goal Met	0	0	1	0	0
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	100%	N/A	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	2	2	7	4	2
Average FDA days to MDUFA III decision	176.5	179.5	177.3	156.3	178.0
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	178
60th Percentile FDA days to MDUFA III decision	177	180	178	175	178
80th Percentile FDA days to MDUFA III decision	178	180	179	178	179
Maximum FDA days to MDUFA III decision	179	180	180	179	179
Average Industry days to MDUFA III decision	266.5	119.0	97.6	133.8	41.0
20th Percentile Industry days to MDUFA III decision	186	48	4	16	16
40th Percentile Industry days to MDUFA III decision	240	95	55	70	33
60th Percentile Industry days to MDUFA III decision	293	143	122	201	49
80th Percentile Industry days to MDUFA III decision	347	190	139	252	66
Maximum Industry days to MDUFA III decision	400	238	283	264	82
Average Total days to MDUFA III decision	443.0	298.5	274.9	290.0	219.0
20th Percentile Total days to MDUFA III decision	361	227	183	156	194
40th Percentile Total days to MDUFA III decision	416	275	232	238	211
60th Percentile Total days to MDUFA III decision	470	322	301	376	227
80th Percentile Total days to MDUFA III decision	525	370	314	430	244
Maximum Total days to MDUFA III decision	579	418	459	443	261

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	0
Average FDA days to MDUFA III decision	0	0	299.0	0	0
20th Percentile FDA days to MDUFA III decision	0	0	299	0	0
40th Percentile FDA days to MDUFA III decision	0	0	299	0	0
60th Percentile FDA days to MDUFA III decision	0	0	299	0	0
80th Percentile FDA days to MDUFA III decision	0	0	299	0	0
Maximum FDA days to MDUFA III decision	0	0	299	0	0
Average Industry days to MDUFA III decision	0	0	153.0	0	0
20th Percentile Industry days to MDUFA III decision	0	0	153	0	0
40th Percentile Industry days to MDUFA III decision	0	0	153	0	0
60th Percentile Industry days to MDUFA III decision	0	0	153	0	0
80th Percentile Industry days to MDUFA III decision	0	0	153	0	0
Maximum Industry days to MDUFA III decision	0	0	153	0	0
Average Total days to MDUFA III decision	0	0	452.0	0	0
20th Percentile Total days to MDUFA III decision	0	0	452	0	0
40th Percentile Total days to MDUFA III decision	0	0	452	0	0
60th Percentile Total days to MDUFA III decision	0	0	452	0	0
80th Percentile Total days to MDUFA III decision	0	0	452	0	0
Maximum Total days to MDUFA III decision	0	0	452	0	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	2	7	4	5
Number with MDUFA decision	2	2	7	4	2
Number of Withdrawals	0	0	0	0	1
Number of Not Approvable	0	0	1	1	0
Rate of Withdrawals	0%	0%	0%	0%	50.0%
Rate of Not Approvable	0%	0%	14.3%	25.0%	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	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	0%	N/A	N/A
Rate of Not Approvable	N/A	N/A	0%	N/A	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	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%	33.3%

*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	2
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	2
SI Goal Met	2	1	2	8	1
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	1
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%	66.7%	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	1
Average number of FDA days to Substantive Interaction	86.0	83.0	88.7	81.0	79.0
20th Percentile FDA days to Substantive Interaction	86	83	87	83	79
40th Percentile FDA days to Substantive Interaction	86	83	88	85	79
60th Percentile FDA days to Substantive Interaction	86	83	89	87	79
80th Percentile FDA days to Substantive Interaction	86	83	90	88	79
Maximum FDA days to Substantive Interaction	86	83	91	90	79

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	2
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	1	1	3	7	1
MDUFA III Decisions Goal Met	1	1	3	7	1
PMAs pending MDUFA III Decision	0	0	0	1	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	7	1
Average FDA days to MDUFA III decision	177.0	179.0	167.3	174.9	170.0
20th Percentile FDA days to MDUFA III decision	177	179	163	173	170
40th Percentile FDA days to MDUFA III decision	177	179	168	175	170
60th Percentile FDA days to MDUFA III decision	177	179	171	177	170
80th Percentile FDA days to MDUFA III decision	177	179	172	178	170
Maximum FDA days to MDUFA III decision	177	179	173	178	170
Average Industry days to MDUFA III decision	107.0	0	26.0	60.1	56.0
20th Percentile Industry days to MDUFA III decision	107	0	0	7	56
40th Percentile Industry days to MDUFA III decision	107	0	0	38	56
60th Percentile Industry days to MDUFA III decision	107	0	16	63	56
80th Percentile Industry days to MDUFA III decision	107	0	47	122	56
Maximum Industry days to MDUFA III decision	107	0	78	134	56
Average Total days to MDUFA III decision	284.0	179.0	193.3	235.0	226.0
20th Percentile Total days to MDUFA III decision	284	179	171	184	226
40th Percentile Total days to MDUFA III decision	284	179	172	215	226
60th Percentile Total days to MDUFA III decision	284	179	186	240	226
80th Percentile Total days to MDUFA III decision	284	179	211	291	226
Maximum Total days to MDUFA III decision	284	179	237	307	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	297.0	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	297.0	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	2
Number with MDUFA decision	1	1	3	7	1
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%	14.3%	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	9
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	2
Number Not Accepted for Filing Review	0	0	0	0	0
Rate of submissions not accepted for filing review	0%	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.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	9
Completed RTF	4	1	6	10	9
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	9
SI Goal Met	4	1	6	9	8
SI Goal Not Met	0	0	0	1	0
SI Pending Within Goal	0	0	0	0	1
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%	90.0%	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	8
Average number of FDA days to Substantive Interaction	95.3	86.0	86.8	82.8	97.3
20th Percentile FDA days to Substantive Interaction	90	86	90	79	88
40th Percentile FDA days to Substantive Interaction	90	86	90	86	90
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	9
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	2	1	6	10	6
MDUFA III Decisions Goal Met	2	1	6	10	6
PMAs pending MDUFA III Decision	0	0	0	0	3
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	6
Average FDA days to MDUFA III decision	107.5	86.0	128.0	122.2	152.7
20th Percentile FDA days to MDUFA III decision	102	86	95	97	115
40th Percentile FDA days to MDUFA III decision	106	86	114	115	144
60th Percentile FDA days to MDUFA III decision	109	86	133	128	156
80th Percentile FDA days to MDUFA III decision	113	86	164	137	166
Maximum FDA days to MDUFA III decision	116	86	171	177	245
Average Industry days to MDUFA III decision	94.5	0.0	40.7	110.3	60.8
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	26
60th Percentile Industry days to MDUFA III decision	99	0	58	127	36
80th Percentile Industry days to MDUFA III decision	109	0	63	148	133
Maximum Industry days to MDUFA III decision	118	0	84	267	170
Average Total days to MDUFA III decision	202.0	86.0	168.7	232.5	213.5
20th Percentile Total days to MDUFA III decision	193	86	164	170	180
40th Percentile Total days to MDUFA III decision	199	86	172	197	192
60th Percentile Total days to MDUFA III decision	205	86	179	251	245
80th Percentile Total days to MDUFA III decision	211	86	196	302	248
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	320.0	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	147.0	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	467.0	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	9
Number with MDUFA decision	2	1	6	10	6
Number of Withdrawals	0	0	0	1	1
Number of Not Approvable	0	0	0	0	0
Rate of Withdrawals	0%	0%	0%	10.0%	16.7%
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	50.0%	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%	50.0%	N/A	33.3%	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	77.5	86.5	0	79.3	90.0
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	0
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	1
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	167.0	178.0	0	162.3	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	81.0	113.0	0	69.7	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	248.0	291.0	0	232.0	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	206.0	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	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	206.0	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	33.3%	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

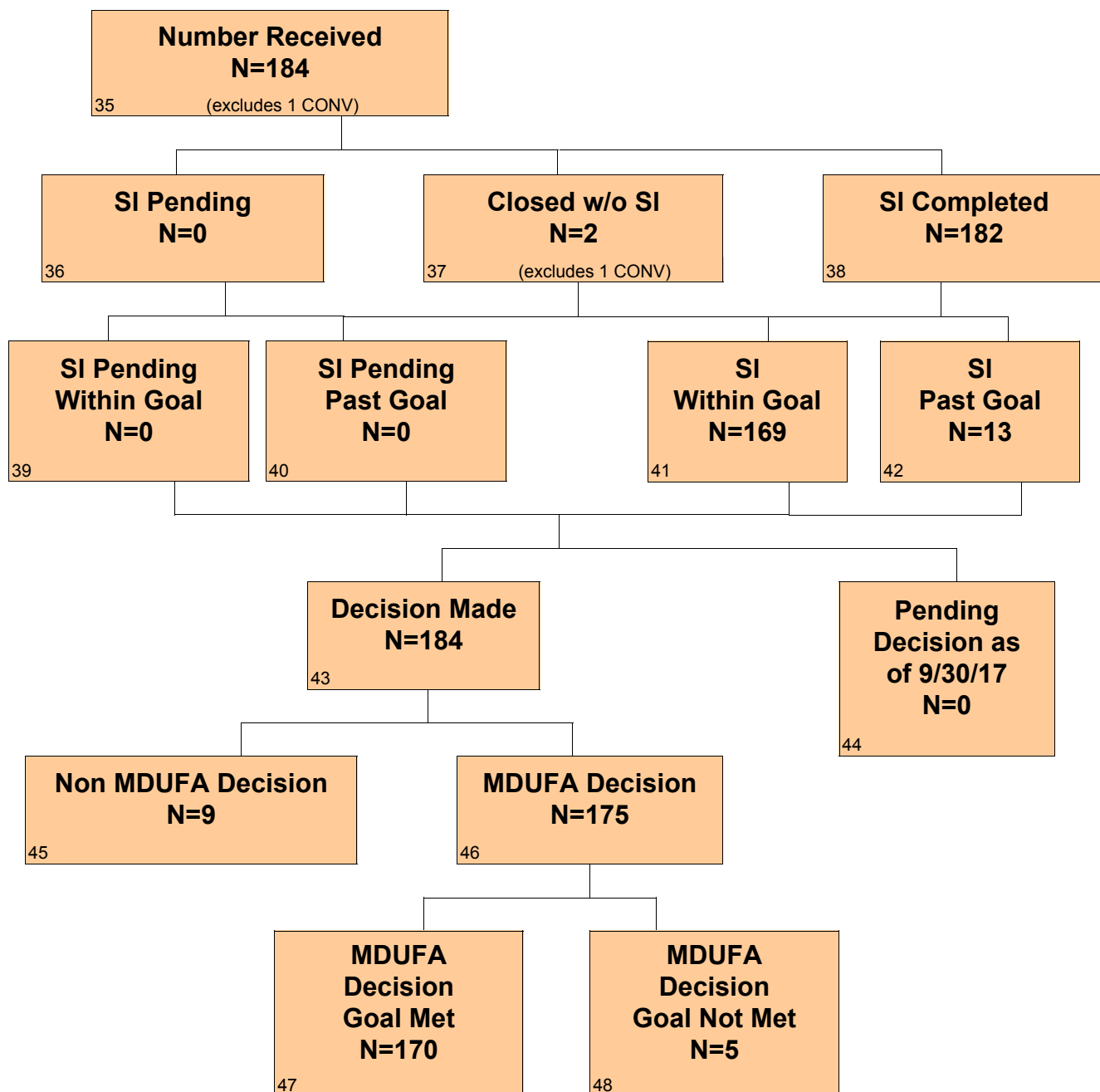
Table 1.11.DRH - OIR – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

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

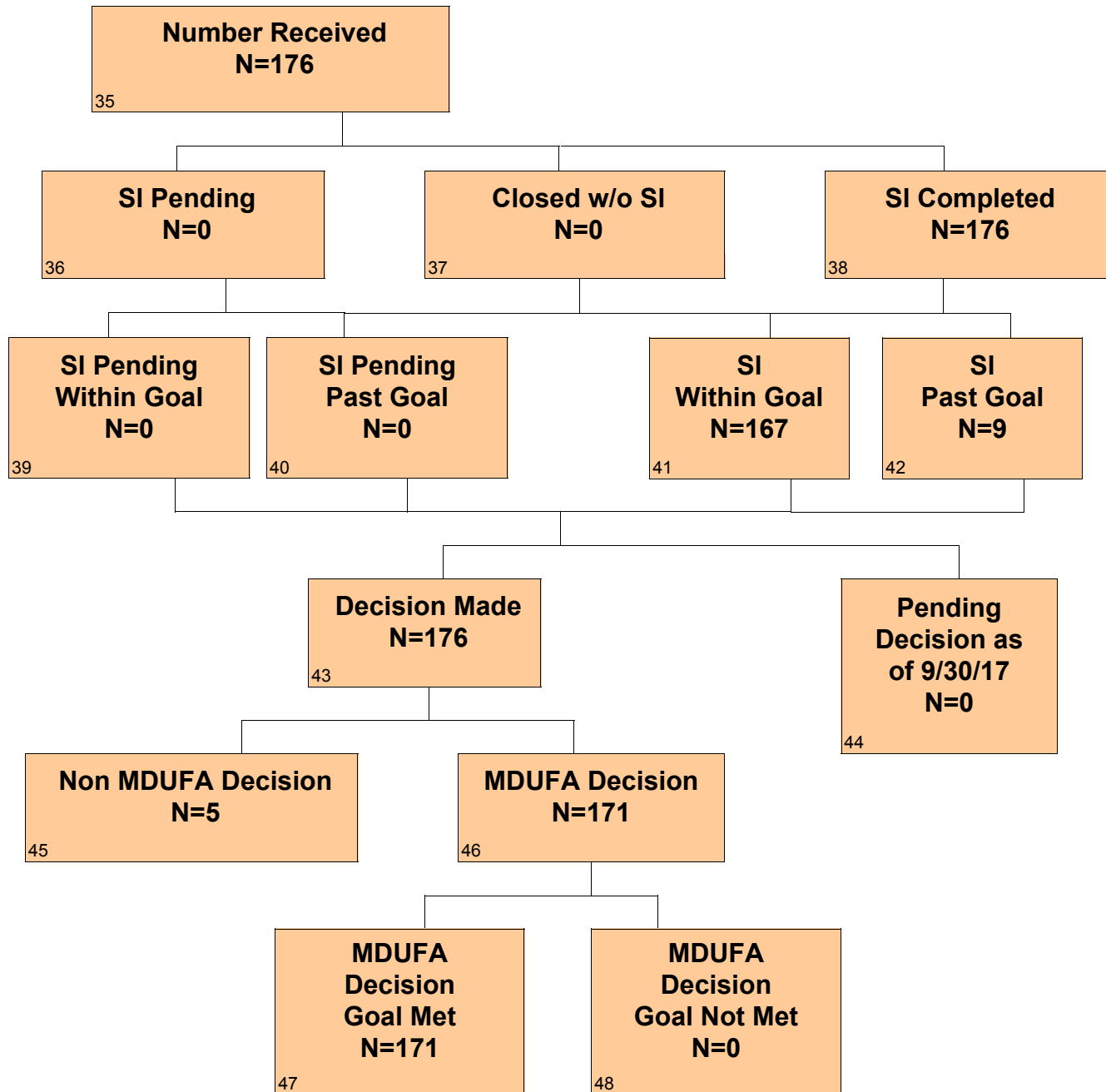
Table 1.12.DRH - OIR – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

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

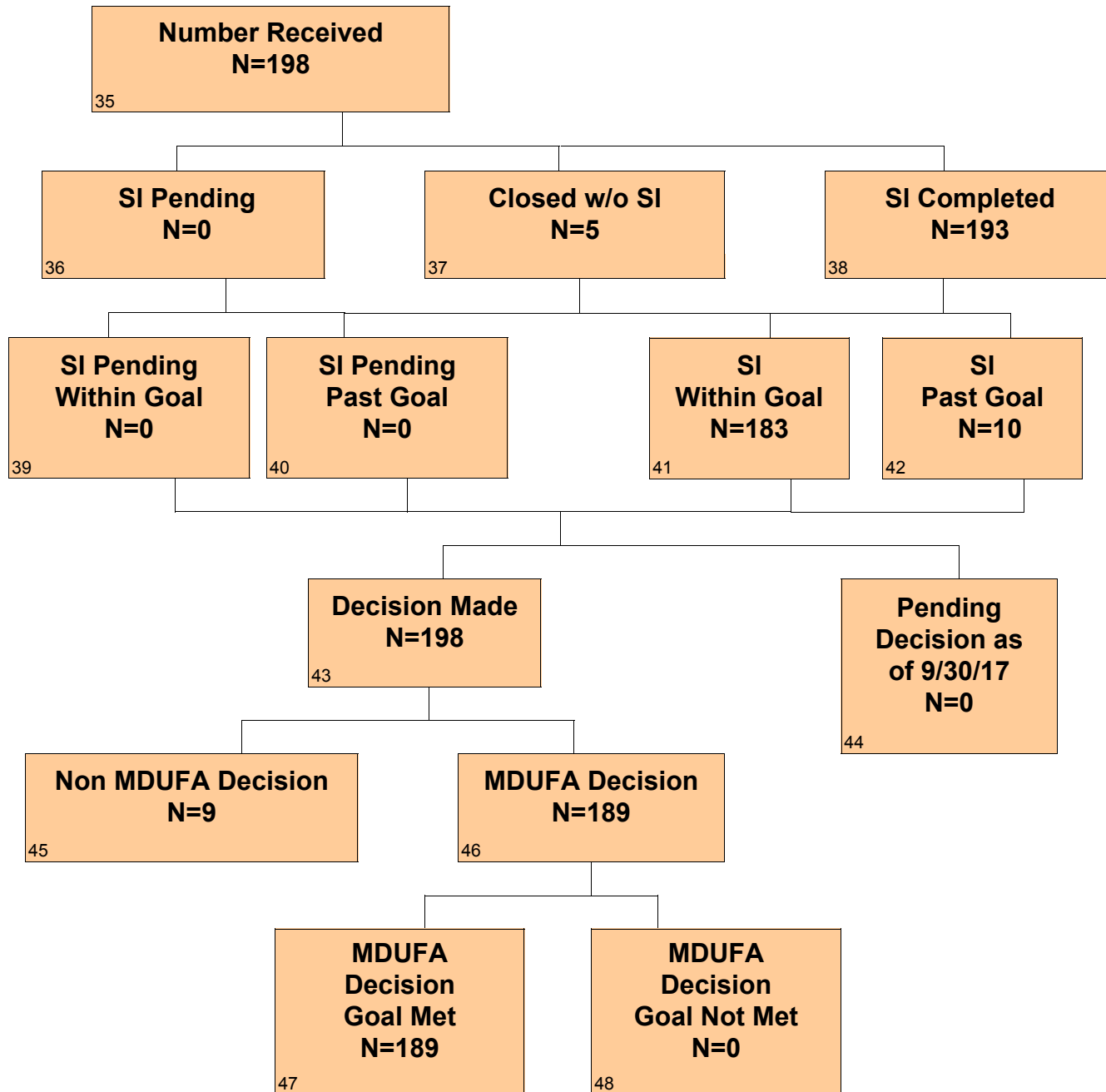
CDRH PMA 180 Day Supplements - FY 2013 As of 9/30/17



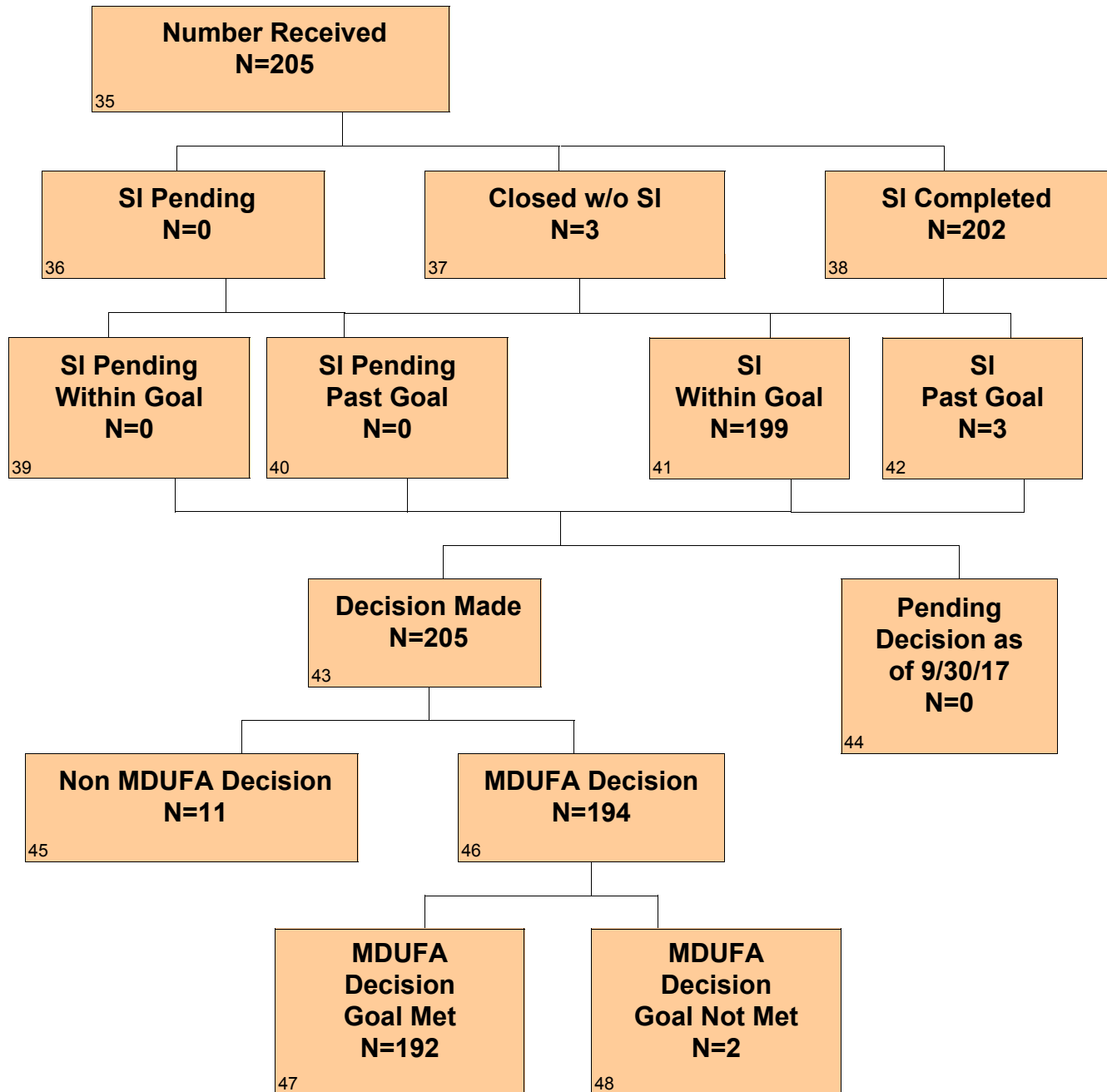
CDRH PMA 180 Day Supplements - FY 2014 As of 9/30/17



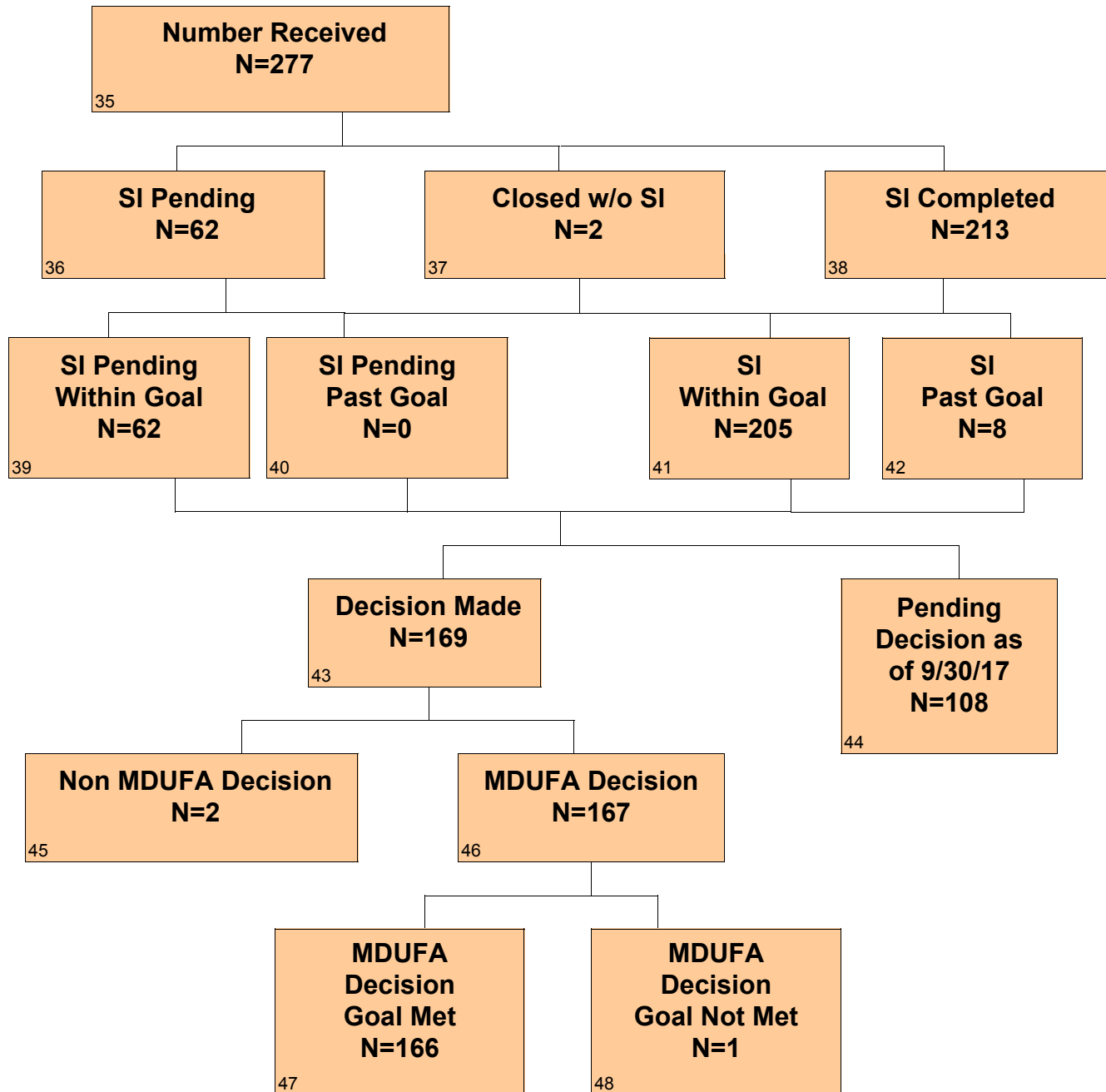
CDRH PMA 180 Day Supplements - FY 2015 As of 9/30/17



CDRH PMA 180 Day Supplements - FY 2016 As of 9/30/17



CDRH PMA 180 Day Supplements - FY 2017 As of 9/30/17



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Section 2 PMA 180 Day Supplements - Center Level

Table 2.1 CDRH – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	184	176	198	205	277
SI Goal Met	169	167	183	199	205
SI Goal Not Met	13	9	10	3	8
SI Pending Within Goal	0	0	0	0	62
SI Pending Past Goal	0	0	0	0	0
Closed without SI	3	3	5	3	2
Current SI Performance Percent Goal Met	92.9%	94.9%	94.8%	98.5%	96.2%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	184	176	198	205	277
Non-MDUFA III Decisions	9	5	9	11	2
MDUFA III Decisions	175	171	189	194	167
MDUFA III Decisions Goal Met	170	171	189	192	166
Supplements pending MDUFA III Decision	0	0	0	0	108
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	97.1%	100%	100%	99.0%	99.4%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	184	176	198	205	277
Number with MDUFA decision	175	171	189	194	167
Number of Not Approvable	11	5	11	1	0
Rate of Not Approvable	6.3%	2.9%	5.8%	0.5%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	5	0	0	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

Section 2 PMA 180 Day Supplements - Office Level

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	163	163	164	182	225
SI Goal Met	148	154	150	176	177
SI Goal Not Met	13	9	9	3	8
SI Pending Within Goal	0	0	0	0	39
SI Pending Past Goal	0	0	0	0	0
Closed without SI	2	0	5	3	1
Current SI Performance Percent Goal Met	91.9%	94.5%	94.3%	98.3%	95.7%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	163	163	164	182	225
Non-MDUFA III Decisions	8	4	7	10	1
MDUFA III Decisions	155	159	157	172	147
MDUFA III Decisions Goal Met	150	159	157	170	146
Supplements pending MDUFA III Decision	0	0	0	0	77
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	96.8%	100%	100%	98.8%	99.3%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	163	163	164	182	225
Number with MDUFA decision	155	159	157	172	147
Number of Not Approvable	11	5	7	1	0
Rate of Not Approvable	7.1%	3.1%	4.5%	0.6%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	5	0	0	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	52
SI Goal Met	21	13	33	23	28
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	23
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	1
Current SI Performance Percent Goal Met	100%	100%	97.1%	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	52
Non-MDUFA III Decisions	1	1	2	1	1
MDUFA III Decisions	20	12	32	22	20
MDUFA III Decisions Goal Met	20	12	32	22	20
Supplements pending MDUFA III Decision	0	0	0	0	31
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.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	20
Number of Not Approvable	0	0	4	0	0
Rate of Not Approvable	0%	0%	12.5%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	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 - 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	5
SI Goal Not Met	2	2	1	1	5
SI Pending Within Goal	0	0	0	0	2
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	80.0%	77.8%	85.7%	83.3%	50.0%

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	4
MDUFA III Decisions Goal Met	6	8	7	6	4
Supplements pending MDUFA III Decision	0	0	0	0	8
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	75.0%	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	4
Number of Not Approvable	1	2	1	0	0
Rate of Not Approvable	12.5%	25.0%	14.3%	0%	0%

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	116	94	104	116	141
SI Goal Met	108	93	97	114	118
SI Goal Not Met	6	1	2	2	3
SI Pending Within Goal	0	0	0	0	19
SI Pending Past Goal	0	0	0	0	0
Closed without SI	2	0	5	0	1
Current SI Performance Percent Goal Met	94.7%	98.9%	98.0%	98.3%	97.5%

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	116	94	104	116	141
Non-MDUFA III Decisions	3	1	6	5	1
MDUFA III Decisions	113	93	98	111	107
MDUFA III Decisions Goal Met	112	93	98	111	107
Supplements pending MDUFA III Decision	0	0	0	0	33
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	99.1%	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	116	94	104	116	141
Number with MDUFA decision	113	93	98	111	107
Number of Not Approvable	6	0	5	1	0
Rate of Not Approvable	5.3%	0%	5.1%	0.9%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0	0	0	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	22
SI Goal Met	6	13	13	17	19
SI Goal Not Met	1	0	1	0	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	85.7%	100%	92.9%	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	22
Non-MDUFA III Decisions	2	0	0	1	0
MDUFA III Decisions	5	13	14	16	13
MDUFA III Decisions Goal Met	5	13	14	16	13
Supplements pending MDUFA III Decision	0	0	0	0	9
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	22
Number with MDUFA decision	5	13	14	16	13
Number of Not Approvable	1	0	0	0	0
Rate of Not Approvable	20.0%	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	6
SI Goal Not Met	0	2	1	0	0
SI Pending Within Goal	0	0	0	0	1
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	100%	50.0%	83.3%	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	5
MDUFA III Decisions Goal Met	3	4	6	7	5
Supplements pending MDUFA III Decision	0	0	0	0	2
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	5
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	25
SI Goal Met	11	24	17	17	18
SI Goal Not Met	1	0	1	0	0
SI Pending Within Goal	0	0	0	0	7
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	91.7%	100%	94.4%	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	25
Non-MDUFA III Decisions	0	2	0	2	0
MDUFA III Decisions	12	22	18	16	9
MDUFA III Decisions Goal Met	12	22	18	14	9
Supplements pending MDUFA III Decision	0	0	0	0	16
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	87.5%	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	25
Number with MDUFA decision	12	22	18	16	9
Number of Not Approvable	1	1	0	0	0
Rate of Not Approvable	8.3%	4.5%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	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	5
SI Goal Not Met	1	0	0	0	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	90.0%	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	5
MDUFA III Decisions Goal Met	10	7	8	11	4
Supplements pending MDUFA III Decision	0	0	0	0	3
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	80.0%

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	5
Number of Not Approvable	1	1	0	0	0
Rate of Not Approvable	10.0%	14.3%	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	10
SI Goal Met	3	8	4	5	6
SI Goal Not Met	2	4	3	0	0
SI Pending Within Goal	0	0	0	0	4
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	60.0%	66.7%	57.1%	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	10
Non-MDUFA III Decisions	1	0	1	0	0
MDUFA III Decisions	4	12	6	5	4
MDUFA III Decisions Goal Met	2	12	6	5	4
Supplements pending MDUFA III Decision	0	0	0	0	6
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	50.0%	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	10
Number with MDUFA decision	4	12	6	5	4
Number of Not Approvable	1	1	1	0	0
Rate of Not Approvable	25.0%	8.3%	16.7%	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	7
SI Goal Met	3	3	3	3	5
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	2
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%	75.0%	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	7
Non-MDUFA III Decisions	0	0	0	1	0
MDUFA III Decisions	3	3	4	2	5
MDUFA III Decisions Goal Met	3	3	4	2	5
Supplements pending MDUFA III Decision	0	0	0	0	2
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	5
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	0
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	5
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%	N/A

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	1	3	2	5
Number with MDUFA decision	1	0	3	2	0
Number of Not Approvable	0	0	2	0	0
Rate of Not Approvable	0%	N/A	66.7%	0%	N/A

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	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	11
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	12
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	7
MDUFA III Decisions Goal Met	6	4	13	7	7
Supplements pending MDUFA III Decision	0	0	0	0	16
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	7
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	11
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	0	0
Closed without SI	0	0	0	0	1
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	8
MDUFA III Decisions Goal Met	5	4	8	4	8
Supplements pending MDUFA III Decision	0	0	0	0	6
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.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	14
Number with MDUFA decision	5	4	8	4	8
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0%	0%	0%	0%	0%

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	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.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	1
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	1
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	0
MDUFA III Decisions Goal Met	5	1	4	7	0
Supplements pending MDUFA III Decision	0	0	0	0	2
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	N/A

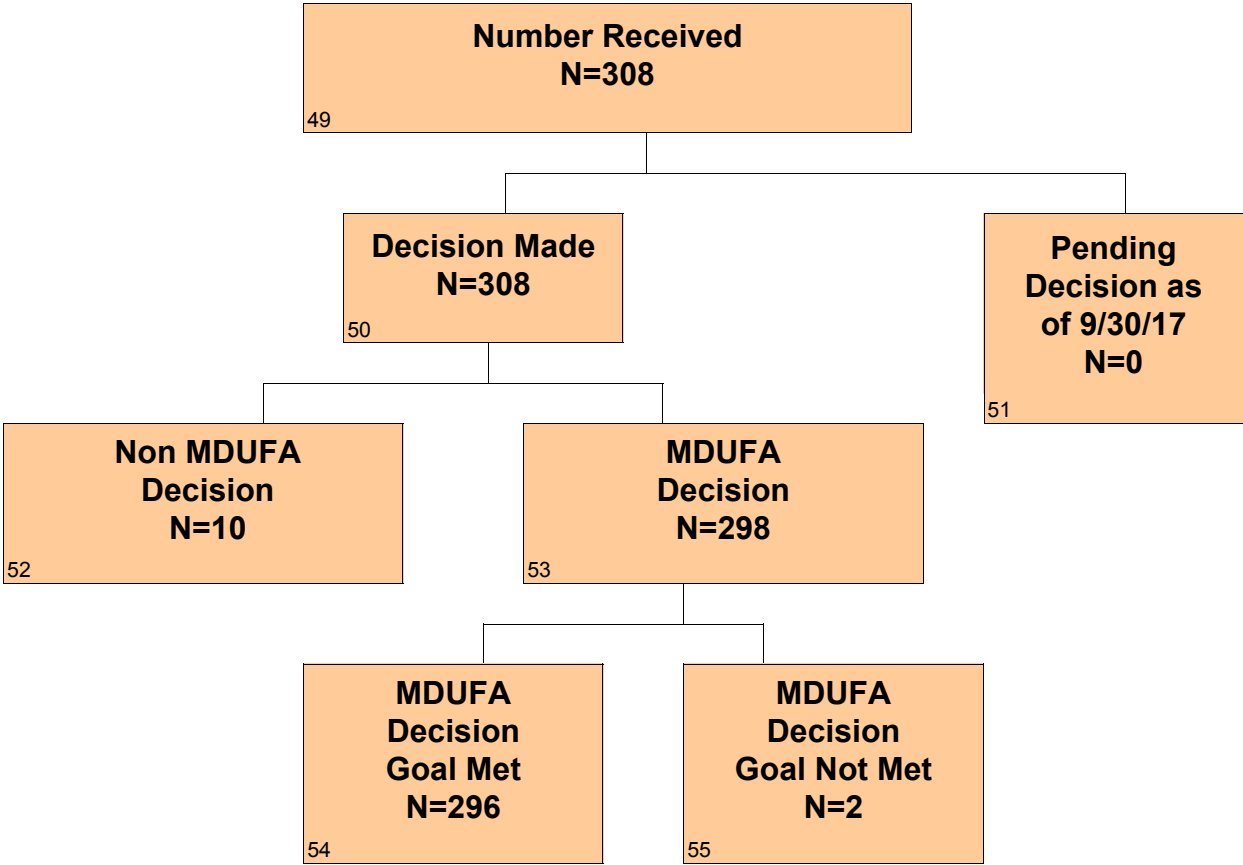
Table 2.3.DRH DRH - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1	4	7	2
Number with MDUFA decision	5	1	4	7	0
Number of Not Approvable	0	0	2	0	0
Rate of Not Approvable	0%	0%	50.0%	0%	N/A

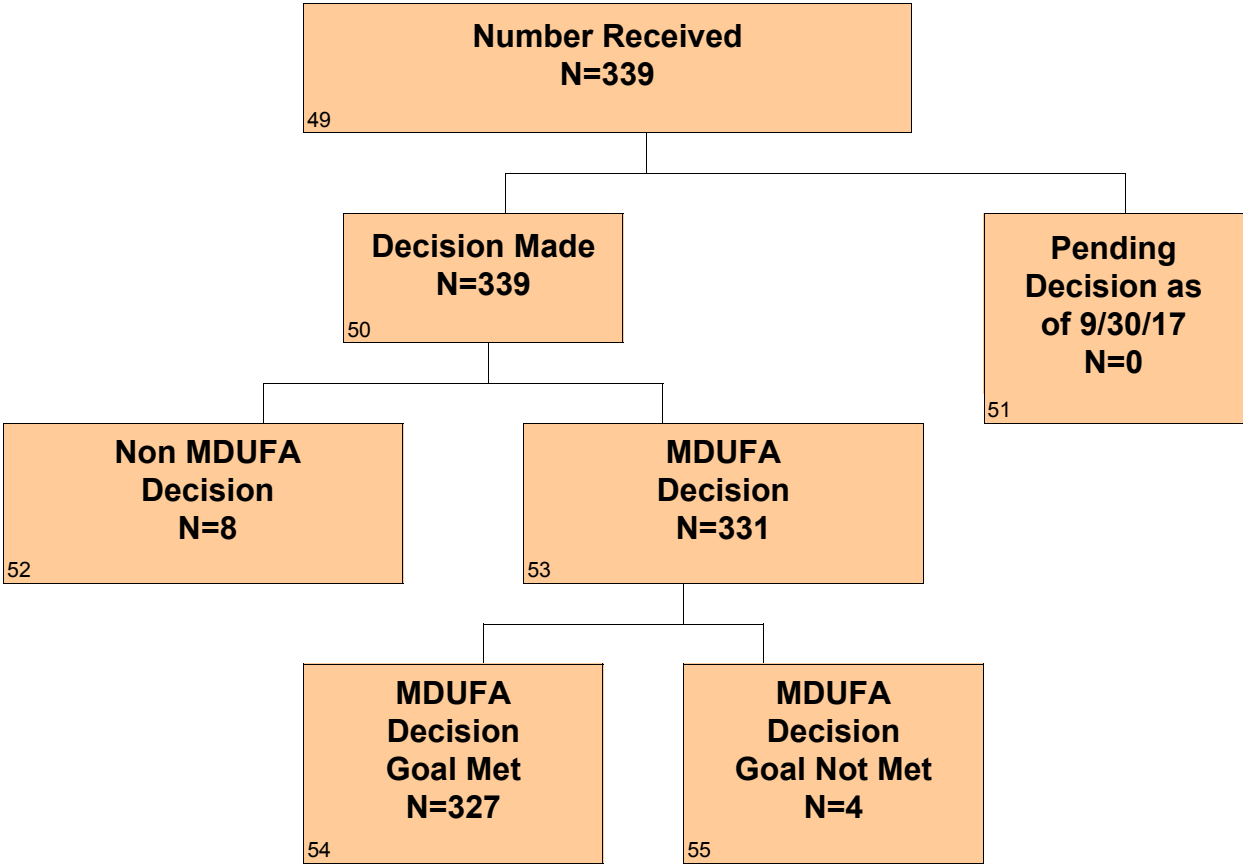
Table 2.4.DRH - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

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

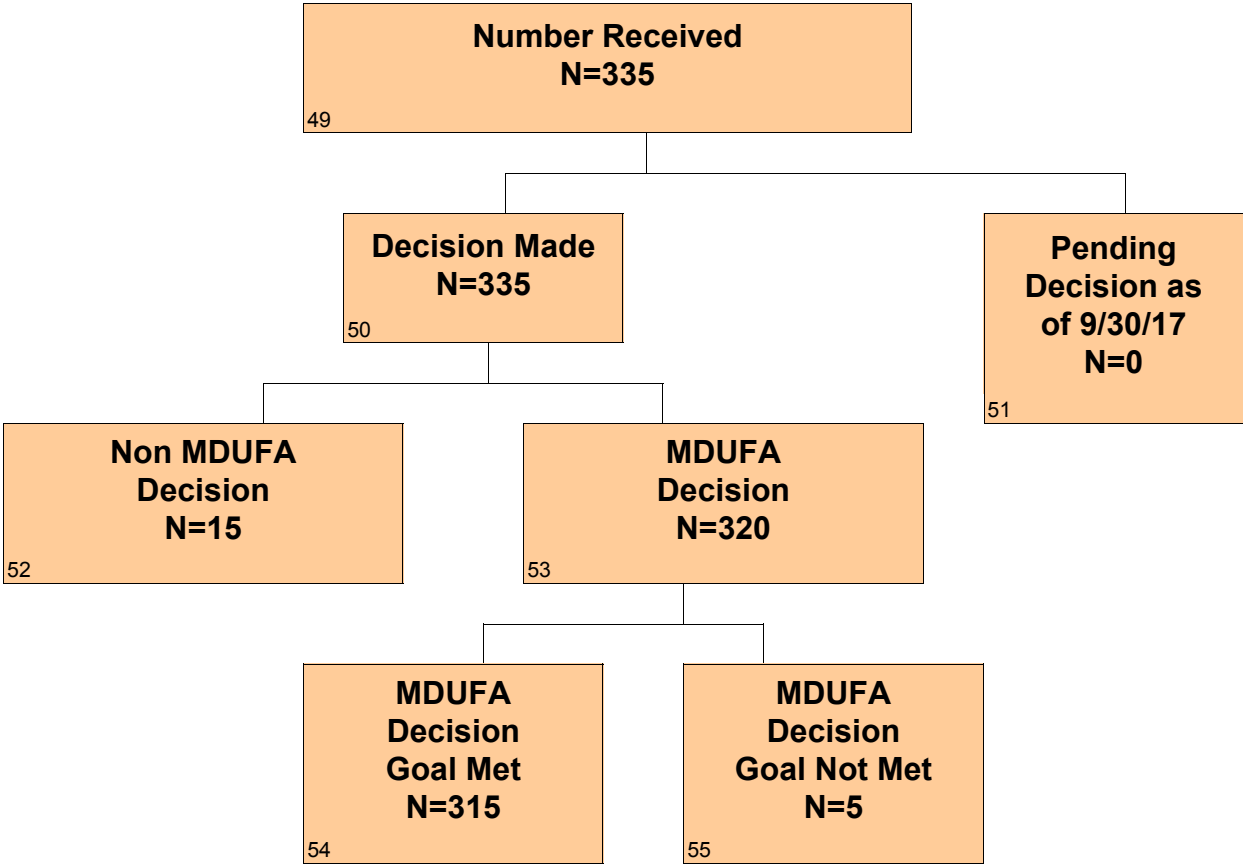
CDRH PMA Real Time Supplements - FY 2013 As of 9/30/17



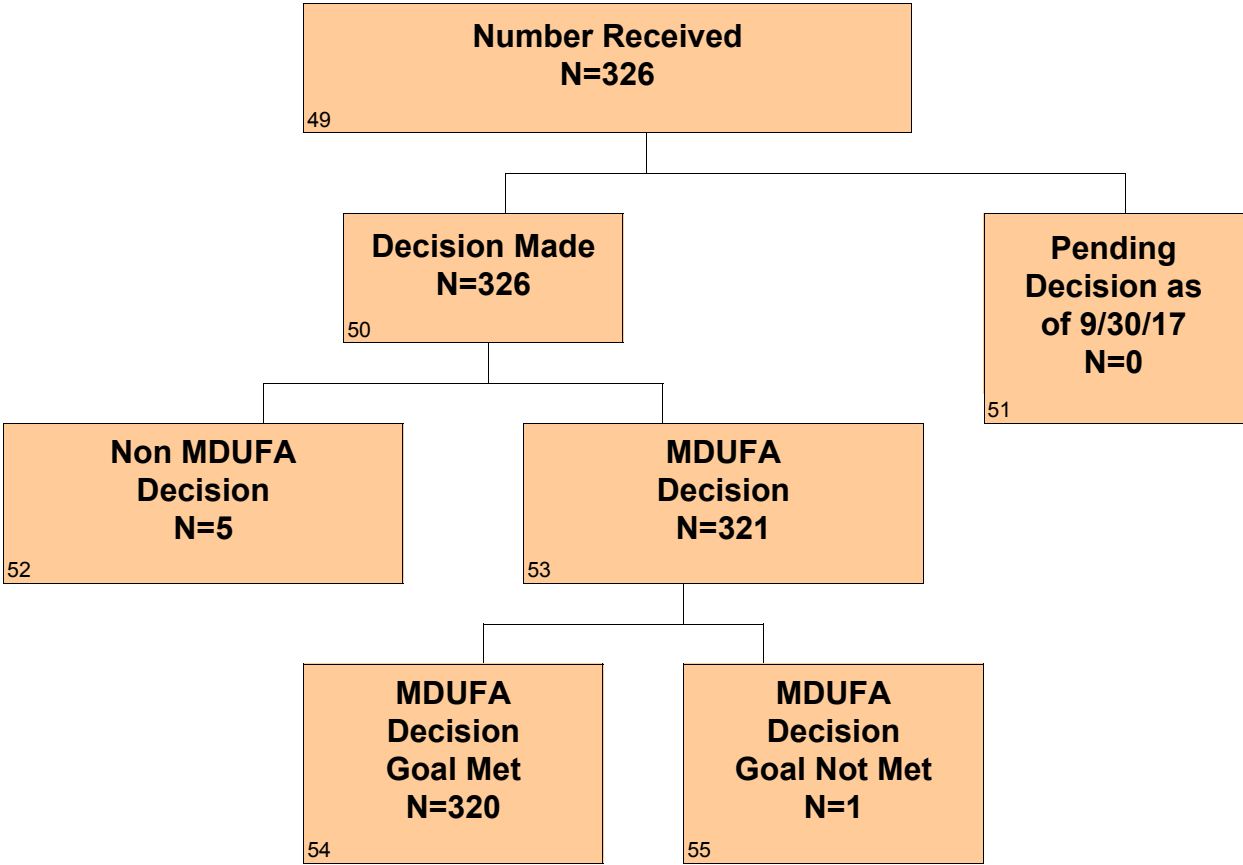
CDRH PMA Real Time Supplements - FY 2014 As of 9/30/17



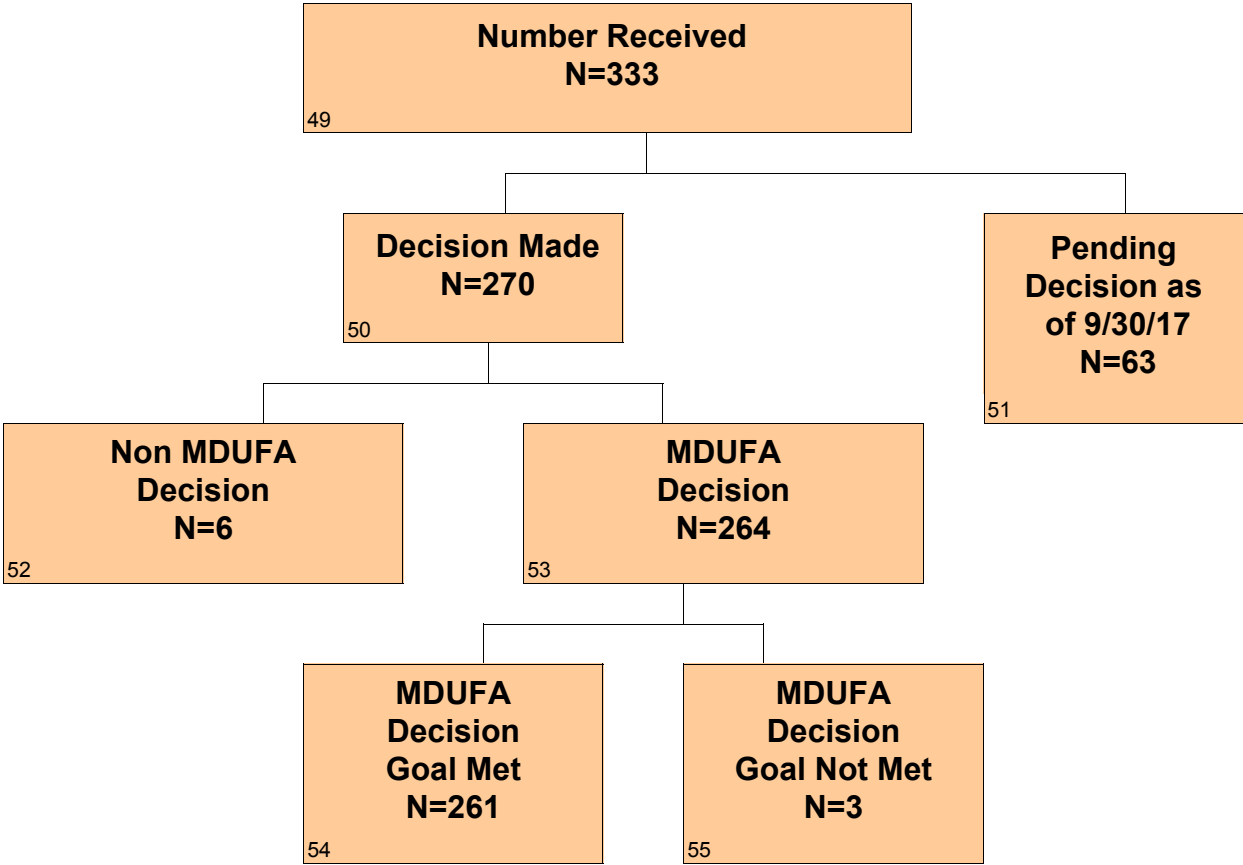
CDRH PMA Real Time Supplements - FY 2015 As of 9/30/17



CDRH PMA Real Time Supplements - FY 2016 As of 9/30/17



CDRH PMA Real Time Supplements - FY 2017 As of 9/30/17



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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	333
Non-MDUFA III Decisions	10	8	15	5	6
MDUFA III Decisions	298	331	320	321	264
MDUFA III Decisions Goal Met	296	327	315	320	261
Supplements pending MDUFA III Decision	0	0	0	0	63
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	99.3%	98.8%	98.4%	99.7%	98.9%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	308	339	335	326	333
Number with MDUFA decision	298	331	320	321	264
Number of Not Approvable	20	3	20	6	9
Rate of Not Approvable	6.7%	0.9%	6.3%	1.9%	3.4%

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 - 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	333
Non-MDUFA III Decisions	10	8	15	5	6
MDUFA III Decisions	298	331	320	321	264
MDUFA III Decisions Goal Met	296	327	315	320	261
Supplements pending MDUFA III Decision	0	0	0	0	63
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	99.3%	98.8%	98.4%	99.7%	98.9%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	308	339	335	326	333
Number with MDUFA decision	298	331	320	321	264
Number of Not Approvable	20	3	20	6	9
Rate of Not Approvable	6.7%	0.9%	6.3%	1.9%	3.4%

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	280
Non-MDUFA III Decisions	9	6	14	5	2
MDUFA III Decisions	260	277	269	279	221
MDUFA III Decisions Goal Met	258	273	264	278	218
Supplements pending MDUFA III Decision	0	0	0	0	57
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	99.2%	98.6%	98.1%	99.6%	98.6%

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	280
Number with MDUFA decision	260	277	269	279	221
Number of Not Approvable	15	3	14	4	2
Rate of Not Approvable	5.8%	1.1%	5.2%	1.4%	0.9%

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	4
MDUFA III Decisions	38	54	51	42	43
MDUFA III Decisions Goal Met	38	54	51	42	43
Supplements pending MDUFA III Decision	0	0	0	0	6
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	43
Number of Not Approvable	5	0	6	2	7
Rate of Not Approvable	13.2%	0%	11.8%	4.8%	16.3%

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	5
MDUFA III Decisions Goal Met	13	5	5	9	5
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%	71.4%	83.3%	90.0%	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	5
Number of Not Approvable	1	1	2	1	0
Rate of Not Approvable	7.7%	14.3%	33.3%	10.0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	2	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	190
Non-MDUFA III Decisions	6	3	11	3	1
MDUFA III Decisions	170	215	189	191	150
MDUFA III Decisions Goal Met	170	215	185	191	150
Supplements pending MDUFA III Decision	0	0	0	0	39
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	97.9%	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	190
Number with MDUFA decision	170	215	189	191	150
Number of Not Approvable	7	1	10	0	1
Rate of Not Approvable	4.1%	0.5%	5.3%	0%	0.7%

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	18
MDUFA III Decisions Goal Met	23	14	22	22	18
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	100%	87.5%	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	18
Number of Not Approvable	1	1	0	0	0
Rate of Not Approvable	4.3%	6.3%	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	6
MDUFA III Decisions Goal Met	8	9	13	10	6
Supplements pending MDUFA III Decision	0	0	0	0	3
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	6
Number of Not Approvable	2	0	0	1	1
Rate of Not Approvable	25.0%	0%	0%	10.0%	16.7%

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	20
MDUFA III Decisions Goal Met	16	17	21	19	17
Supplements pending MDUFA III Decision	0	0	0	0	3
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	85.0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	16	17	22	20	23
Number with MDUFA decision	16	17	21	19	20
Number of Not Approvable	0	0	0	2	0
Rate of Not Approvable	0%	0%	0%	10.5%	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	16
MDUFA III Decisions Goal Met	17	2	11	18	16
Supplements pending MDUFA III Decision	0	0	0	0	2
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	16
Number of Not Approvable	1	0	0	0	0
Rate of Not Approvable	5.9%	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	6
MDUFA III Decisions Goal Met	11	11	7	9	6
Supplements pending MDUFA III Decision	0	0	0	0	4
Supplements pending MDUFA III Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	84.6%	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	6
Number of Not Approvable	3	0	2	0	0
Rate of Not Approvable	23.1%	0%	28.6%	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	19
MDUFA III Decisions Goal Met	6	17	20	18	19
Supplements pending MDUFA III Decision	0	0	0	0	4
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	19
Number of Not Approvable	0	0	4	1	3
Rate of Not Approvable	0%	0%	20.0%	5.6%	15.8%

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	16.7%	0%	0%	N/A	50.0%

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	23.1%	0%	0%	11.1%	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%	16.7%	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	0
MDUFA III Decisions	0	2	2	0	1
MDUFA III Decisions Goal Met	0	2	2	0	1
Supplements pending MDUFA III Decision	0	0	0	0	2
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	1
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

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2016 and September 30, 2017.

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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	3	1	1	1	0
Original PMAs (No Panel) – Priority	2	3	4	7	3
Original PMAs (Panel) – Non-Priority	8	4	3	0	2
Original PMAs (No Panel) – Non-Priority	16	21	38	48	37
Panel-Tracked Supplements (Panel) – Priority	2	0	0	0	0
Panel-Tracked Supplements (No Panel) – Priority	0	1	1	4	1
Panel-Tracked Supplements (Panel) – Non-Priority	4	1	1	0	0
Panel-Tracked Supplements (No Panel) – Non-Priority	10	12	24	12	25
PMA Modules	52	67	98	84	88
180-Day Supplements	185	178	198	206	278
Real-Time Supplements	308	339	335	326	331

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	43	42	69	69	62
Number with a decision (MDUFA or Non-MDUFA)	43	42	69	58	26
% of FY closed	100%	100%	100%	84.1%	41.9%

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

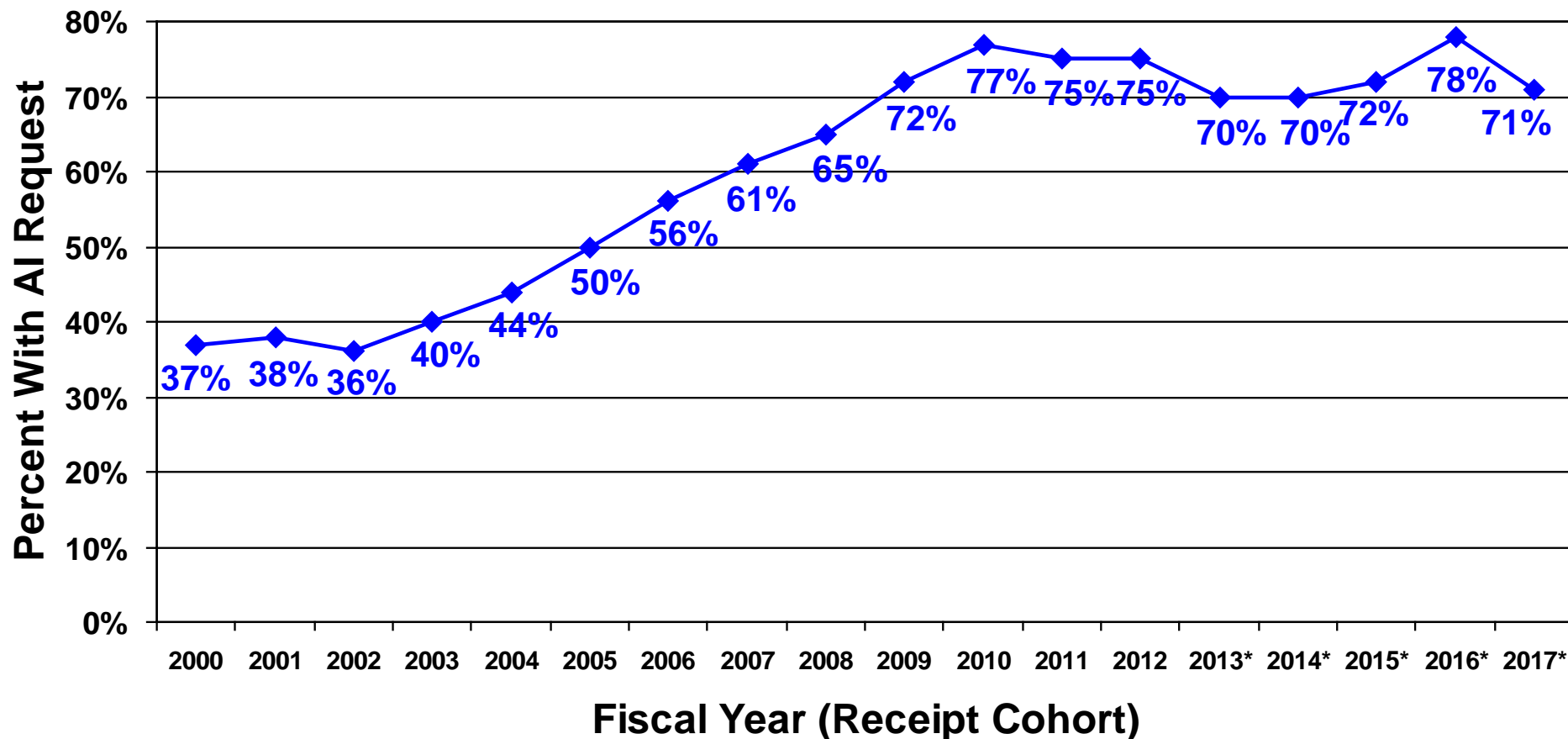
Performance Metric	FY 2013 3 year cohort 395 days	FY 2014 3 year cohort 395 days	FY 2015 3 year cohort 390 days	FY 2016 3 year cohort 390 days	FY 2017 3 year cohort 385 days
Number with a MDUFA decision	121	113	147	N/A	N/A
Number with a MDUFA decision after trimming the upper and lower 5%	109	101	133	N/A	N/A
Three-year Rolling Average Total Time to MDUFA decision	316.83	302.18	292.32	N/A	N/A

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510(k)s

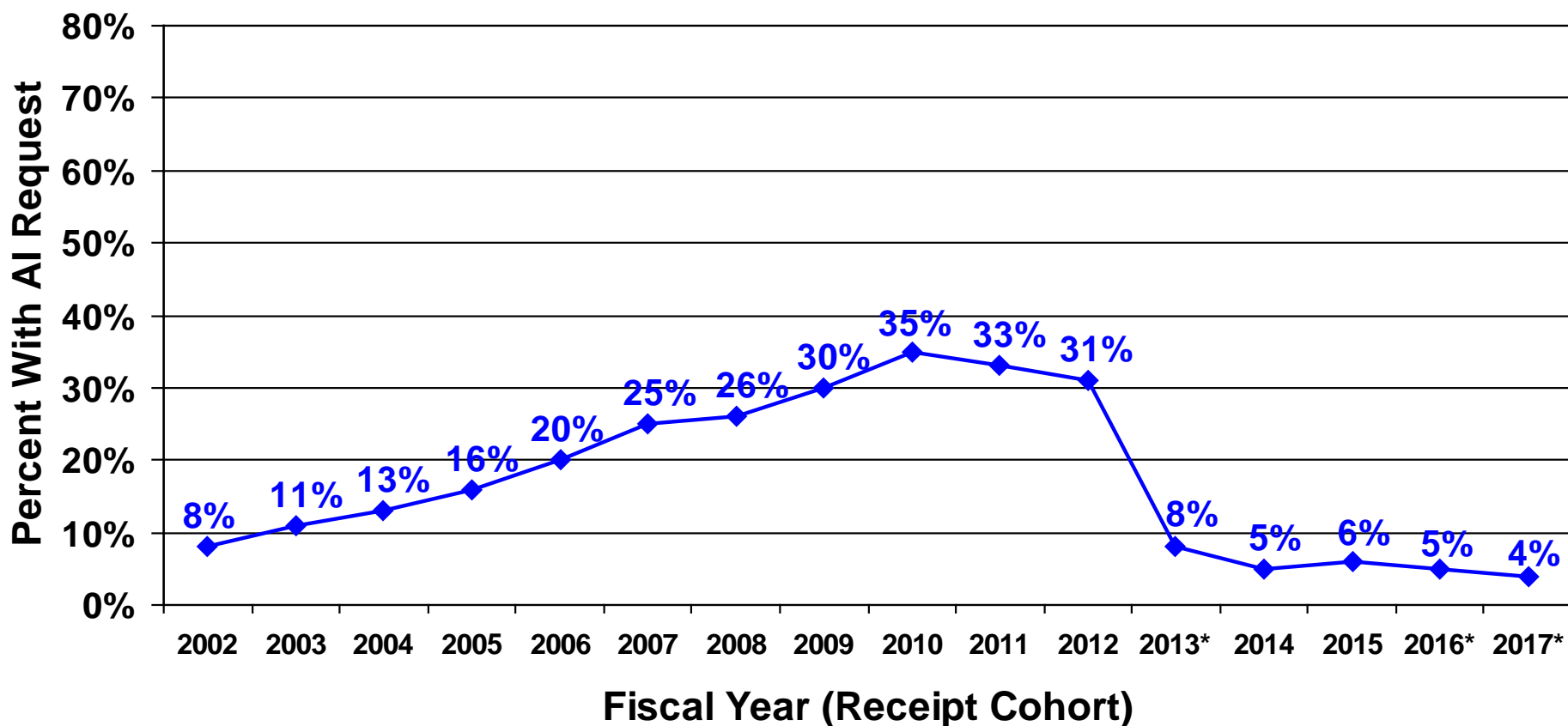
Q4 FY17

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



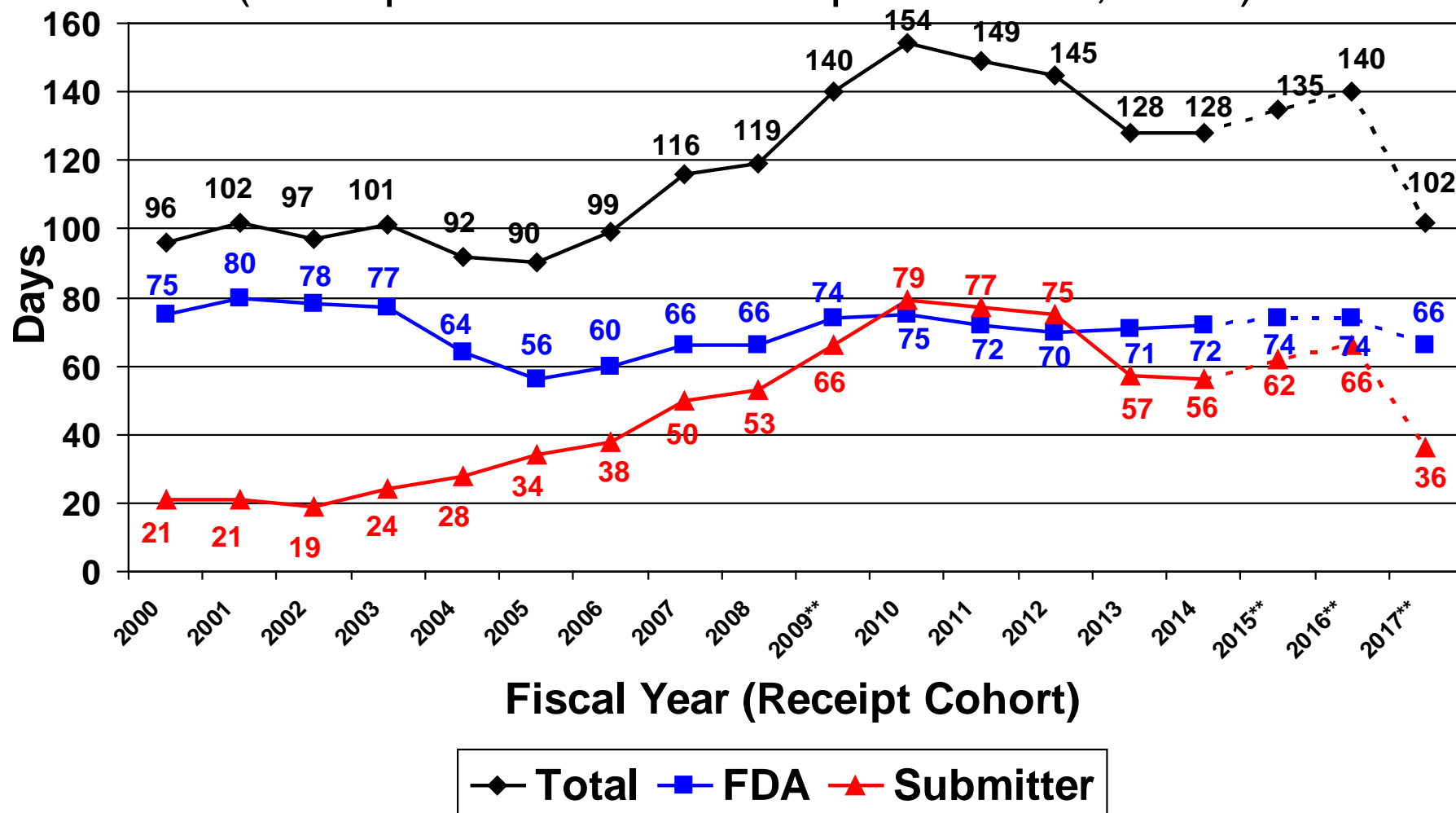
*FY 2013 - FY 2017 data are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for submissions accepted as of 6/30/2017.

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



*FY 2013 – FY 2017 data are for 510(k)s accepted as of 2/28/2017;
FY 2016 & FY 2017 2nd cycle cohorts are still open as of 9/30/2017; data may change

Average Time to MDUFA Decision: 510(k)s* (Receipt Cohorts as of September 30, 2017)



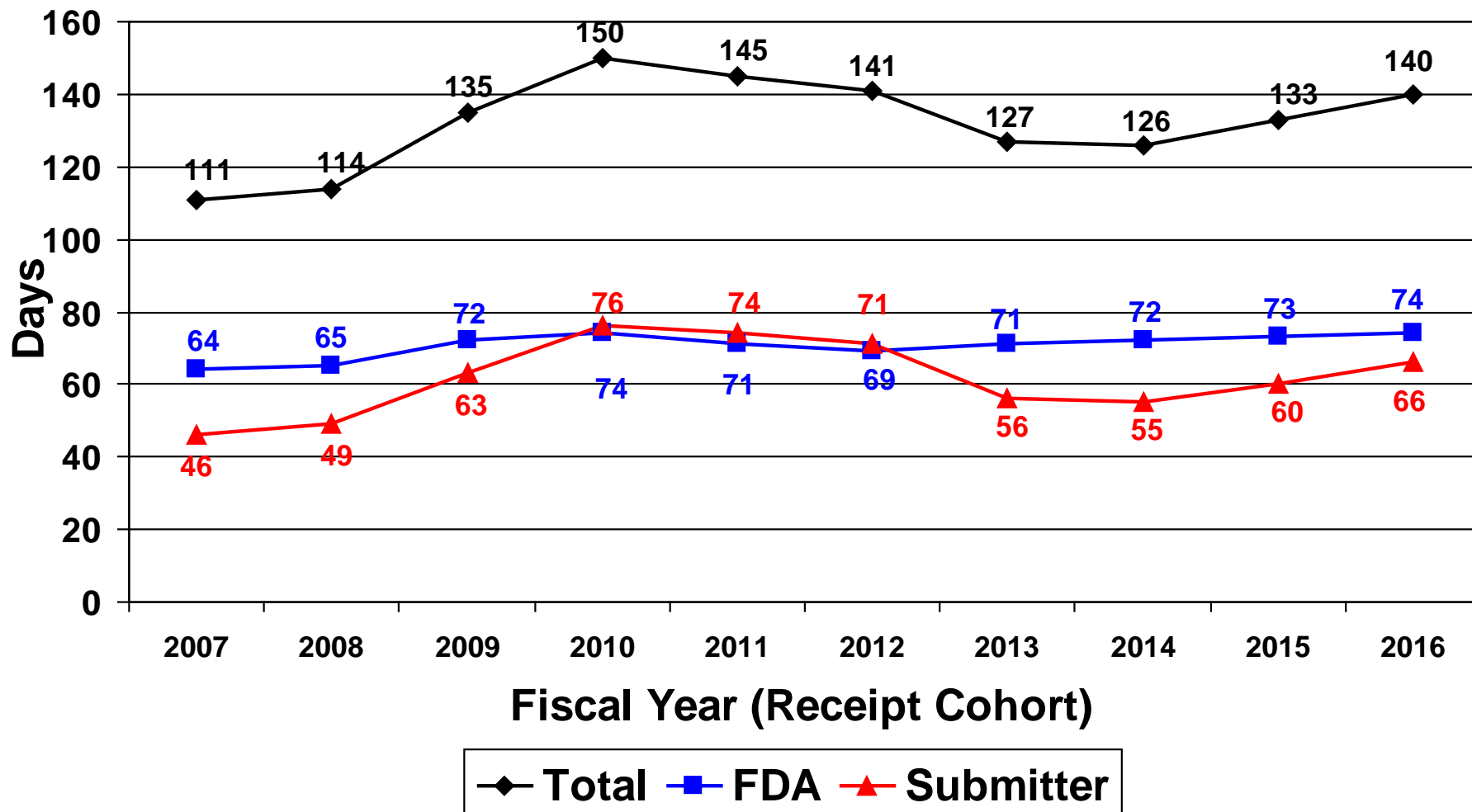
*SE and NSE decisions only; times may not add to total due to rounding

**Cohorts still open; percentage of cohort closed: FY 2009 = 99.97%, FY 2016 = 98.55% and FY2016 = 58.43% => avg times for FY2016 & FY2017 will increase

- Performance data map to Table 6.5 in the CDRH MDUFA III performance report.

Average Time to Decision: 510(k)s*

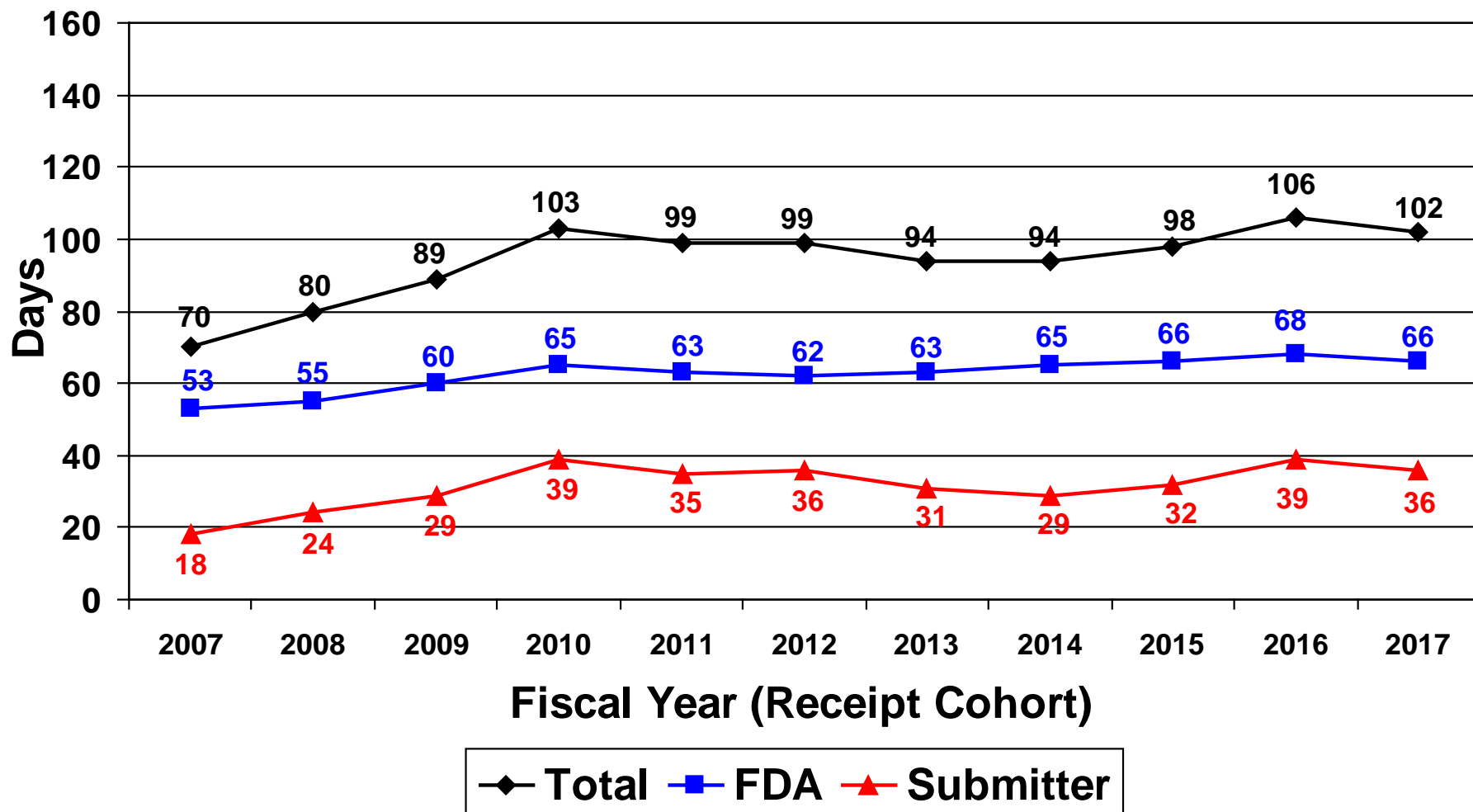
- Comparison of Receipt Cohorts When 98.6% Closed -



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

Average Time to Decision: 510(k)s*

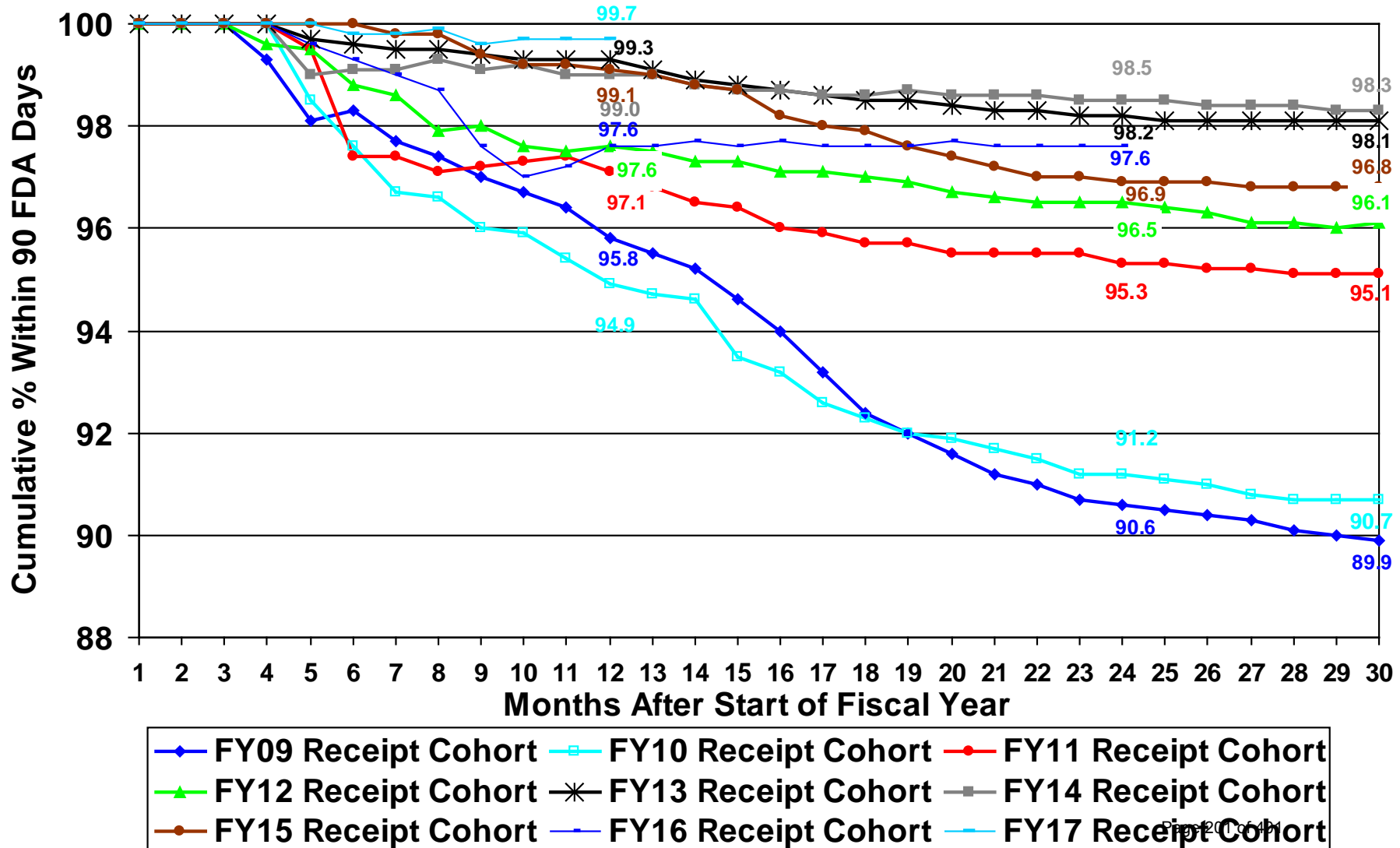
- Comparison of Receipt Cohorts When 58.4% Closed -



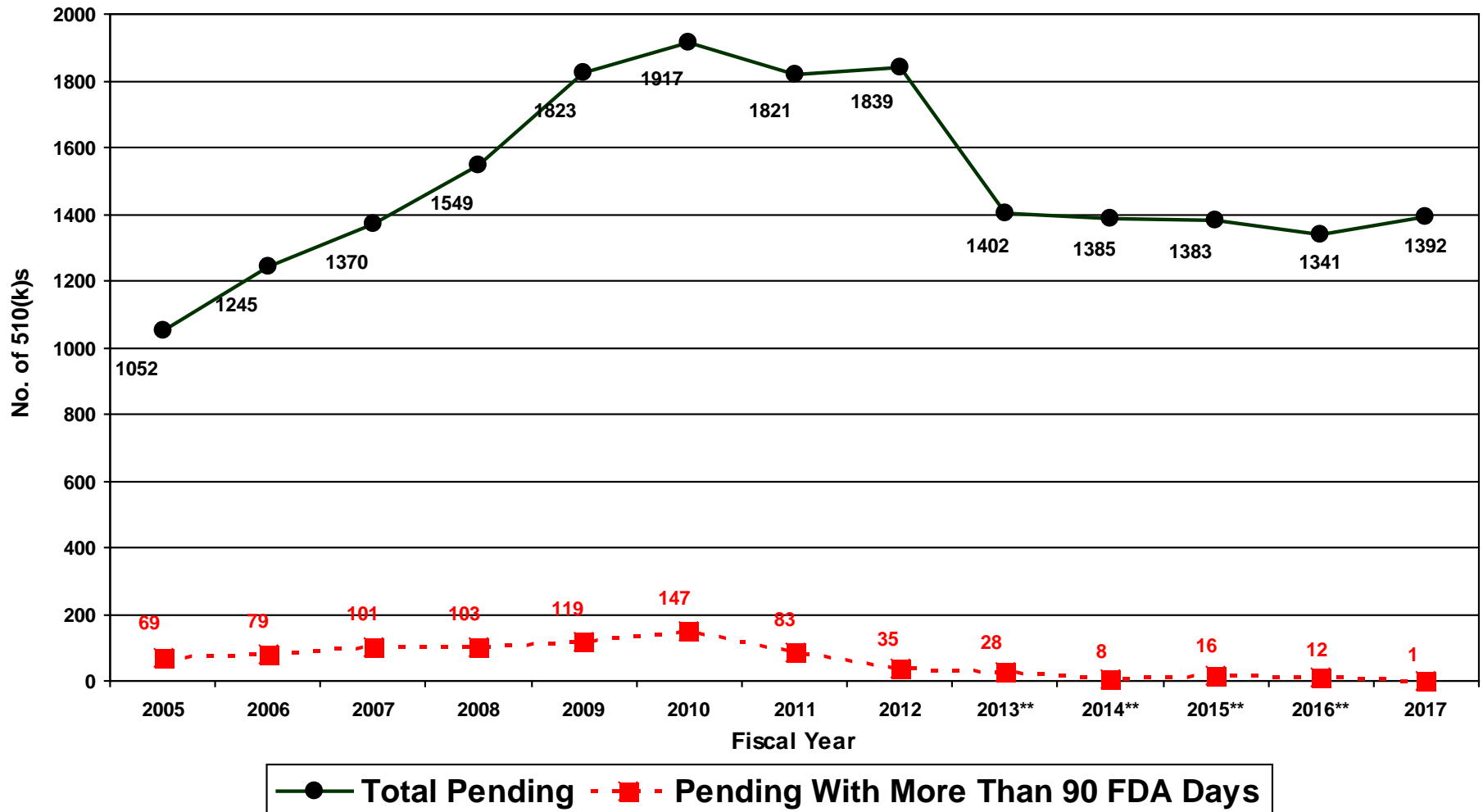
*SE and NSE decisions only; times may not add to total due to rounding

Trend in 510(k) MDUFA Decision Goal Performance

- Comparison of FY09 - FY17 Receipt Cohorts -



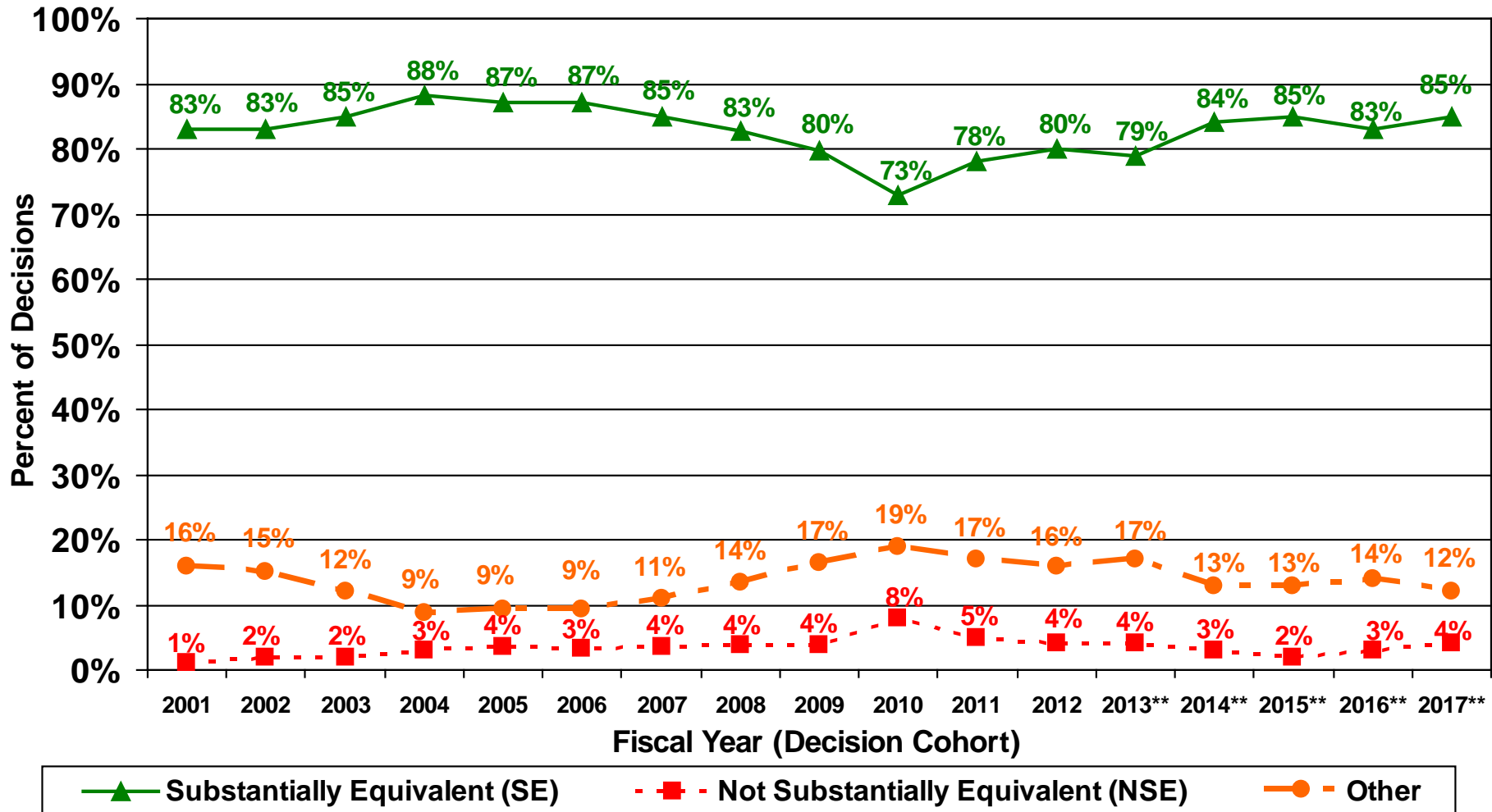
510(k)s Pending* at End of Year



*Under review or on hold

**Excludes FY 2013 - FY 2017 receipts that were not accepted for review as of end of year

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



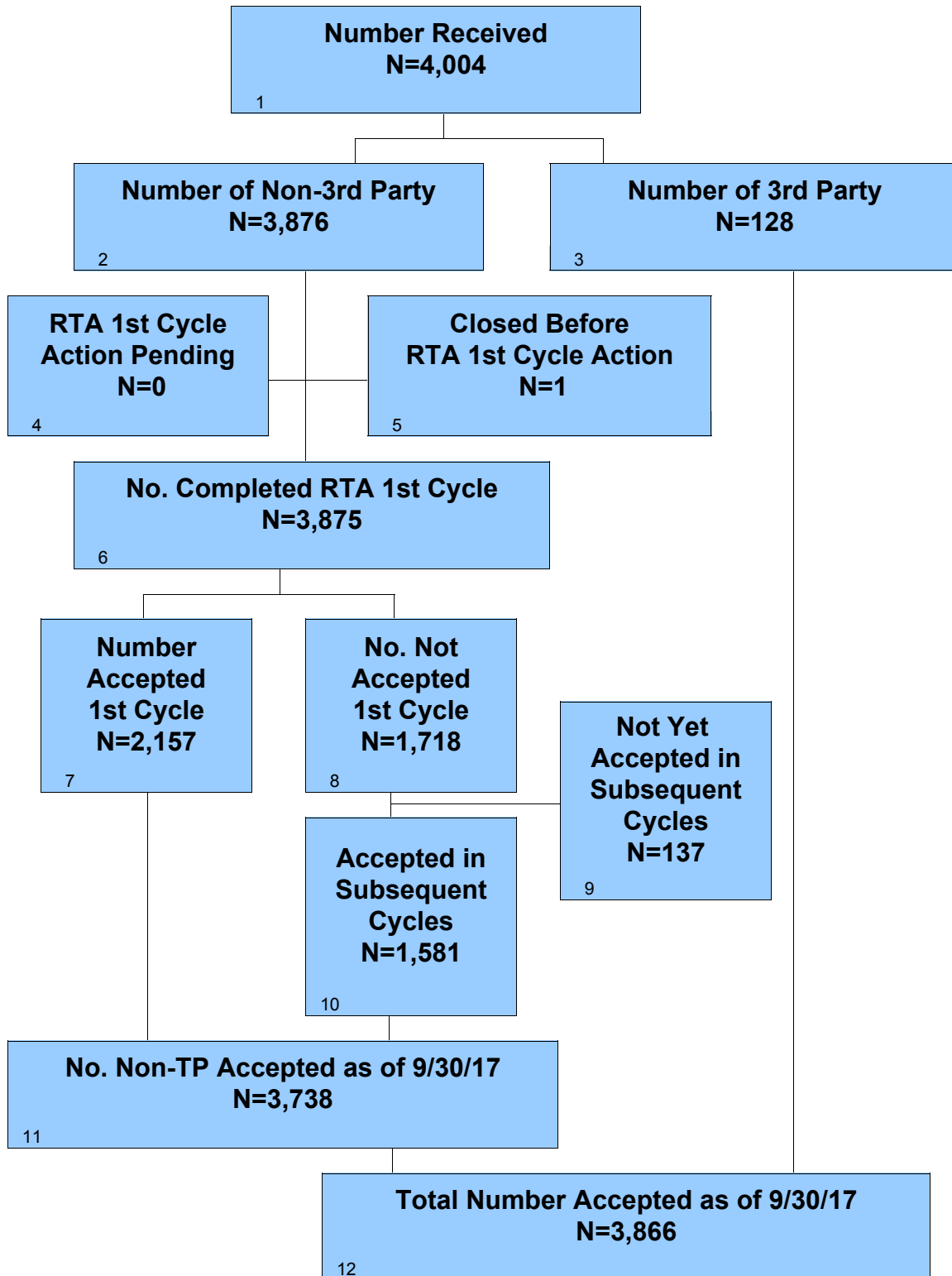
*Percentages may not add to 100% due to rounding

**Excludes final decisions made on FY 2013 - FY 2017 receipts that were not accepted for review as of 9/30/2017

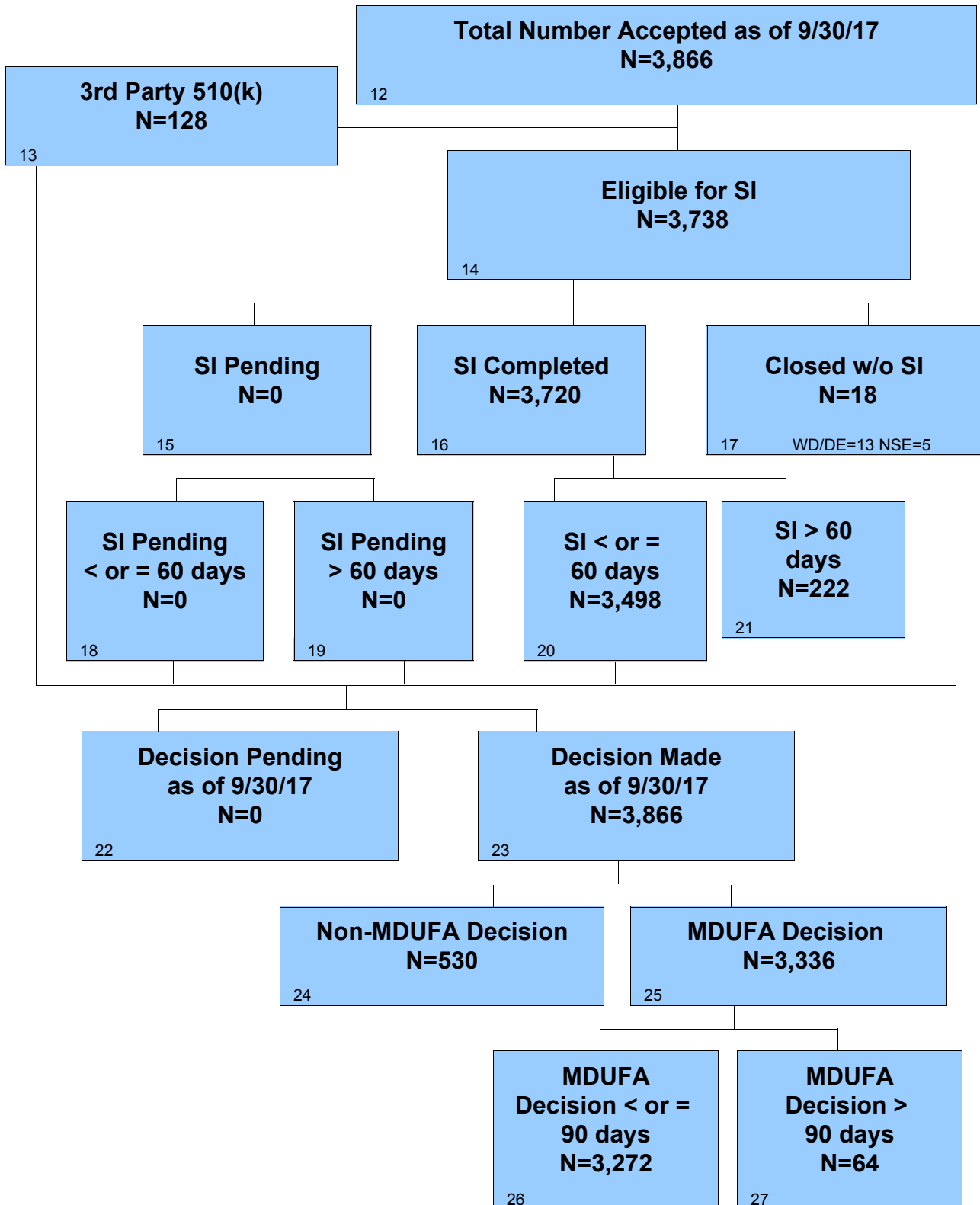
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CDRH 510(k)s - FY 2013

As of 9/30/17

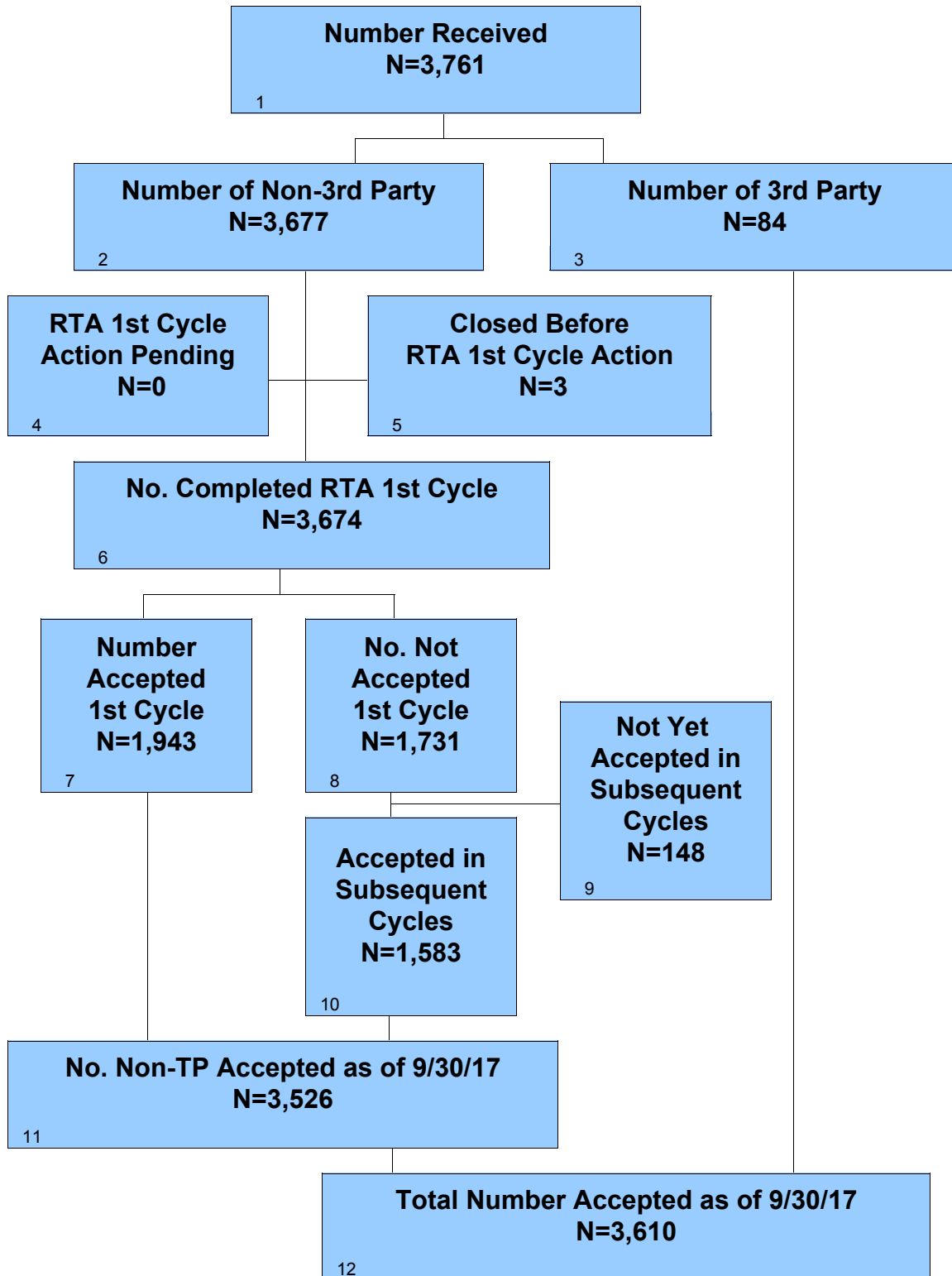


CDRH 510(k)s - FY 2013
As of 9/30/17 Continued



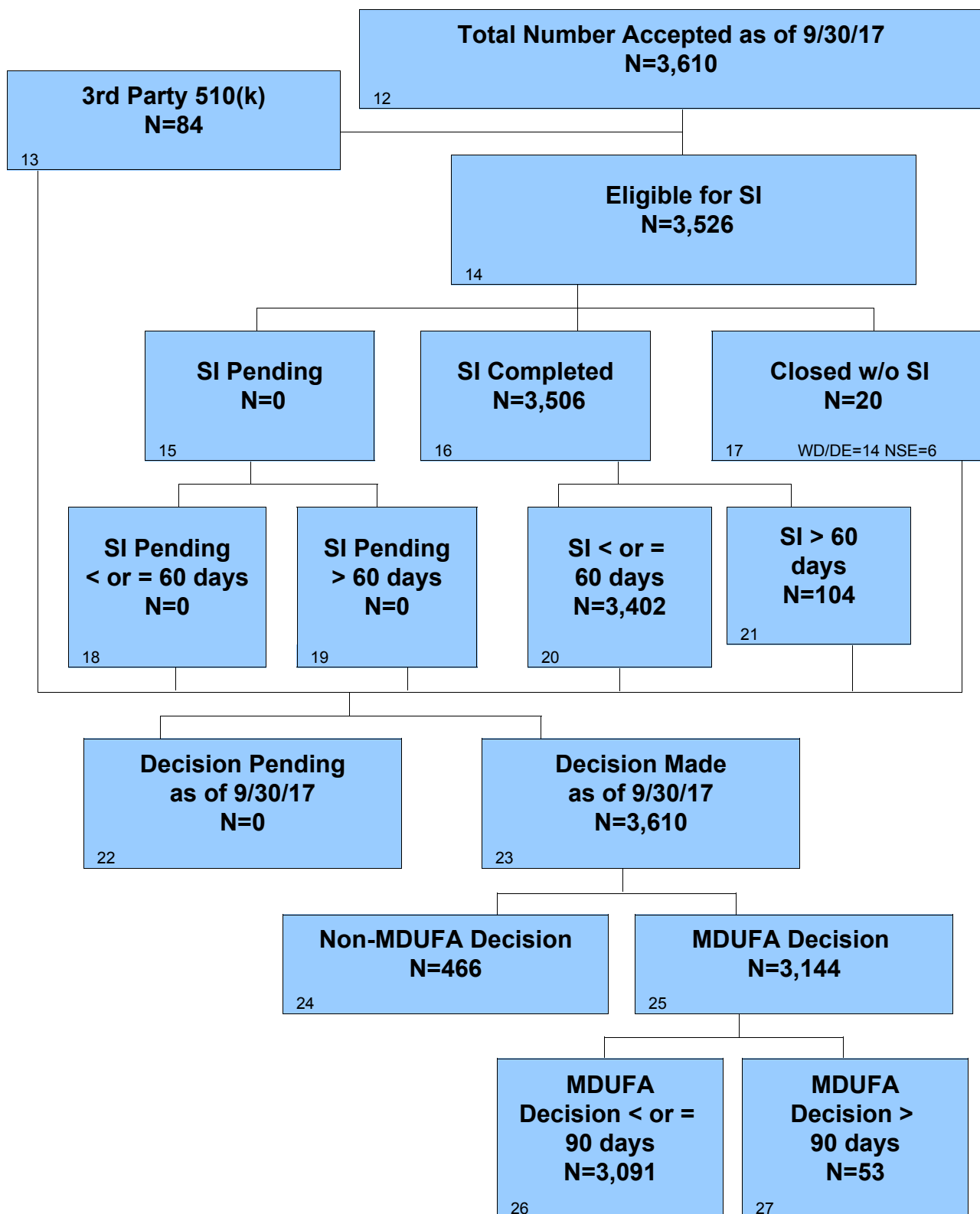
CDRH 510(k)s - FY 2014

As of 9/30/17



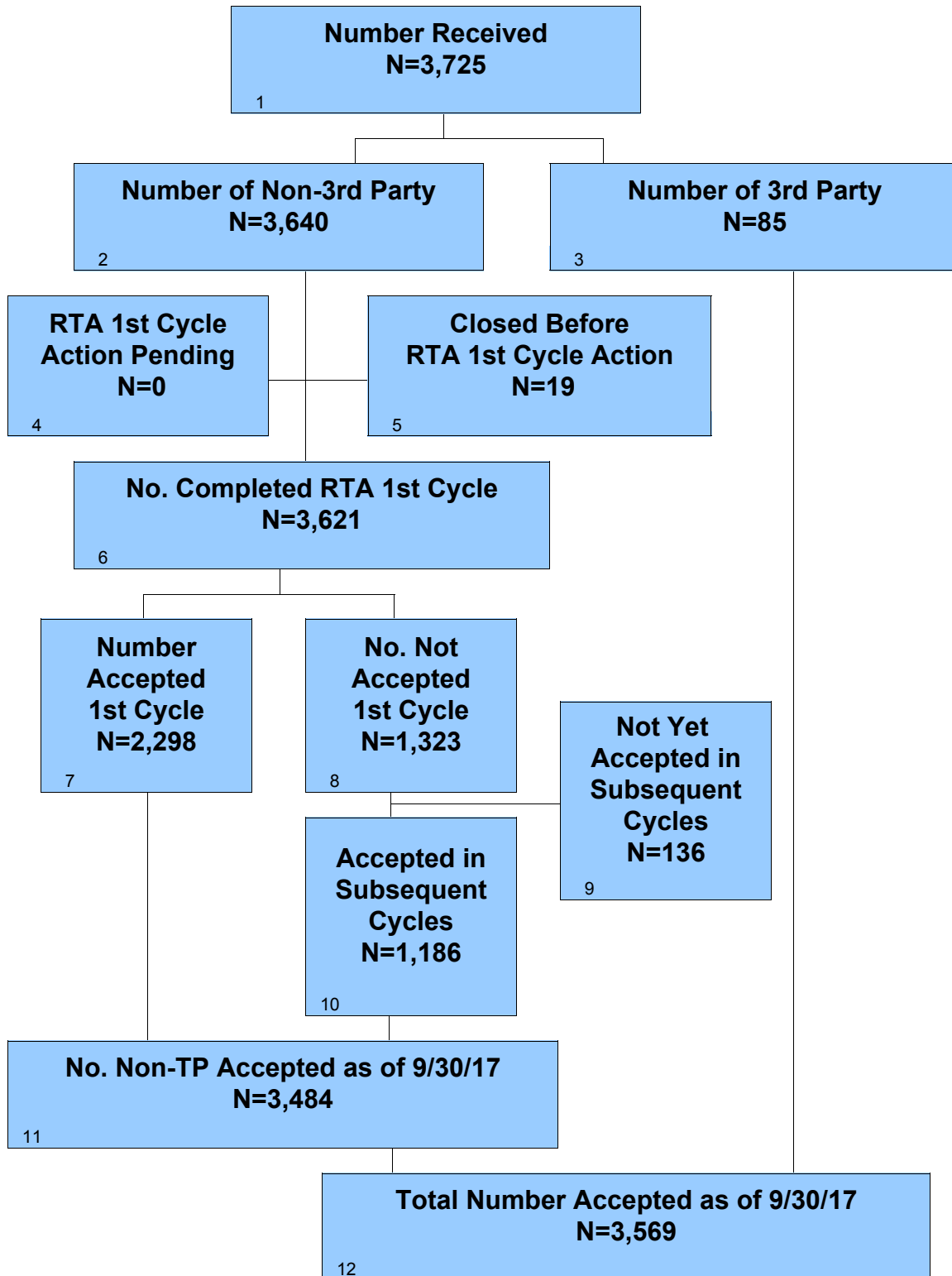
CDRH 510(k)s - FY 2014

As of 9/30/17 Continued



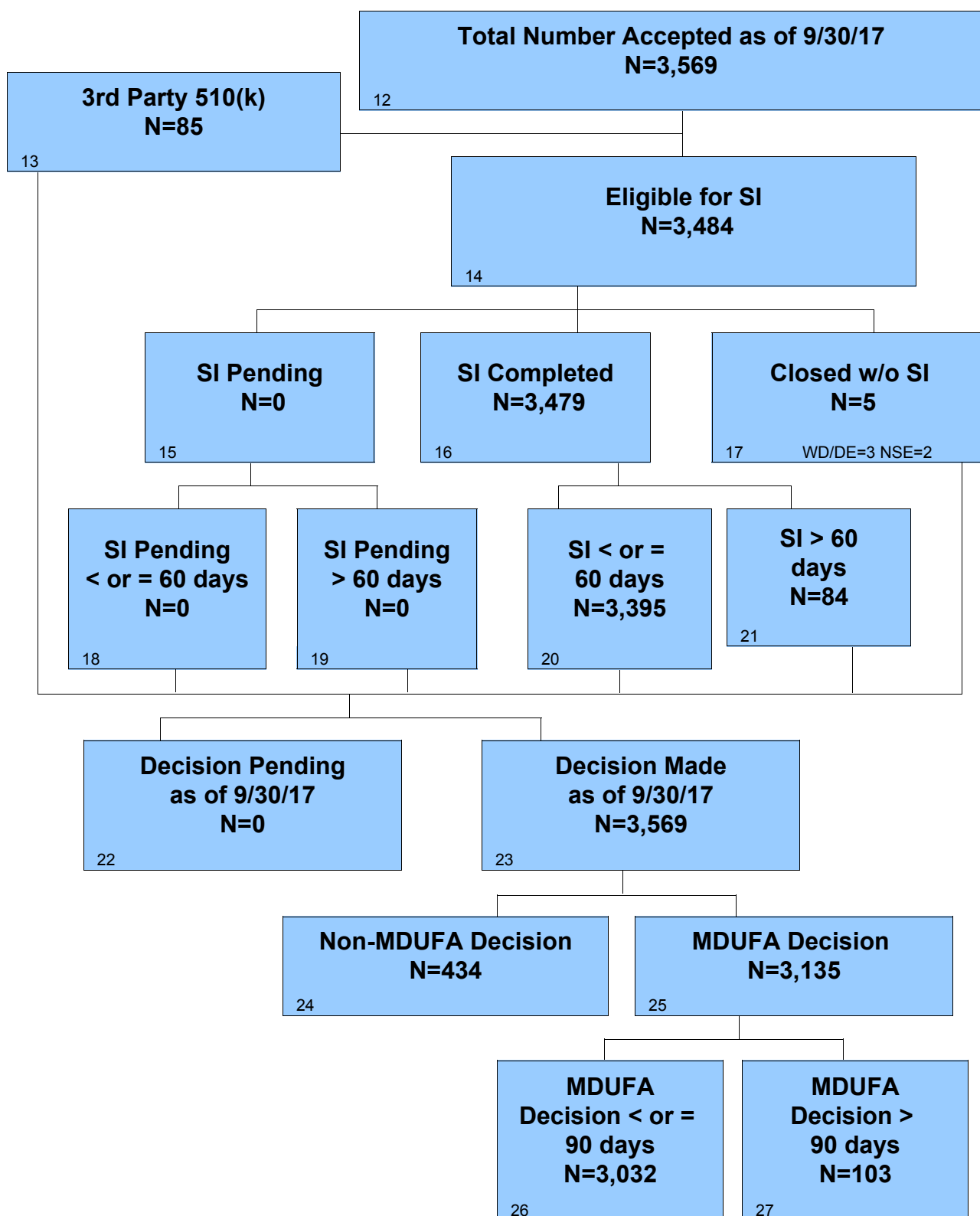
CDRH 510(k)s - FY 2015

As of 9/30/17



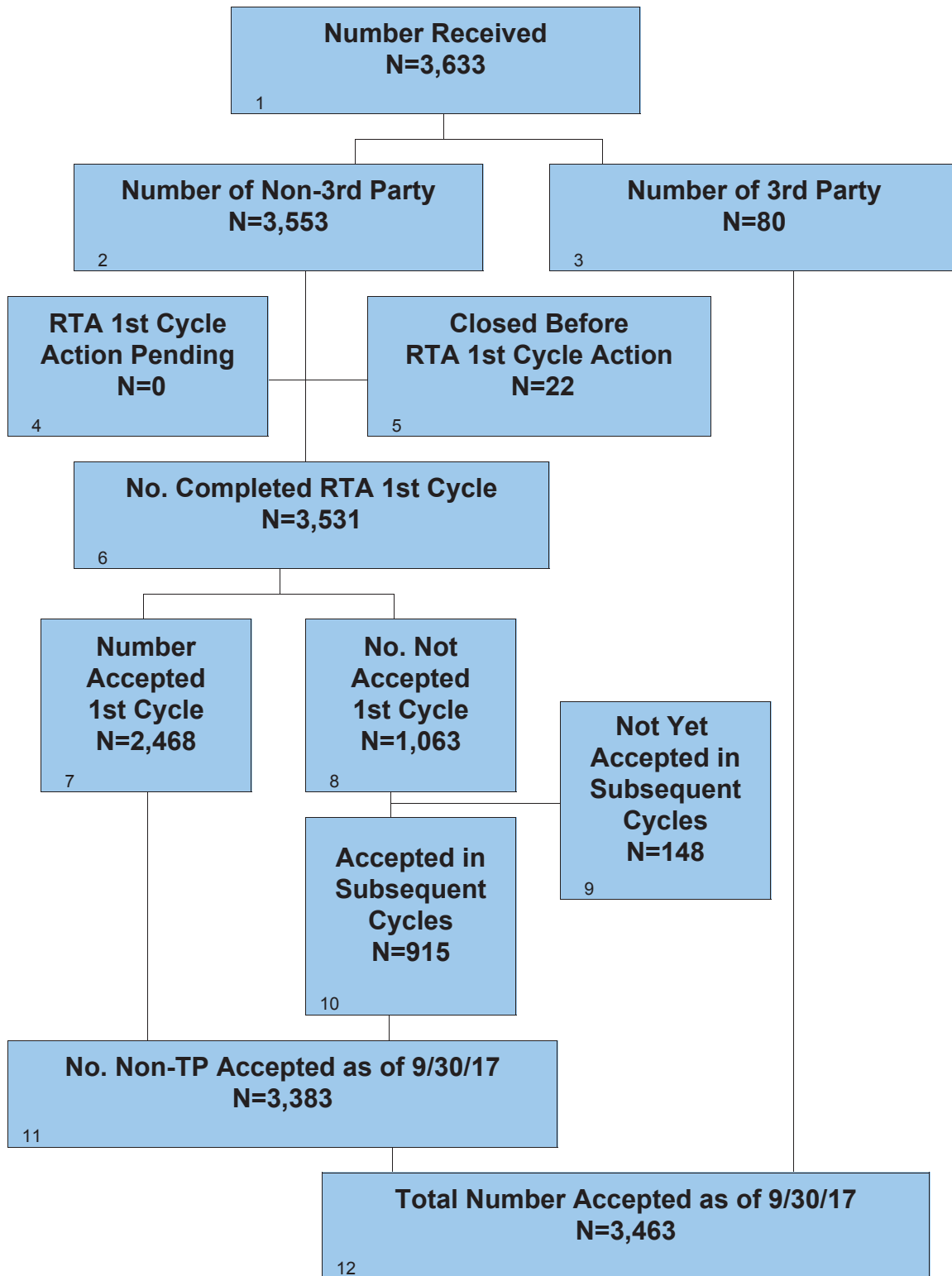
CDRH 510(k)s - FY 2015

As of 9/30/17 Continued



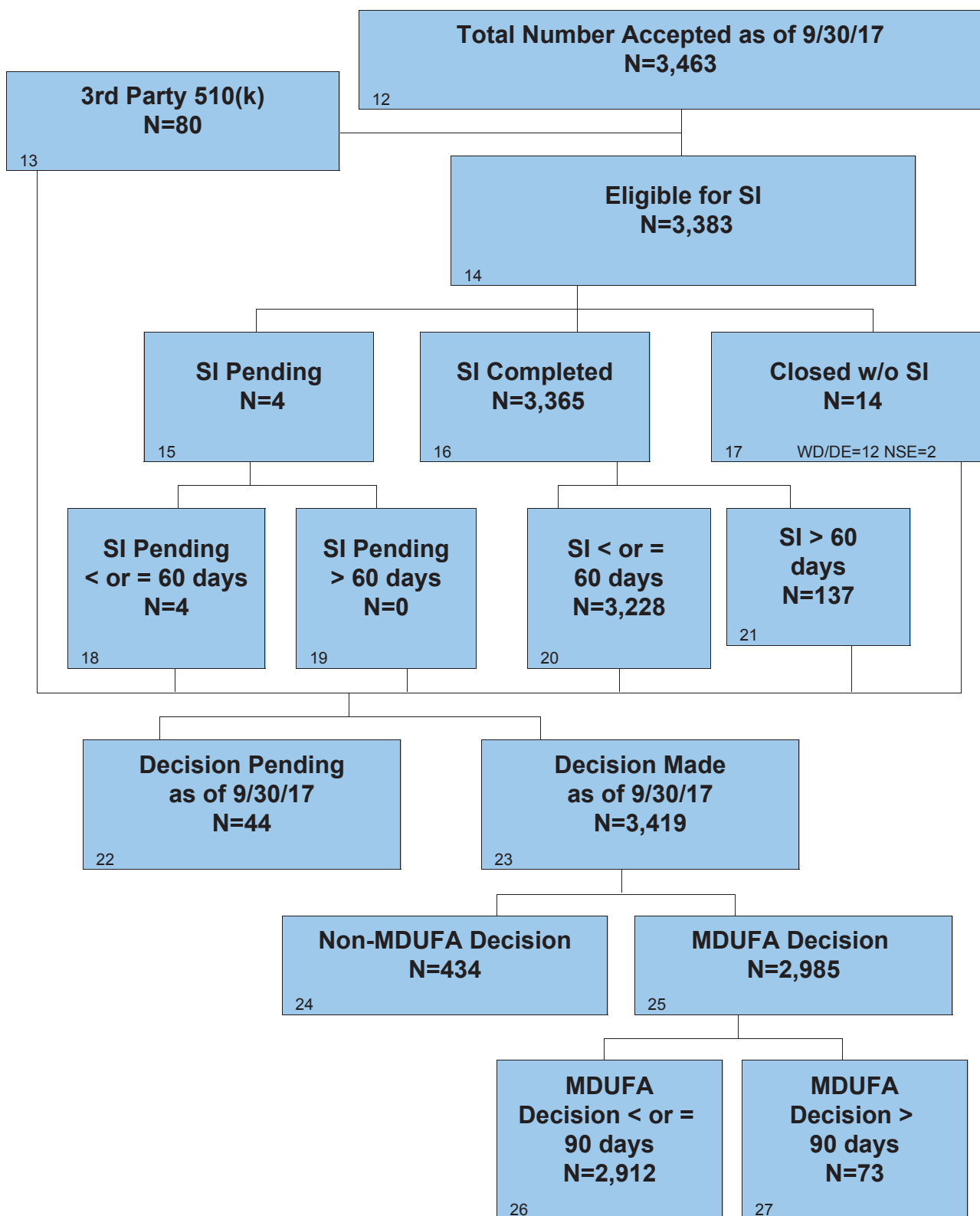
CDRH 510(k)s - FY 2016

As of 9/30/17



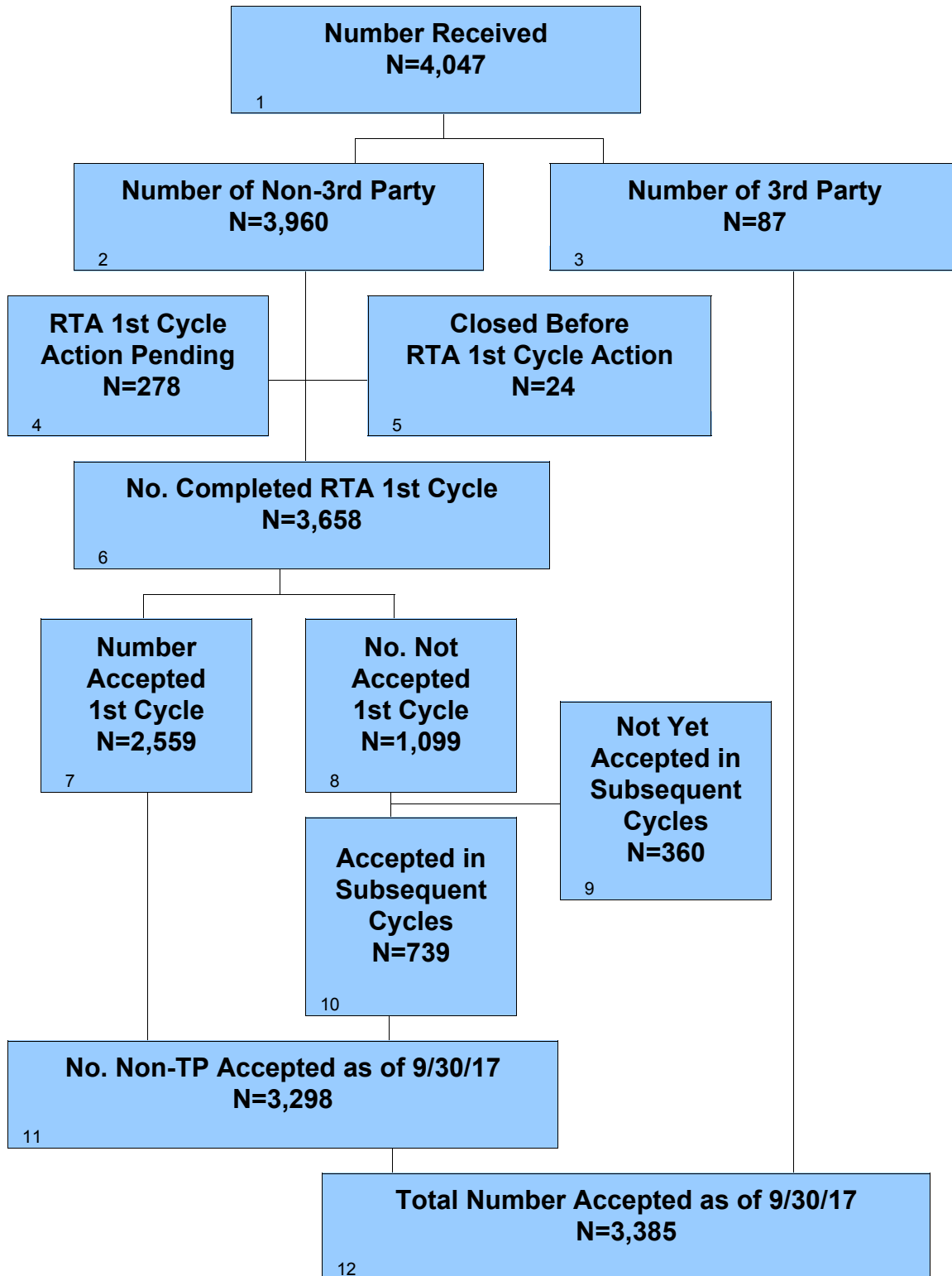
CDRH 510(k)s - FY 2016

As of 9/30/17 Continued



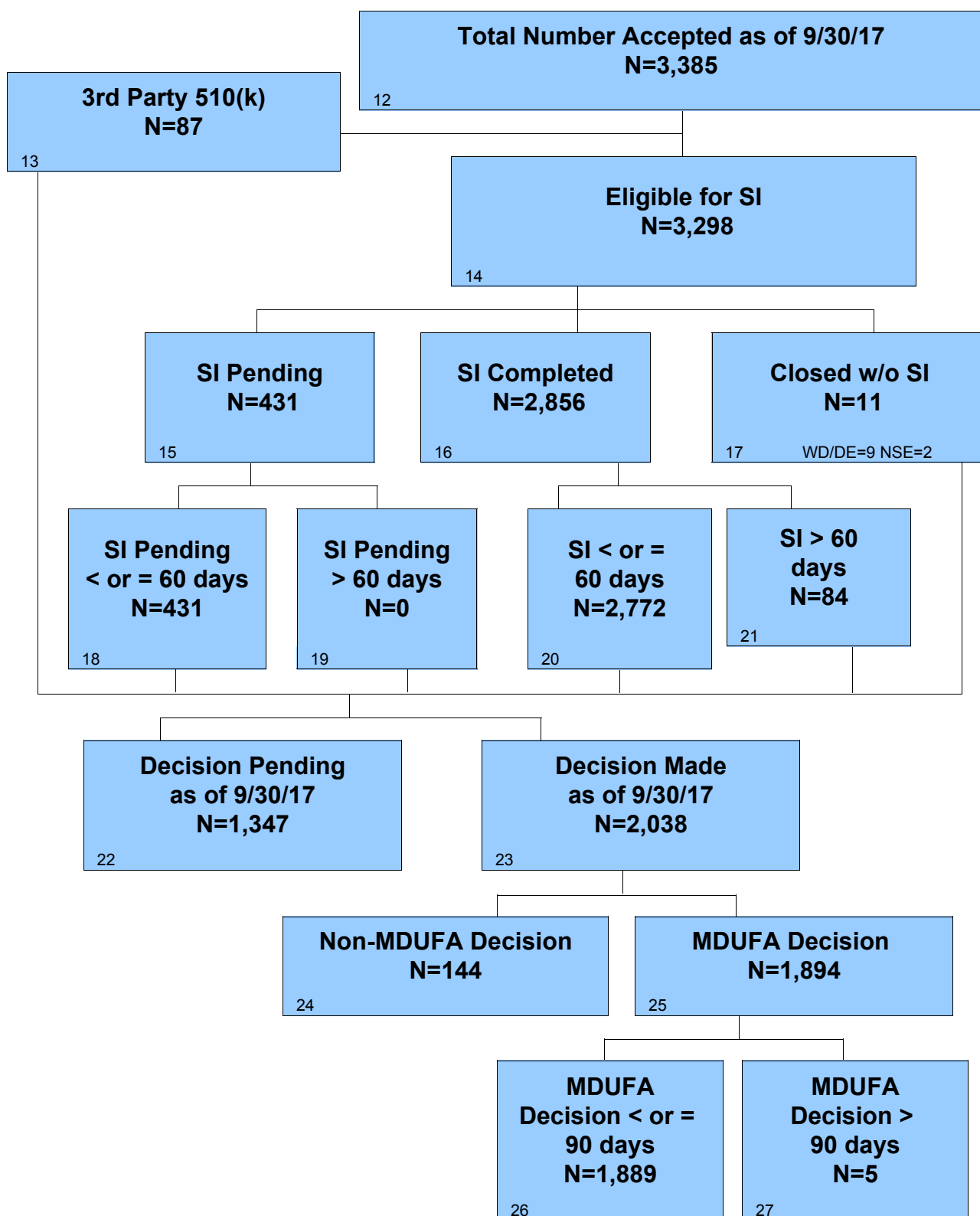
CDRH 510(k)s - FY 2017

As of 9/30/17



CDRH 510(k)s - FY 2017

As of 9/30/17 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	3,960
Closed before RTA action	1	3	19	22	24
Number Accepted	1,197	1,886	2,272	2,441	2,527
Number without a RTA Review and > 15 Days since Date Received	41	57	26	27	32
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	278
Number Not Accepted	1,715	1,731	1,323	1,063	1,099
Rate of submissions not accepted for filing review	58.1%	47.1%	36.5%	30.1%	30.0%

* 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 CDRH – 510(k) Substantive Interaction Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	3,738	3,526	3,484	3,383	3,298
Deleted or withdrawn prior to SI	13	14	3	12	9
SI within 60 FDA days	3,498	3,402	3,395	3,228	2,772
SI over 60 FDA days	222	104	84	137	84
SI pending within 60 FDA days	0	0	0	4	431
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	5	6	2	2	2
Current SI Performance Percent within 60 FDA days	93.9%	96.9%	97.5%	95.9%	97.0%

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	3,365	2,856
Average number of FDA days to Substantive Interaction	47.61	49.43	50.02	50.40	49.76
20th Percentile FDA days to Substantive Interaction	30	33	39	41	37
40th Percentile FDA days to Substantive Interaction	48	52	53	53	52
60th Percentile FDA days to Substantive Interaction	56	57	57	57	57
80th Percentile FDA days to Substantive Interaction	59	59	59	59	59
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	3,463	3,385
Non-MDUFA III Decisions	530	466	434	434	144
MDUFA III Decisions (SE/NSE)	3,336	3,144	3,135	2,985	1,894
MDUFA III Decisions within 90 FDA Days	3,272	3,091	3,032	2,912	1,889
510(k)s pending MDUFA III Decision	0	0	0	44	1,347
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	1	1
Current Performance Percent within 90 FDA Days	98.1%	98.3%	96.7%	97.5%	99.7%

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	1.58
Number with MDUFA III decision	3,336	3,144	3,135	2,985	1,894
Average FDA days to MDUFA III decision	70.76	72.09	73.56	73.89	66.14
20th Percentile FDA days to MDUFA III decision	48	51	54	56	30
40th Percentile FDA days to MDUFA III decision	76	80	81	82	64
60th Percentile FDA days to MDUFA III decision	86	87	87	88	84
80th Percentile FDA days to MDUFA III decision	89	89	89	89	88
Maximum FDA days to MDUFA III decision	342	245	373	267	97
Average Industry days to MDUFA III decision	57.22	55.76	61.85	65.84	35.64
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	0
60th Percentile Industry days to MDUFA III decision	44	45	53	62	25
80th Percentile Industry days to MDUFA III decision	116	117	138	143	67
Maximum Industry days to MDUFA III decision	489	469	597	529	236
Average Total days to MDUFA III decision	127.98	127.85	135.41	139.73	101.79
20th Percentile Total days to MDUFA III decision	56	58	58	63	36
40th Percentile Total days to MDUFA III decision	90	90	95	104	79
60th Percentile Total days to MDUFA III decision	127	128	137	147	105
80th Percentile Total days to MDUFA III decision	199	203	224	227	149
Maximum Total days to MDUFA III decision	691	556	744	628	326

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	3,463	3,385
Number with MDUFA decision	3,336	3,144	3,135	2,985	1,894
Number of SE decisions	3,203	3,057	3,040	2,858	1,855
Number of NSE decisions	133	87	95	127	39
Number of Withdrawals	230	213	199	183	80
Number deleted	279	221	224	235	50
Rate of SE decisions	96.0%	97.2%	97.0%	95.7%	97.9%
Rate of NSE decisions	4.0%	2.8%	3.0%	4.3%	2.1%
Rate of Withdrawals	5.9%	5.9%	5.6%	5.3%	2.4%
Rate of Deleted	7.2%	6.1%	6.3%	6.8%	1.5%

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	73	5
Mean FDA days for submissions that missed goal	119	106	116	108	94
Mean industry days for submissions that missed goal	138	128	147	120	91

Section 6 510(k) Office Level Metrics

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,380	2,952	2,986	2,869	3,216
Closed before RTA action	1	2	17	18	9
Number Accepted	821	1,339	1,730	1,856	1,942
Number without a RTA Review and > 15 Days since Date Received	23	50	23	24	19
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	239
Number Not Accepted	1,535	1,561	1,216	971	1,007
Rate of submissions not accepted for filing review	64.5%	52.9%	41.0%	34.1%	33.9%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	2,975	2,829	2,851	2,722	2,643
Deleted or withdrawn prior to SI	12	14	2	9	5
SI within 60 FDA days	2,779	2,720	2,767	2,572	2,192
SI over 60 FDA days	179	89	80	135	82
SI pending within 60 FDA days	0	0	0	4	362
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	5	6	2	2	2
Current SI Performance Percent within 60 FDA days	93.8%	96.6%	97.1%	94.9%	96.3%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2,958	2,809	2,847	2,707	2,274
Average number of FDA days to Substantive Interaction	48.28	50.36	51.06	51.51	50.63
20th Percentile FDA days to Substantive Interaction	30	37	43	45	42
40th Percentile FDA days to Substantive Interaction	49	54	54	55	53
60th Percentile FDA days to Substantive Interaction	57	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 - 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	3,049	2,876	2,904	2,761	2,696
Non-MDUFA III Decisions	444	392	371	367	114
MDUFA III Decisions (SE/NSE)	2,605	2,484	2,533	2,355	1,471
MDUFA III Decisions within 90 FDA Days	2,548	2,446	2,432	2,286	1,466
510(k)s pending MDUFA III Decision	0	0	0	39	1,111
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	1
Current Performance Percent within 90 FDA Days	97.8%	98.5%	96.0%	97.1%	99.6%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.76	1.72	1.75	1.82	1.60
Number with MDUFA III decision	2,605	2,484	2,533	2,355	1,471
Average FDA days to MDUFA III decision	72.80	73.81	75.97	76.27	67.97
20th Percentile FDA days to MDUFA III decision	53	55	57	58	42
40th Percentile FDA days to MDUFA III decision	80	83	84	85	70
60th Percentile FDA days to MDUFA III decision	87	87	88	88	85
80th Percentile FDA days to MDUFA III decision	89	89	90	90	89
Maximum FDA days to MDUFA III decision	342	245	373	267	97
Average Industry days to MDUFA III decision	57.36	56.11	63.01	67.79	36.62
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	17	16	17	27	0
60th Percentile Industry days to MDUFA III decision	46	48	55	67	28
80th Percentile Industry days to MDUFA III decision	117	118	139	145	69
Maximum Industry days to MDUFA III decision	438	408	597	529	236
Average Total days to MDUFA III decision	130.16	129.92	138.99	144.05	104.59
20th Percentile Total days to MDUFA III decision	59	61	63	73	49
40th Percentile Total days to MDUFA III decision	94	94	100	111	85
60th Percentile Total days to MDUFA III decision	129	131	141	152	111
80th Percentile Total days to MDUFA III decision	200	204	226	231	151
Maximum Total days to MDUFA III decision	691	512	744	628	326

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,049	2,876	2,904	2,761	2,696
Number with MDUFA decision	2,605	2,484	2,533	2,355	1,471
Number of SE decisions	2,494	2,416	2,457	2,246	1,436
Number of NSE decisions	111	68	76	109	35
Number of Withdrawals	188	176	167	154	64
Number deleted	237	185	193	198	41
Rate of SE decisions	95.7%	97.3%	97.0%	95.4%	97.6%
Rate of NSE decisions	4.3%	2.7%	3.0%	4.6%	2.4%
Rate of Withdrawals	6.2%	6.1%	5.8%	5.6%	2.4%
Rate of Deleted	7.8%	6.4%	6.6%	7.2%	1.5%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	57	38	101	69	5
Mean FDA days for submissions that missed goal	121	109	115	105	94
Mean industry days for submissions that missed goal	137	153	146	118	91

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	574	725	654	684	744
Closed before RTA action	0	1	2	4	15
Number Accepted	376	547	542	585	585
Number without a RTA Review and > 15 Days since Date Received	18	7	3	3	13
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	39
Number Not Accepted	180	170	107	92	92
Rate of submissions not accepted for filing review	31.4%	23.5%	16.4%	13.5%	13.3%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	763	697	633	661	655
Deleted or withdrawn prior to SI	1	0	1	3	4
SI within 60 FDA days	719	682	628	656	580
SI over 60 FDA days	43	15	4	2	2
SI pending within 60 FDA days	0	0	0	0	69
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	94.4%	97.8%	99.4%	99.7%	99.7%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	762	697	632	658	582
Average number of FDA days to Substantive Interaction	45.02	45.66	45.33	45.81	46.38
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	54
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 - CDRH – 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	817	734	665	702	689
Non-MDUFA III Decisions	86	74	63	67	30
MDUFA III Decisions (SE/NSE)	731	660	602	630	423
MDUFA III Decisions within 90 FDA Days	724	645	600	626	423
510(k)s pending MDUFA III Decision	0	0	0	5	236
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	1	0
Current Performance Percent within 90 FDA Days	99.0%	97.7%	99.7%	99.2%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.69	1.71	1.68	1.73	1.51
Number with MDUFA III decision	731	660	602	630	423
Average FDA days to MDUFA III decision	63.51	65.64	63.39	64.99	59.78
20th Percentile FDA days to MDUFA III decision	34	33	30	30	28
40th Percentile FDA days to MDUFA III decision	58	60	59	63	55
60th Percentile FDA days to MDUFA III decision	81	84	79	81	77
80th Percentile FDA days to MDUFA III decision	88	88	87	88	87
Maximum FDA days to MDUFA III decision	121	137	232	229	90
Average Industry days to MDUFA III decision	56.69	54.43	56.98	58.58	32.25
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	44	14
80th Percentile Industry days to MDUFA III decision	112	107	127	132	55
Maximum Industry days to MDUFA III decision	489	469	477	357	225
Average Total days to MDUFA III decision	120.21	120.07	120.37	123.57	92.03
20th Percentile Total days to MDUFA III decision	36	35	32	35	29
40th Percentile Total days to MDUFA III decision	77	85	75	85	60
60th Percentile Total days to MDUFA III decision	111	113	115	120	90
80th Percentile Total days to MDUFA III decision	194	189	208	211	139
Maximum Total days to MDUFA III decision	579	556	564	444	312

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	817	734	665	702	689
Number with MDUFA decision	731	660	602	630	423
Number of SE decisions	709	641	583	612	419
Number of NSE decisions	22	19	19	18	4
Number of Withdrawals	42	37	32	29	16
Number deleted	42	36	31	37	9
Rate of SE decisions	97.0%	97.1%	96.8%	97.1%	99.1%
Rate of NSE decisions	3.0%	2.9%	3.2%	2.9%	0.9%
Rate of Withdrawals	5.1%	5.0%	4.8%	4.1%	2.3%
Rate of Deleted	5.1%	4.9%	4.7%	5.3%	1.3%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	7	15	2	4	0
Mean FDA days for submissions that missed goal	103	100	162	156	0
Mean industry days for submissions that missed goal	143	68	172	165	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	632	774	776	767	842
Closed before RTA action	1	0	3	3	3
Number Accepted	189	317	375	322	304
Number without a RTA Review and > 15 Days since Date Received	5	14	6	6	11
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	81
Number Not Accepted	437	443	392	436	443
Rate of submissions not accepted for filing review	69.3%	57.2%	50.7%	57.1%	58.4%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	782	723	720	695	606
Deleted or withdrawn prior to SI	2	6	0	2	0
SI within 60 FDA days	751	711	704	623	458
SI over 60 FDA days	26	3	14	67	45
SI pending within 60 FDA days	0	0	0	3	103
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	3	3	2	0	0
Current SI Performance Percent within 60 FDA days	96.3%	99.2%	97.8%	90.3%	91.1%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	777	714	718	690	503
Average number of FDA days to Substantive Interaction	50.83	53.20	54.62	55.56	54.67
20th Percentile FDA days to Substantive Interaction	43	50	52	53	51
40th Percentile FDA days to Substantive Interaction	54	57	57	58	57
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	85

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	797	737	736	711	625
Non-MDUFA III Decisions	165	118	110	98	25
MDUFA III Decisions (SE/NSE)	632	619	626	595	290
MDUFA III Decisions within 90 FDA Days	613	602	553	558	288
510(k)s pending MDUFA III Decision	0	0	0	18	310
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	97.0%	97.3%	88.3%	93.8%	99.3%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.79	1.83	1.88	1.99	1.82
Number with MDUFA III decision	632	619	626	595	290
Average FDA days to MDUFA III decision	78.01	80.06	86.36	84.60	76.18
20th Percentile FDA days to MDUFA III decision	63	78	86	85	62
40th Percentile FDA days to MDUFA III decision	84	86	88	88	84
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	89
Maximum FDA days to MDUFA III decision	280	107	373	267	93
Average Industry days to MDUFA III decision	64.17	69.05	81.32	84.23	50.02
20th Percentile Industry days to MDUFA III decision	0	0	7	21	2
40th Percentile Industry days to MDUFA III decision	21	28	36	53	20
60th Percentile Industry days to MDUFA III decision	54	70	89	94	41
80th Percentile Industry days to MDUFA III decision	141	144	163	155	95
Maximum Industry days to MDUFA III decision	420	361	597	360	184
Average Total days to MDUFA III decision	142.18	149.11	167.68	168.83	126.20
20th Percentile Total days to MDUFA III decision	78	87	90	107	77
40th Percentile Total days to MDUFA III decision	102	114	122	140	106
60th Percentile Total days to MDUFA III decision	140	157	178	180	127
80th Percentile Total days to MDUFA III decision	220	233	253	244	179
Maximum Total days to MDUFA III decision	610	450	744	453	274

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	797	737	736	711	625
Number with MDUFA decision	632	619	626	595	290
Number of SE decisions	603	593	603	553	286
Number of NSE decisions	29	26	23	42	4
Number of Withdrawals	56	52	47	39	12
Number deleted	104	55	58	53	11
Rate of SE decisions	95.4%	95.8%	96.3%	92.9%	98.6%
Rate of NSE decisions	4.6%	4.2%	3.7%	7.1%	1.4%
Rate of Withdrawals	7.0%	7.1%	6.4%	5.5%	1.9%
Rate of Deleted	13.0%	7.5%	7.9%	7.5%	1.8%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	19	17	73	37	2
Mean FDA days for submissions that missed goal	125	97	114	106	93
Mean industry days for submissions that missed goal	157	163	136	89	119

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	335	408	406	406	454
Closed before RTA action	0	1	2	6	3
Number Accepted	151	196	278	280	310
Number without a RTA Review and > 15 Days since Date Received	9	9	5	12	3
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	32
Number Not Accepted	175	202	121	108	106
Rate of submissions not accepted for filing review	52.2%	49.6%	30.0%	27.0%	25.3%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	431	401	397	391	393
Deleted or withdrawn prior to SI	1	2	1	2	1
SI within 60 FDA days	392	380	380	366	341
SI over 60 FDA days	38	19	16	21	6
SI pending within 60 FDA days	0	0	0	1	45
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	1	0
Current SI Performance Percent within 60 FDA days	91.2%	95.2%	96.0%	94.3%	98.3%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	430	399	396	387	347
Average number of FDA days to Substantive Interaction	45.52	46.64	47.39	50.03	48.78
20th Percentile FDA days to Substantive Interaction	29	30	29	30	30
40th Percentile FDA days to Substantive Interaction	43	47	49	52	52
60th Percentile FDA days to Substantive Interaction	50	55	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	67

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	455	415	409	400	407
Non-MDUFA III Decisions	27	42	35	49	18
MDUFA III Decisions (SE/NSE)	428	373	374	345	217
MDUFA III Decisions within 90 FDA Days	413	367	362	335	217
510(k)s pending MDUFA III Decision	0	0	0	6	172
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	96.5%	98.4%	96.8%	97.1%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.72	1.66	1.69	1.82	1.58
Number with MDUFA III decision	428	373	374	345	217
Average FDA days to MDUFA III decision	67.29	68.49	69.07	73.86	64.79
20th Percentile FDA days to MDUFA III decision	36	40	37	55	30
40th Percentile FDA days to MDUFA III decision	59	60	60	85	58
60th Percentile FDA days to MDUFA III decision	86	87	87	88	86
80th Percentile FDA days to MDUFA III decision	89	89	90	90	89
Maximum FDA days to MDUFA III decision	237	210	190	135	90
Average Industry days to MDUFA III decision	47.88	49.07	47.66	65.59	34.80
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	12	10	13	22	0
60th Percentile Industry days to MDUFA III decision	38	34	38	62	24
80th Percentile Industry days to MDUFA III decision	85	113	99	133	63
Maximum Industry days to MDUFA III decision	358	295	381	360	193
Average Total days to MDUFA III decision	115.17	117.56	116.74	139.45	99.59
20th Percentile Total days to MDUFA III decision	41	46	43	60	30
40th Percentile Total days to MDUFA III decision	85	87	90	105	72
60th Percentile Total days to MDUFA III decision	119	119	125	147	105
80th Percentile Total days to MDUFA III decision	173	197	189	221	147
Maximum Total days to MDUFA III decision	451	505	478	457	281

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	455	415	409	400	407
Number with MDUFA decision	428	373	374	345	217
Number of SE decisions	419	369	366	320	209
Number of NSE decisions	9	4	8	25	8
Number of Withdrawals	13	21	18	24	11
Number deleted	14	21	17	22	6
Rate of SE decisions	97.9%	98.9%	97.9%	92.8%	96.3%
Rate of NSE decisions	2.1%	1.1%	2.1%	7.2%	3.7%
Rate of Withdrawals	2.9%	5.1%	4.4%	6.0%	2.7%
Rate of Deleted	3.1%	5.1%	4.2%	5.5%	1.5%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	15	6	12	10	0
Mean FDA days for submissions that missed goal	123	127	116	109	0
Mean industry days for submissions that missed goal	114	136	132	138	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	190	205	230	238	269
Closed before RTA action	0	0	0	1	1
Number Accepted	39	81	110	175	155
Number without a RTA Review and > 15 Days since Date Received	1	4	3	2	3
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	23
Number Not Accepted	150	120	117	60	87
Rate of submissions not accepted for filing review	78.9%	58.5%	50.9%	25.3%	35.5%

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

Table 6.2.DNPMD - ODE - 510(k) Substantive Interaction 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
Eligible for SI	230	189	219	224	211
Deleted or withdrawn prior to SI	2	1	0	2	1
SI within 60 FDA days	202	181	218	218	182
SI over 60 FDA days	26	7	1	4	0
SI pending within 60 FDA days	0	0	0	0	28
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	88.6%	96.3%	99.5%	98.2%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	228	188	219	222	182
Average number of FDA days to Substantive Interaction	51.90	53.87	54.38	53.55	52.33
20th Percentile FDA days to Substantive Interaction	43	53	53	51	43
40th Percentile FDA days to Substantive Interaction	55	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	80	64	61	151	60

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	236	192	227	228	216
Non-MDUFA III Decisions	31	38	35	44	6
MDUFA III Decisions (SE/NSE)	205	154	192	180	126
MDUFA III Decisions within 90 FDA Days	199	148	190	176	126
510(k)s pending MDUFA III Decision	0	0	0	4	84
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	97.1%	96.1%	99.0%	97.8%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.90	1.88	1.91	1.93	1.62
Number with MDUFA III decision	205	154	192	180	126
Average FDA days to MDUFA III decision	83.72	83.95	80.76	79.99	70.83
20th Percentile FDA days to MDUFA III decision	86	86	81	73	30
40th Percentile FDA days to MDUFA III decision	88	88	88	87	83
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	77.48	76.73	78.21	77.56	38.19
20th Percentile Industry days to MDUFA III decision	8	7	9	11	0
40th Percentile Industry days to MDUFA III decision	41	44	37	41	7
60th Percentile Industry days to MDUFA III decision	84	82	89	79	30
80th Percentile Industry days to MDUFA III decision	152	159	156	151	72
Maximum Industry days to MDUFA III decision	345	291	359	529	179
Average Total days to MDUFA III decision	161.20	160.69	158.97	157.55	109.02
20th Percentile Total days to MDUFA III decision	90	90	91	90	30
40th Percentile Total days to MDUFA III decision	128	131	124	122	90
60th Percentile Total days to MDUFA III decision	174	170	177	166	116
80th Percentile Total days to MDUFA III decision	240	251	243	241	157
Maximum Total days to MDUFA III decision	435	385	508	628	269

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	236	192	227	228	216
Number with MDUFA decision	205	154	192	180	126
Number of SE decisions	187	145	187	175	122
Number of NSE decisions	18	9	5	5	4
Number of Withdrawals	13	18	10	17	3
Number deleted	13	17	24	24	1
Rate of SE decisions	91.2%	94.2%	97.4%	97.2%	96.8%
Rate of NSE decisions	8.8%	5.8%	2.6%	2.8%	3.2%
Rate of Withdrawals	5.5%	9.4%	4.4%	7.5%	1.4%
Rate of Deleted	5.5%	8.9%	10.6%	10.5%	0.5%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	6	6	2	4	0
Mean FDA days for submissions that missed goal	105	133	134	99	0
Mean industry days for submissions that missed goal	122	152	260	265	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	523	665	669	581	675
Closed before RTA action	0	1	3	3	0
Number Accepted	181	313	395	415	485
Number without a RTA Review and > 15 Days since Date Received	0	3	0	0	2
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	45
Number Not Accepted	342	348	271	163	143
Rate of submissions not accepted for filing review	65.4%	52.4%	40.7%	28.2%	22.7%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	655	654	656	570	608
Deleted or withdrawn prior to SI	3	1	0	1	0
SI within 60 FDA days	623	636	638	560	523
SI over 60 FDA days	29	15	18	9	17
SI pending within 60 FDA days	0	0	0	0	68
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	2	0	0	0
Current SI Performance Percent within 60 FDA days	95.6%	97.4%	97.3%	98.4%	96.9%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	652	651	656	569	540
Average number of FDA days to Substantive Interaction	47.88	48.80	48.89	48.89	49.21
20th Percentile FDA days to Substantive Interaction	30	29	34	34	35
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 - ODE - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	656	654	656	570	608
Non-MDUFA III Decisions	73	50	62	58	23
MDUFA III Decisions (SE/NSE)	583	604	594	511	373
MDUFA III Decisions within 90 FDA Days	579	602	593	506	370
510(k)s pending MDUFA III Decision	0	0	0	1	212
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	1
Current Performance Percent within 90 FDA Days	99.3%	99.7%	99.8%	99.0%	98.9%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.61	1.56	1.60	1.70	1.57
Number with MDUFA III decision	583	604	594	511	373
Average FDA days to MDUFA III decision	69.88	68.99	69.96	71.44	67.01
20th Percentile FDA days to MDUFA III decision	49	47	51	53	43
40th Percentile FDA days to MDUFA III decision	74	73	72	77	66
60th Percentile FDA days to MDUFA III decision	85	85	85	85	84
80th Percentile FDA days to MDUFA III decision	88	88	88	88	88
Maximum FDA days to MDUFA III decision	100	94	106	130	97
Average Industry days to MDUFA III decision	40.51	38.57	41.27	55.53	30.24
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	2	0	0	13	0
60th Percentile Industry days to MDUFA III decision	30	23	25	48	23
80th Percentile Industry days to MDUFA III decision	75	78	79	126	54
Maximum Industry days to MDUFA III decision	430	264	354	360	180
Average Total days to MDUFA III decision	110.38	107.56	111.24	126.97	97.24
20th Percentile Total days to MDUFA III decision	52	50	53	58	48
40th Percentile Total days to MDUFA III decision	85	84	86	90	77
60th Percentile Total days to MDUFA III decision	110	105	105	130	99
80th Percentile Total days to MDUFA III decision	163	162	163	208	136
Maximum Total days to MDUFA III decision	520	352	443	461	270

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	656	654	656	570	608
Number with MDUFA decision	583	604	594	511	373
Number of SE decisions	564	596	582	499	364
Number of NSE decisions	19	8	12	12	9
Number of Withdrawals	37	26	36	26	10
Number deleted	35	24	26	32	12
Rate of SE decisions	96.7%	98.7%	98.0%	97.7%	97.6%
Rate of NSE decisions	3.3%	1.3%	2.0%	2.3%	2.4%
Rate of Withdrawals	5.6%	4.0%	5.5%	4.6%	1.6%
Rate of Deleted	5.3%	3.7%	4.0%	5.6%	2.0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4	2	1	5	3
Mean FDA days for submissions that missed goal	97	93	106	109	95
Mean industry days for submissions that missed goal	104	53	115	183	72

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	118	142	142	136	139
Closed before RTA action	0	0	1	0	0
Number Accepted	59	75	79	104	106
Number without a RTA Review and > 15 Days since Date Received	5	2	2	1	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	5
Number Not Accepted	54	65	60	31	28
Rate of submissions not accepted for filing review	45.8%	45.8%	42.6%	22.8%	20.9%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	139	137	138	134	125
Deleted or withdrawn prior to SI	0	1	0	0	1
SI within 60 FDA days	134	135	136	132	108
SI over 60 FDA days	5	1	2	2	0
SI pending within 60 FDA days	0	0	0	0	16
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	96.4%	99.3%	98.6%	98.5%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	139	136	138	134	108
Average number of FDA days to Substantive Interaction	48.74	51.29	52.49	48.72	50.19
20th Percentile FDA days to Substantive Interaction	43	46	49	44	46
40th Percentile FDA days to Substantive Interaction	49	53	56	49	50
60th Percentile FDA days to Substantive Interaction	54	57	58	53	54
80th Percentile FDA days to Substantive Interaction	57	59	60	59	58
Maximum FDA days to Substantive Interaction	88	62	64	64	60

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	146	139	141	135	127
Non-MDUFA III Decisions	20	26	21	16	6
MDUFA III Decisions (SE/NSE)	126	113	120	118	74
MDUFA III Decisions within 90 FDA Days	123	113	120	118	74
510(k)s pending MDUFA III Decision	0	0	0	1	47
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	97.6%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.85	1.81	1.73	1.81	1.61
Number with MDUFA III decision	126	113	120	118	74
Average FDA days to MDUFA III decision	75.45	78.47	76.00	75.96	70.15
20th Percentile FDA days to MDUFA III decision	56	60	57	57	50
40th Percentile FDA days to MDUFA III decision	84	87	87	86	68
60th Percentile FDA days to MDUFA III decision	88	89	88	88	84
80th Percentile FDA days to MDUFA III decision	90	90	90	90	88
Maximum FDA days to MDUFA III decision	91	90	90	90	90
Average Industry days to MDUFA III decision	62.85	57.07	55.85	54.93	33.95
20th Percentile Industry days to MDUFA III decision	0	0	0	2	0
40th Percentile Industry days to MDUFA III decision	21	21	14	22	6
60th Percentile Industry days to MDUFA III decision	60	43	44	56	24
80th Percentile Industry days to MDUFA III decision	160	115	131	99	70
Maximum Industry days to MDUFA III decision	250	333	180	189	178
Average Total days to MDUFA III decision	138.30	135.54	131.85	130.89	104.09
20th Percentile Total days to MDUFA III decision	70	80	62	65	53
40th Percentile Total days to MDUFA III decision	105	105	94	105	83
60th Percentile Total days to MDUFA III decision	135	132	131	139	108
80th Percentile Total days to MDUFA III decision	230	204	219	183	149
Maximum Total days to MDUFA III decision	332	423	270	279	267

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	146	139	141	135	127
Number with MDUFA decision	126	113	120	118	74
Number of SE decisions	121	106	109	113	71
Number of NSE decisions	5	7	11	5	3
Number of Withdrawals	8	7	10	6	5
Number deleted	11	17	10	9	1
Rate of SE decisions	96.0%	93.8%	90.8%	95.8%	95.9%
Rate of NSE decisions	4.0%	6.2%	9.2%	4.2%	4.1%
Rate of Withdrawals	5.5%	5.0%	7.1%	4.4%	3.9%
Rate of Deleted	7.5%	12.2%	7.1%	6.7%	0.8%

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	210	275	270	272	323
Closed before RTA action	0	0	7	3	1
Number Accepted	66	145	185	210	237
Number without a RTA Review and > 15 Days since Date Received	0	7	2	1	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	24
Number Not Accepted	144	123	76	58	61
Rate of submissions not accepted for filing review	68.6%	44.7%	28.9%	21.6%	20.5%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	265	267	248	259	279
Deleted or withdrawn prior to SI	1	3	1	1	0
SI within 60 FDA days	253	256	245	256	238
SI over 60 FDA days	9	7	2	2	0
SI pending within 60 FDA days	0	0	0	0	40
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	95.8%	97.0%	99.2%	99.2%	99.6%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	262	263	247	258	238
Average number of FDA days to Substantive Interaction	48.13	48.81	48.35	49.88	48.95
20th Percentile FDA days to Substantive Interaction	37	37	37	42	41
40th Percentile FDA days to Substantive Interaction	49	50	47	51	49
60th Percentile FDA days to Substantive Interaction	56	56	56	57	56
80th Percentile FDA days to Substantive Interaction	58	59	59	59	59
Maximum FDA days to Substantive Interaction	73	100	87	89	60

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	278	274	252	264	286
Non-MDUFA III Decisions	42	37	26	39	10
MDUFA III Decisions (SE/NSE)	236	237	226	220	124
MDUFA III Decisions within 90 FDA Days	236	237	223	218	124
510(k)s pending MDUFA III Decision	0	0	0	5	152
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	100%	100%	98.7%	99.1%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.87	1.78	1.76	1.70	1.49
Number with MDUFA III decision	236	237	226	220	124
Average FDA days to MDUFA III decision	71.43	71.07	73.86	71.88	63.44
20th Percentile FDA days to MDUFA III decision	54	52	55	46	30
40th Percentile FDA days to MDUFA III decision	80	77	82	82	59
60th Percentile FDA days to MDUFA III decision	86	86	87	87	78
80th Percentile FDA days to MDUFA III decision	88	88	89	89	87
Maximum FDA days to MDUFA III decision	90	90	136	100	90
Average Industry days to MDUFA III decision	73.14	58.12	81.35	72.44	38.68
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	32	22	26	13	0
60th Percentile Industry days to MDUFA III decision	74	55	95	77	21
80th Percentile Industry days to MDUFA III decision	152	112	170	164	70
Maximum Industry days to MDUFA III decision	416	236	540	368	236
Average Total days to MDUFA III decision	144.56	129.19	155.21	144.32	102.11
20th Percentile Total days to MDUFA III decision	59	60	66	51	39
40th Percentile Total days to MDUFA III decision	112	103	104	92	60
60th Percentile Total days to MDUFA III decision	154	137	181	159	95
80th Percentile Total days to MDUFA III decision	239	199	251	251	147
Maximum Total days to MDUFA III decision	506	316	676	455	326

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	278	274	252	264	286
Number with MDUFA decision	236	237	226	220	124
Number of SE decisions	221	232	219	211	122
Number of NSE decisions	15	5	7	9	2
Number of Withdrawals	18	11	11	17	5
Number deleted	22	22	14	22	5
Rate of SE decisions	93.6%	97.9%	96.9%	95.9%	98.4%
Rate of NSE decisions	6.4%	2.1%	3.1%	4.1%	1.6%
Rate of Withdrawals	6.5%	4.0%	4.4%	6.4%	1.7%
Rate of Deleted	7.9%	8.0%	5.6%	8.3%	1.7%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	3	2	0
Mean FDA days for submissions that missed goal	0	0	119	100	0
Mean industry days for submissions that missed goal	0	0	344	67	0

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	372	483	493	469	514
Closed before RTA action	0	0	1	2	1
Number Accepted	136	212	308	350	345
Number without a RTA Review and > 15 Days since Date Received	3	11	5	2	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	29
Number Not Accepted	233	260	179	115	139
Rate of submissions not accepted for filing review	62.6%	53.8%	36.4%	24.6%	28.7%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	473	458	473	449	421
Deleted or withdrawn prior to SI	3	0	0	1	2
SI within 60 FDA days	424	421	446	417	342
SI over 60 FDA days	46	37	27	30	14
SI pending within 60 FDA days	0	0	0	0	62
SI pending over 60 FDA days	0	0	0	0	0
510(k)s NSE without SI	0	0	0	1	1
Current SI Performance Percent within 60 FDA days	90.2%	91.9%	94.3%	93.1%	95.8%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	470	458	473	447	356
Average number of FDA days to Substantive Interaction	45.29	50.54	51.19	50.65	49.26
20th Percentile FDA days to Substantive Interaction	28	37	42	42	30
40th Percentile FDA days to Substantive Interaction	44	53	55	54	52
60th Percentile FDA days to Substantive Interaction	56	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 - ODE - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	481	465	483	453	427
Non-MDUFA III Decisions	86	81	82	63	26
MDUFA III Decisions (SE/NSE)	395	384	401	386	267
MDUFA III Decisions within 90 FDA Days	385	377	391	375	267
510(k)s pending MDUFA III Decision	0	0	0	4	134
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	97.5%	98.2%	97.5%	97.2%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.77	1.74	1.73	1.72	1.44
Number with MDUFA III decision	395	384	401	386	267
Average FDA days to MDUFA III decision	69.04	72.71	73.98	72.83	63.16
20th Percentile FDA days to MDUFA III decision	43	55	54	54	30
40th Percentile FDA days to MDUFA III decision	70	79	82	82	58
60th Percentile FDA days to MDUFA III decision	85	87	87	87	83
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	60.03	59.91	65.48	57.35	31.51
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	20	17	19	21	0
60th Percentile Industry days to MDUFA III decision	44	51	60	52	13
80th Percentile Industry days to MDUFA III decision	125	123	150	119	60
Maximum Industry days to MDUFA III decision	438	408	342	354	181
Average Total days to MDUFA III decision	129.07	132.62	139.46	130.18	94.66
20th Percentile Total days to MDUFA III decision	51	61	59	61	30
40th Percentile Total days to MDUFA III decision	93	90	97	96	71
60th Percentile Total days to MDUFA III decision	128	134	145	137	90
80th Percentile Total days to MDUFA III decision	204	211	238	200	142
Maximum Total days to MDUFA III decision	691	512	432	515	269

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	481	465	483	453	427
Number with MDUFA decision	395	384	401	386	267
Number of SE decisions	379	375	391	375	262
Number of NSE decisions	16	9	10	11	5
Number of Withdrawals	43	41	35	25	18
Number deleted	38	29	44	36	5
Rate of SE decisions	95.9%	97.7%	97.5%	97.2%	98.1%
Rate of NSE decisions	4.1%	2.3%	2.5%	2.8%	1.9%
Rate of Withdrawals	8.9%	8.8%	7.2%	5.5%	4.2%
Rate of Deleted	7.9%	6.2%	9.1%	7.9%	1.2%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	10	7	10	11	0
Mean FDA days for submissions that missed goal	137	106	117	102	0
Mean industry days for submissions that missed goal	160	171	161	122	0

Table 6.1.DCTD - OIR - 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	187	195	191	174	163
Closed before RTA action	0	1	1	2	6
Number Accepted	118	127	154	140	109
Number without a RTA Review and > 15 Days since Date Received	0	1	1	2	10
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	4
Number Not Accepted	69	66	35	30	34
Rate of submissions not accepted for filing review	36.9%	34.0%	18.4%	17.4%	22.2%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	247	184	179	160	133
Deleted or withdrawn prior to SI	0	0	0	2	1
SI within 60 FDA days	247	184	177	157	125
SI over 60 FDA days	0	0	2	1	0
SI pending within 60 FDA days	0	0	0	0	7
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%	98.9%	99.4%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	247	184	179	158	125
Average number of FDA days to Substantive Interaction	41.03	42.67	43.68	48.15	46.04
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	52
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 - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	247	184	179	160	133
Non-MDUFA III Decisions	34	35	30	38	17
MDUFA III Decisions (SE/NSE)	213	149	149	120	57
MDUFA III Decisions within 90 FDA Days	212	147	148	117	57
510(k)s pending MDUFA III Decision	0	0	0	2	59
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	1	0
Current Performance Percent within 90 FDA Days	99.5%	98.7%	99.3%	96.7%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.86	1.94	1.82	2.04	1.68
Number with MDUFA III decision	213	149	149	120	57
Average FDA days to MDUFA III decision	64.94	67.23	68.53	81.19	65.35
20th Percentile FDA days to MDUFA III decision	34	35	32	74	29
40th Percentile FDA days to MDUFA III decision	58	59	68	87	60
60th Percentile FDA days to MDUFA III decision	84	85	85	88	87
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	77.21	104.88	59.09
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	22
60th Percentile Industry days to MDUFA III decision	69	75	82	143	54
80th Percentile Industry days to MDUFA III decision	166	176	161	180	133
Maximum Industry days to MDUFA III decision	489	469	477	339	198
Average Total days to MDUFA III decision	148.51	153.19	145.74	186.08	124.44
20th Percentile Total days to MDUFA III decision	35	35	32	90	29
40th Percentile Total days to MDUFA III decision	87	84	85	144	91
60th Percentile Total days to MDUFA III decision	148	161	164	232	141
80th Percentile Total days to MDUFA III decision	245	264	244	269	218
Maximum Total days to MDUFA III decision	579	556	564	428	286

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	247	184	179	160	133
Number with MDUFA decision	213	149	149	120	57
Number of SE decisions	207	148	144	109	55
Number of NSE decisions	6	1	5	11	2
Number of Withdrawals	17	20	13	16	10
Number deleted	17	15	17	21	4
Rate of SE decisions	97.2%	99.3%	96.6%	90.8%	96.5%
Rate of NSE decisions	2.8%	0.7%	3.4%	9.2%	3.5%
Rate of Withdrawals	6.9%	10.9%	7.3%	10.0%	7.5%
Rate of Deleted	6.9%	8.2%	9.5%	13.1%	3.0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	2	1	3	0
Mean FDA days for submissions that missed goal	99	121	232	177	0
Mean industry days for submissions that missed goal	193	257	330	136	0

Table 6.1.DIHD - OIR - 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	55	72	60	64	71
Closed before RTA action	0	0	0	0	3
Number Accepted	38	57	50	59	61
Number without a RTA Review and > 15 Days since Date Received	3	0	1	0	0
Number without a RTA Review and <= 15 Days since Date Received	0	0	0	0	2
Number Not Accepted	14	15	9	5	5
Rate of submissions not accepted for filing review	25.5%	20.8%	15.0%	7.8%	7.6%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	69	65	57	62	64
Deleted or withdrawn prior to SI	0	0	1	0	2
SI within 60 FDA days	68	65	56	61	48
SI over 60 FDA days	1	0	0	1	1
SI pending within 60 FDA days	0	0	0	0	13
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	98.6%	100%	100%	98.4%	98.0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	69	65	56	62	49
Average number of FDA days to Substantive Interaction	47.62	50.98	52.45	51.87	54.06
20th Percentile FDA days to Substantive Interaction	41	46	49	49	55
40th Percentile FDA days to Substantive Interaction	50	52	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 - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	69	65	57	62	64
Non-MDUFA III Decisions	22	21	12	8	6
MDUFA III Decisions (SE/NSE)	47	44	45	54	25
MDUFA III Decisions within 90 FDA Days	47	43	45	53	25
510(k)s pending MDUFA III Decision	0	0	0	0	33
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	100%	97.7%	100%	98.1%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.96	1.86	1.96	2.00	1.64
Number with MDUFA III decision	47	44	45	54	25
Average FDA days to MDUFA III decision	71.62	79.45	75.76	76.72	75.36
20th Percentile FDA days to MDUFA III decision	50	70	52	67	59
40th Percentile FDA days to MDUFA III decision	77	88	88	87	84
60th Percentile FDA days to MDUFA III decision	86	89	89	89	89
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	110.67	86.92
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	3
60th Percentile Industry days to MDUFA III decision	157	154	169	165	164
80th Percentile Industry days to MDUFA III decision	177	176	177	187	176
Maximum Industry days to MDUFA III decision	329	325	355	357	209
Average Total days to MDUFA III decision	187.02	186.68	203.76	187.39	162.28
20th Percentile Total days to MDUFA III decision	91	118	66	90	72
40th Percentile Total days to MDUFA III decision	151	143	212	146	92
60th Percentile Total days to MDUFA III decision	236	237	258	249	248
80th Percentile Total days to MDUFA III decision	264	266	267	277	264
Maximum Total days to MDUFA III decision	417	414	442	444	299

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	69	65	57	62	64
Number with MDUFA decision	47	44	45	54	25
Number of SE decisions	43	37	45	54	25
Number of NSE decisions	4	7	0	0	0
Number of Withdrawals	6	8	6	2	3
Number deleted	14	13	6	6	3
Rate of SE decisions	91.5%	84.1%	100%	100%	100%
Rate of NSE decisions	8.5%	15.9%	0%	0%	0%
Rate of Withdrawals	8.7%	12.3%	10.5%	3.2%	4.7%
Rate of Deleted	20.3%	20.0%	10.5%	9.7%	4.7%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	1	0	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

Table 6.1.DMD - OIR - 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	84	69	79	97
Closed before RTA action	0	0	1	1	3
Number Accepted	55	80	66	76	86
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	4
Number Not Accepted	4	3	2	2	3
Rate of submissions not accepted for filing review	6.8%	3.6%	2.9%	2.6%	3.3%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	80	83	67	76	87
Deleted or withdrawn prior to SI	0	0	0	0	0
SI within 60 FDA days	79	82	67	76	75
SI over 60 FDA days	1	1	0	0	0
SI pending within 60 FDA days	0	0	0	0	12
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	98.8%	98.8%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	80	83	67	76	75
Average number of FDA days to Substantive Interaction	43.11	47.63	48.34	49.18	51.51
20th Percentile FDA days to Substantive Interaction	28	29	31	29	47
40th Percentile FDA days to Substantive Interaction	39	51	55	54	55
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 - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	80	83	67	76	87
Non-MDUFA III Decisions	9	7	7	7	1
MDUFA III Decisions (SE/NSE)	71	76	60	69	66
MDUFA III Decisions within 90 FDA Days	71	76	60	69	66
510(k)s pending MDUFA III Decision	0	0	0	0	20
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 - OIR - 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.31	1.46	1.50	1.48	1.21
Number with MDUFA III decision	71	76	60	69	66
Average FDA days to MDUFA III decision	58.48	65.83	67.03	72.68	75.11
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	21.20
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	18
Maximum Industry days to MDUFA III decision	180	349	358	181	179
Average Total days to MDUFA III decision	90.03	118.28	127.02	130.04	96.30
20th Percentile Total days to MDUFA III decision	29	36	35	47	60
40th Percentile Total days to MDUFA III decision	58	85	86	87	87
60th Percentile Total days to MDUFA III decision	81	97	120	144	89
80th Percentile Total days to MDUFA III decision	133	213	231	243	92
Maximum Total days to MDUFA III decision	267	434	447	270	269

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	80	83	67	76	87
Number with MDUFA decision	71	76	60	69	66
Number of SE decisions	71	73	58	67	66
Number of NSE decisions	0	3	2	2	0
Number of Withdrawals	6	5	6	4	0
Number deleted	3	2	1	3	0
Rate of SE decisions	100%	96.1%	96.7%	97.1%	100%
Rate of NSE decisions	0%	3.9%	3.3%	2.9%	0%
Rate of Withdrawals	7.5%	6.0%	9.0%	5.3%	0%
Rate of Deleted	3.8%	2.4%	1.5%	3.9%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	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 6.1.DMGP - OIR - 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	17	9	5	4	13
Closed before RTA action	0	0	0	0	0
Number Accepted	14	9	4	4	10
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	1
Number Not Accepted	3	0	1	0	0
Rate of submissions not accepted for filing review	17.6%	0%	20.0%	0%	0%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	18	9	5	4	12
Deleted or withdrawn prior to SI	0	0	0	0	1
SI within 60 FDA days	18	9	5	4	10
SI over 60 FDA days	0	0	0	0	0
SI pending within 60 FDA days	0	0	0	0	1
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 - OIR - 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	18	9	5	4	10
Average number of FDA days to Substantive Interaction	51.72	45.78	44.60	43.00	48.00
20th Percentile FDA days to Substantive Interaction	44	29	30	33	30
40th Percentile FDA days to Substantive Interaction	55	47	41	39	57
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 - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	18	9	5	4	12
Non-MDUFA III Decisions	4	2	4	1	1
MDUFA III Decisions (SE/NSE)	14	7	1	3	4
MDUFA III Decisions within 90 FDA Days	14	7	1	3	4
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	100%	100%	100%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	2.36	1.57	3.00	2.00	1.25
Number with MDUFA III decision	14	7	1	3	4
Average FDA days to MDUFA III decision	83.71	78.14	90.00	69.00	38.25
20th Percentile FDA days to MDUFA III decision	81	79	90	53	17
40th Percentile FDA days to MDUFA III decision	88	88	90	76	20
60th Percentile FDA days to MDUFA III decision	88	89	90	88	27
80th Percentile FDA days to MDUFA III decision	89	90	90	89	54
Maximum FDA days to MDUFA III decision	90	90	90	90	89
Average Industry days to MDUFA III decision	151.93	81.71	164.00	177.33	41
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	0
80th Percentile Industry days to MDUFA III decision	233	177	164	283	65
Maximum Industry days to MDUFA III decision	320	179	164	352	163
Average Total days to MDUFA III decision	235.64	159.86	254.00	246.33	79.00
20th Percentile Total days to MDUFA III decision	103	80	254	125	17
40th Percentile Total days to MDUFA III decision	255	106	254	220	20
60th Percentile Total days to MDUFA III decision	263	211	254	303	27
80th Percentile Total days to MDUFA III decision	317	266	254	372	119
Maximum Total days to MDUFA III decision	408	267	254	442	252

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	18	9	5	4	12
Number with MDUFA decision	14	7	1	3	4
Number of SE decisions	11	6	1	2	4
Number of NSE decisions	3	1	0	1	0
Number of Withdrawals	3	2	4	1	1
Number deleted	1	0	0	0	0
Rate of SE decisions	78.6%	85.7%	100%	66.7%	100%
Rate of NSE decisions	21.4%	14.3%	0%	33.3%	0%
Rate of Withdrawals	16.7%	22.2%	80.0%	25.0%	8.3%
Rate of Deleted	5.6%	0%	0%	0%	0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	0	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 6.1.DRH - OIR - 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	256	365	329	363	400
Closed before RTA action	0	0	0	1	3
Number Accepted	151	274	268	306	319
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	28
Number Not Accepted	90	86	60	55	50
Rate of submissions not accepted for filing review	35.2%	23.6%	18.2%	15.2%	13.6%

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	349	356	325	359	359
Deleted or withdrawn prior to SI	1	0	0	1	0
SI within 60 FDA days	307	342	323	358	322
SI over 60 FDA days	41	14	2	0	1
SI pending within 60 FDA days	0	0	0	0	36
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	88.2%	96.1%	99.4%	100%	99.7%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	348	356	325	358	323
Average number of FDA days to Substantive Interaction	47.42	45.76	44.40	43.04	44.05
20th Percentile FDA days to Substantive Interaction	31	30	29	28	28
40th Percentile FDA days to Substantive Interaction	44	44	44	43	44
60th Percentile FDA days to Substantive Interaction	56	54	50	50	51
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 - OIR - 510(k) MDUFA Decision Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	403	393	357	400	393
Non-MDUFA III Decisions	17	9	10	13	5
MDUFA III Decisions (SE/NSE)	386	384	347	384	271
MDUFA III Decisions within 90 FDA Days	380	372	346	384	271
510(k)s pending MDUFA III Decision	0	0	0	3	117
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	98.4%	96.9%	99.7%	100%	100%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.61	1.65	1.61	1.65	1.54
Number with MDUFA III decision	386	384	347	384	271
Average FDA days to MDUFA III decision	61.93	63.17	58.87	56.86	53.76
20th Percentile FDA days to MDUFA III decision	35	31	29	28	28
40th Percentile FDA days to MDUFA III decision	56	58	56	53	42
60th Percentile FDA days to MDUFA III decision	77	79	72	70	68
80th Percentile FDA days to MDUFA III decision	87	88	81	81	80
Maximum FDA days to MDUFA III decision	121	137	91	90	89
Average Industry days to MDUFA III decision	35.89	36.05	38.25	36.07	24.13
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	20	27	24	27	13
80th Percentile Industry days to MDUFA III decision	60	64	67	62	46
Maximum Industry days to MDUFA III decision	358	346	319	348	225
Average Total days to MDUFA III decision	97.82	99.22	97.12	92.93	77.89
20th Percentile Total days to MDUFA III decision	37	32	30	29	28
40th Percentile Total days to MDUFA III decision	71	77	60	62	51
60th Percentile Total days to MDUFA III decision	90	102	96	98	84
80th Percentile Total days to MDUFA III decision	137	141	146	136	124
Maximum Total days to MDUFA III decision	466	428	406	438	312

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	403	393	357	400	393
Number with MDUFA decision	386	384	347	384	271
Number of SE decisions	377	377	335	380	269
Number of NSE decisions	9	7	12	4	2
Number of Withdrawals	10	2	3	6	2
Number deleted	7	6	7	7	2
Rate of SE decisions	97.7%	98.2%	96.5%	99.0%	99.3%
Rate of NSE decisions	2.3%	1.8%	3.5%	1.0%	0.7%
Rate of Withdrawals	2.5%	0.5%	0.8%	1.5%	0.5%
Rate of Deleted	1.7%	1.5%	2.0%	1.8%	0.5%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	6	12	1	0	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

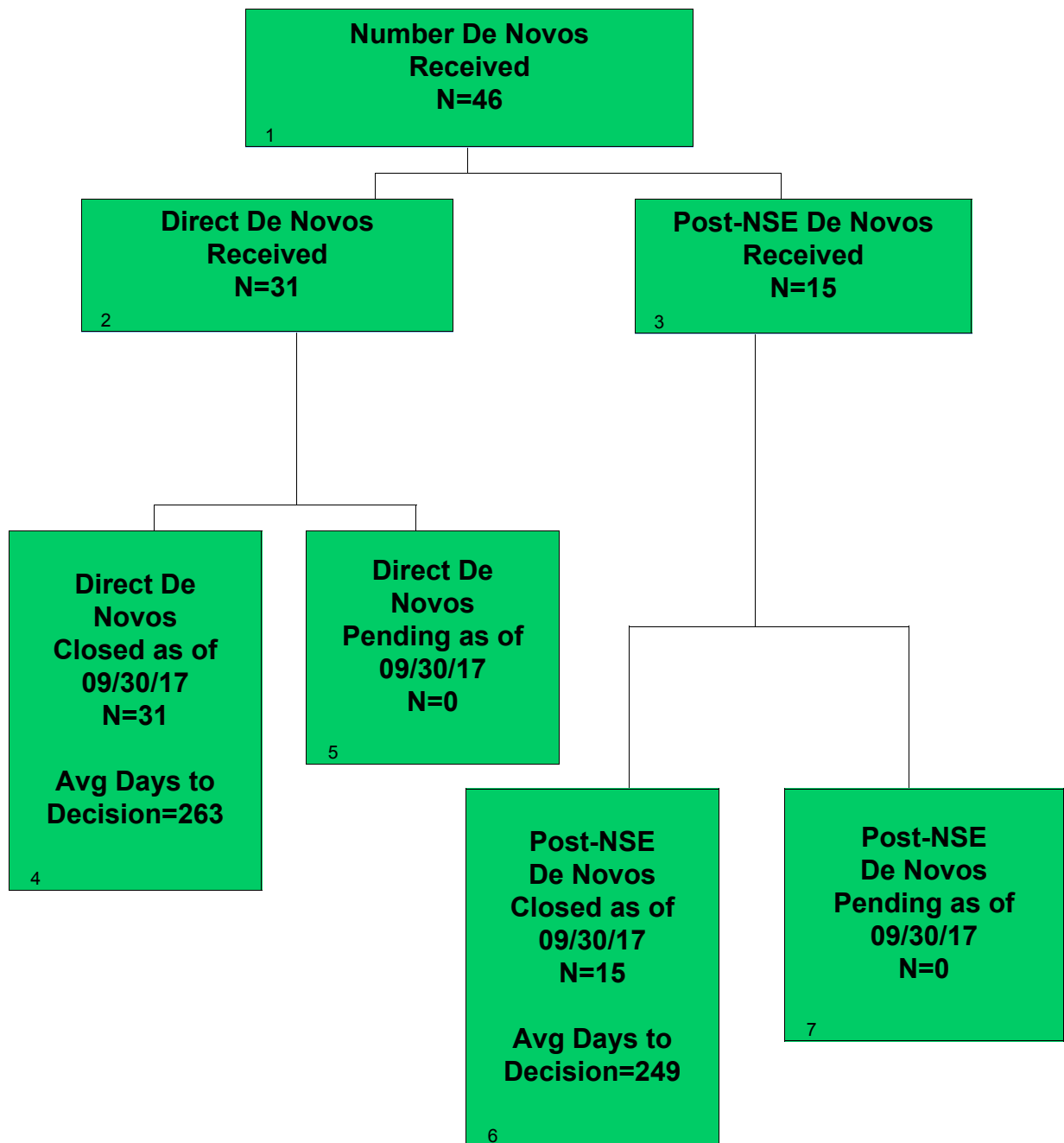
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	3,866	3,610	3,569	3,463	3,385
Number of Traditional submissions	3,035	2,903	2,921	2,806	2,774
Number of Special submissions	577	524	488	489	450
Number of Abbreviated submissions	126	99	75	88	74
Average number of days to Accept / Refuse to Accept	10.76	10.11	9.87	9.99	10.05
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	3,463	3,385
Currently Under Review	0	0	0	44	1,347
Number with Non-MDUFA Decision	530	466	434	434	144
Number with MDUFA III Decision	3,336	3,144	3,135	2,985	1,894
Percent of cohort closed	100%	100%	100%	99%	58%
Number with MDUFA III decision after trimming the upper and lower 2%	3,190	3,004	2,989	N/A	N/A
Average Total Time to MDUFA III decision	123	125	131	N/A	N/A

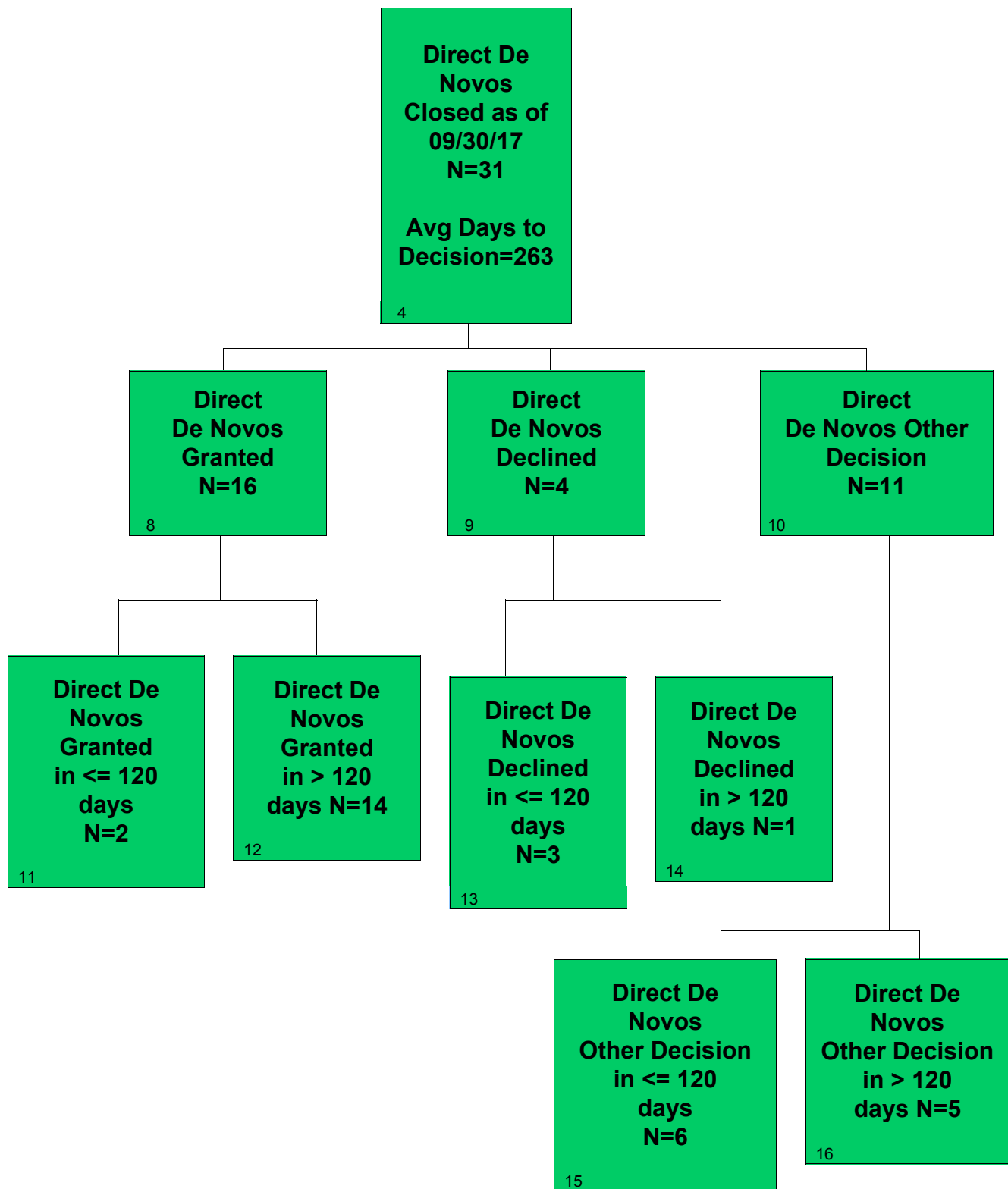
CDRH De Novos - FY 2013

As of 9/30/17



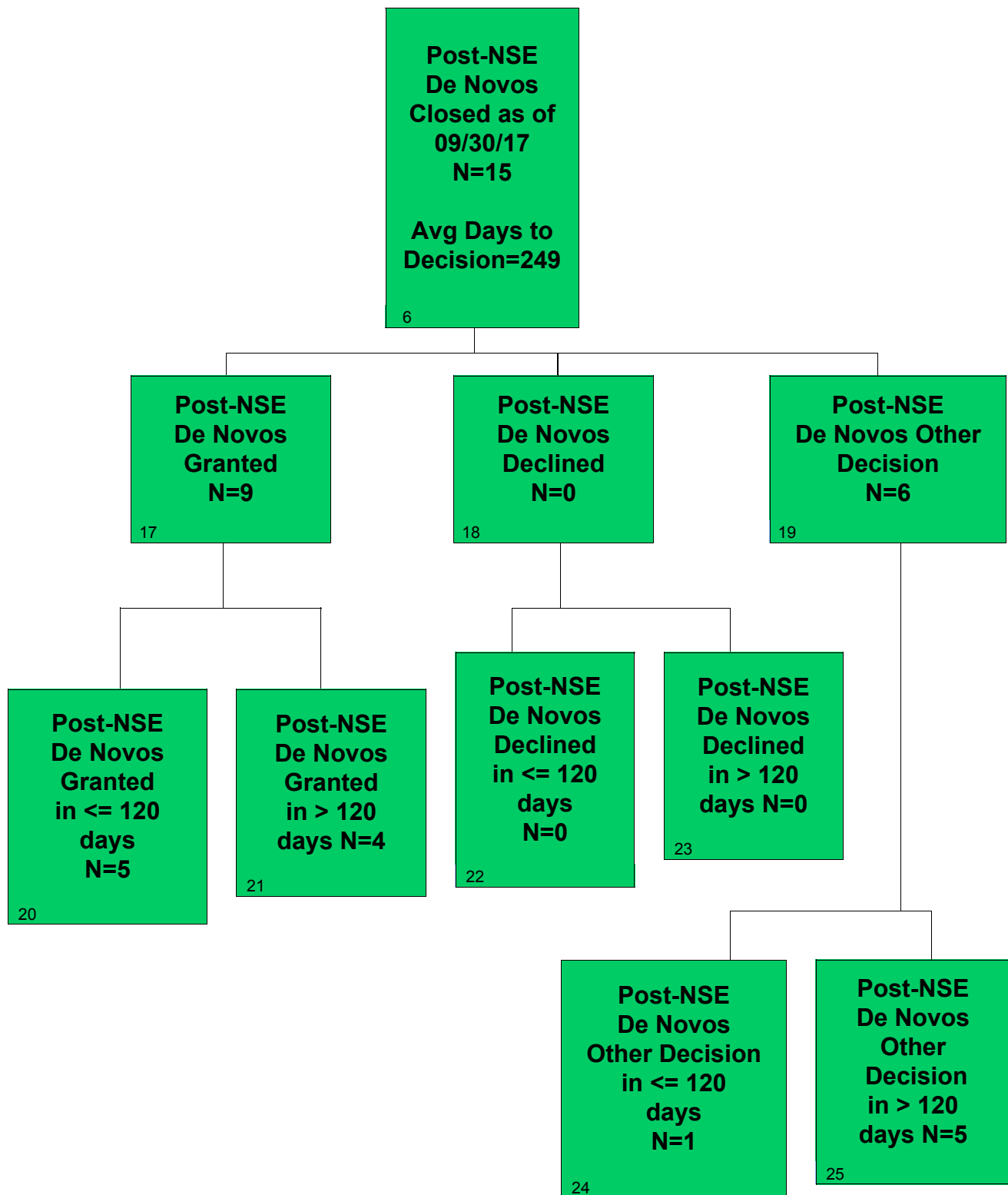
CDRH De Novos - FY 2013

As of 9/30/17



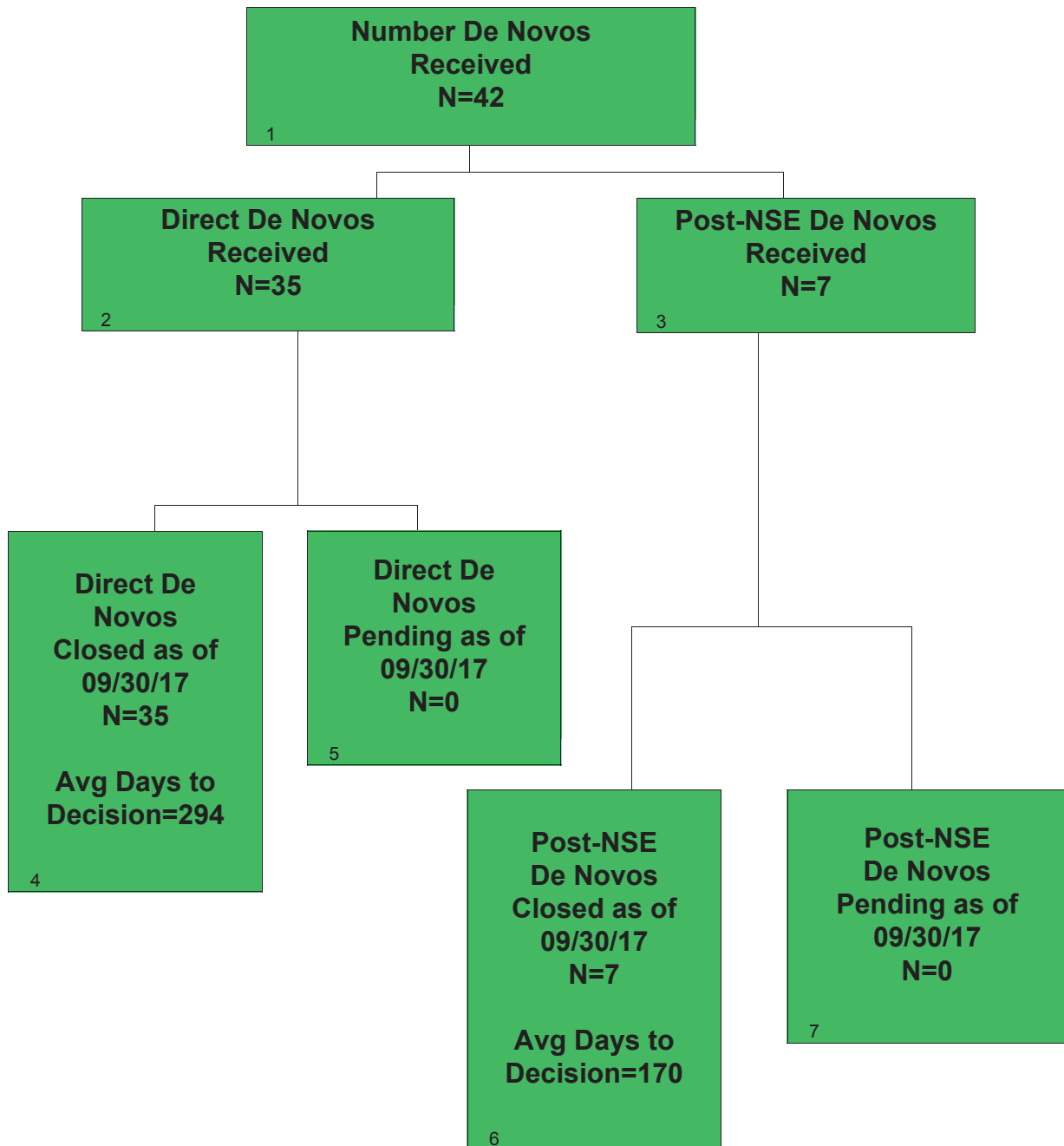
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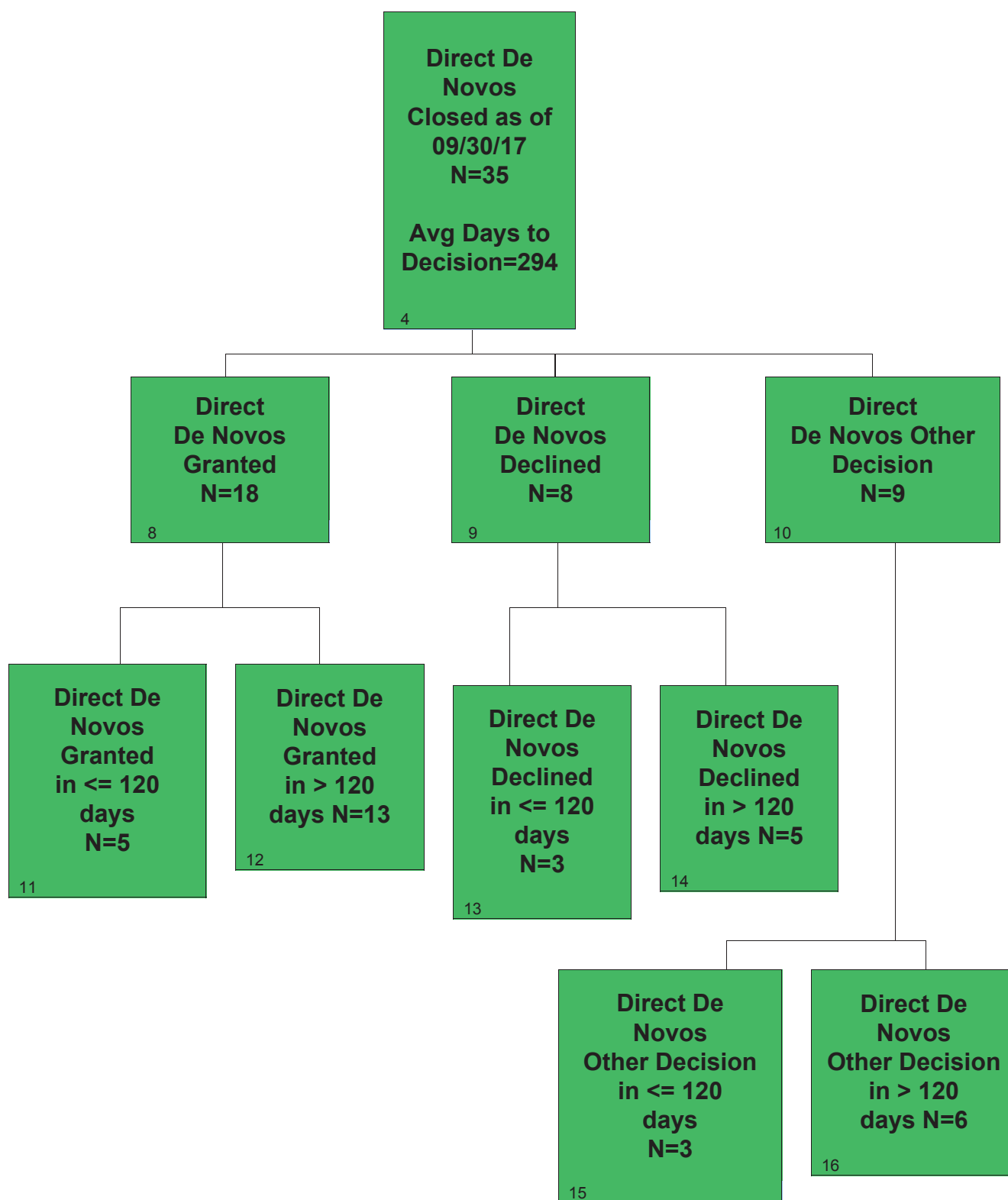
CDRH De Novos - FY 2014

As of 9/30/17



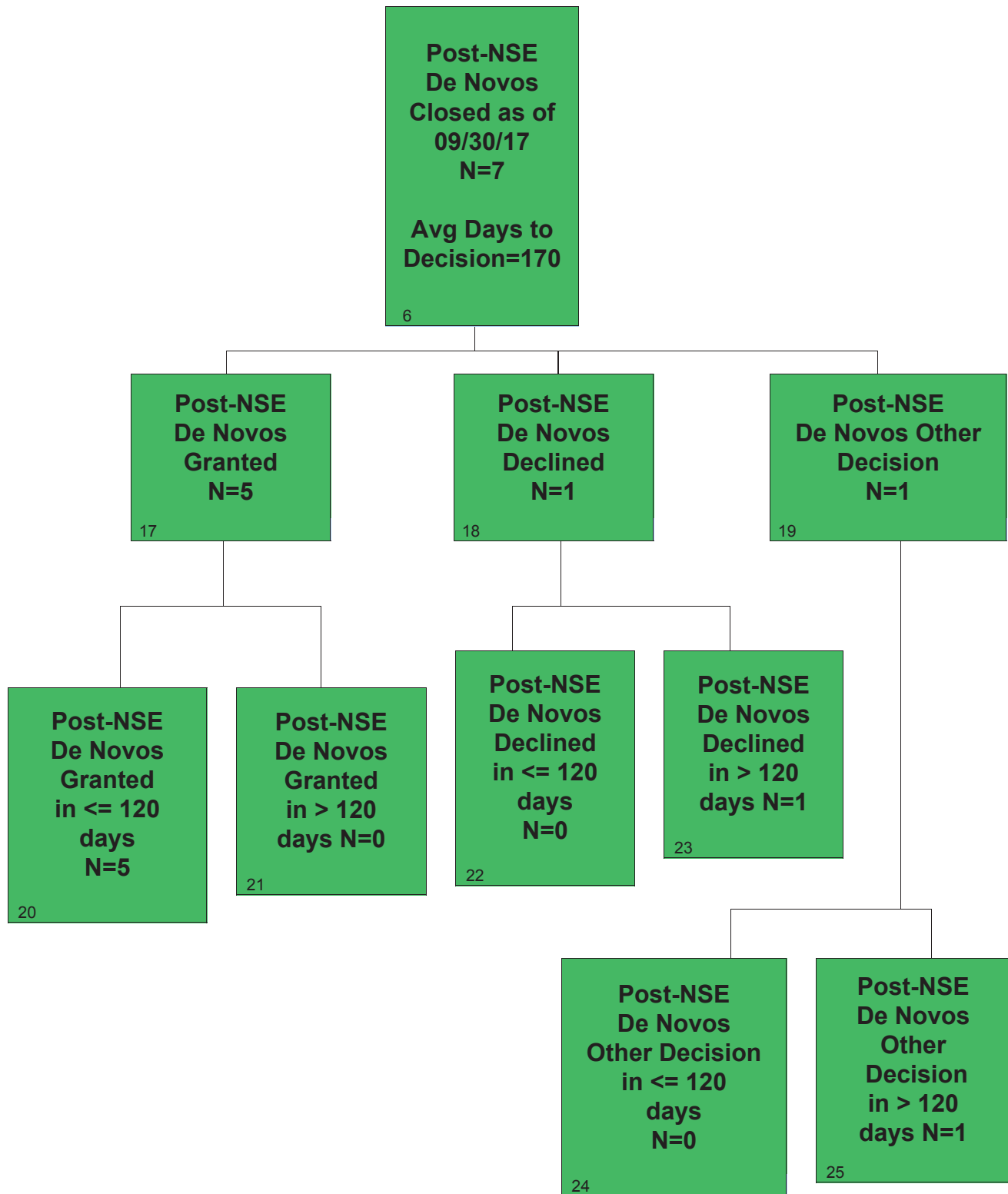
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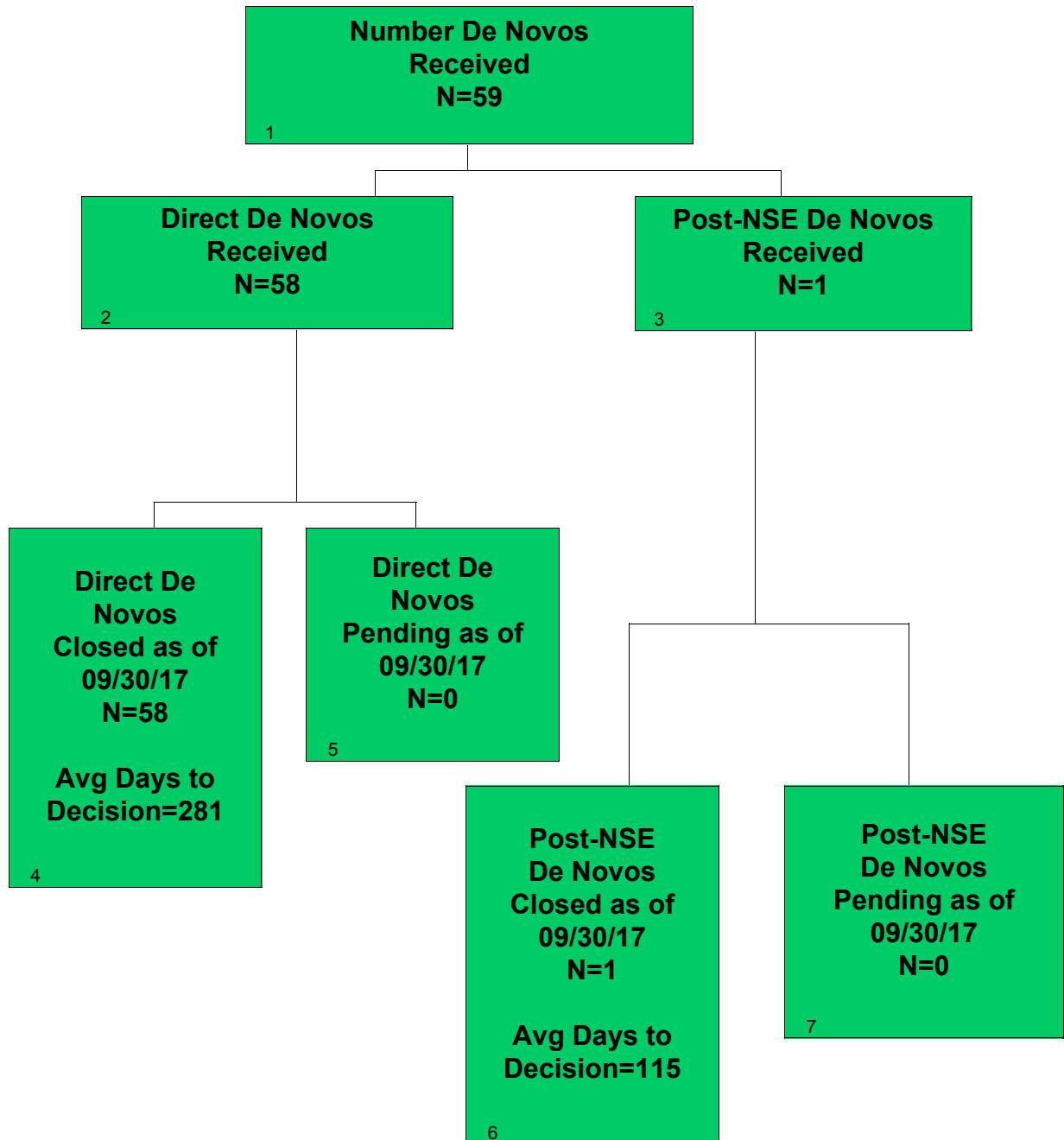
CDRH De Novos - FY 2014

As of 9/30/17



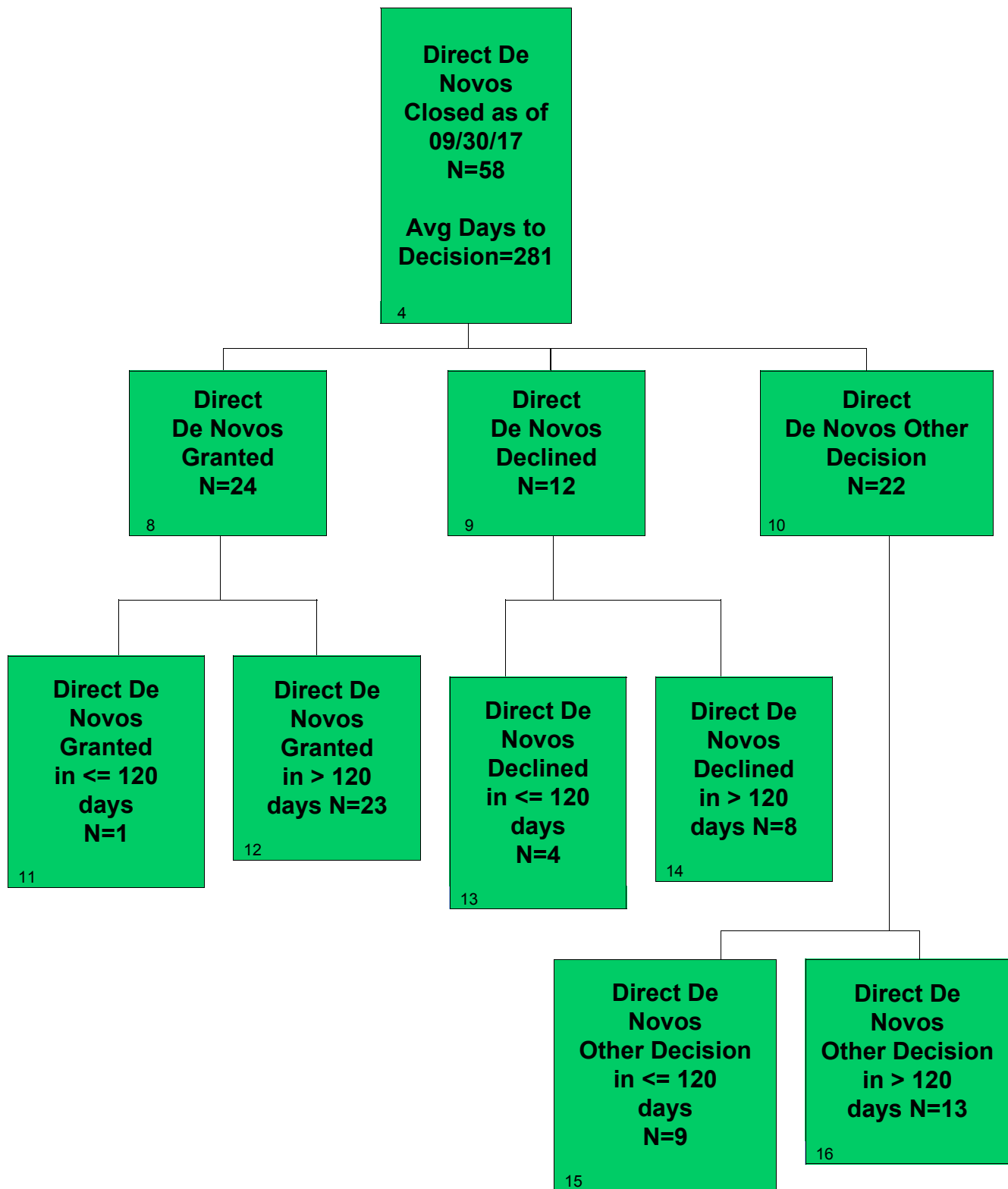
CDRH De Novos - FY 2015

As of 9/30/17



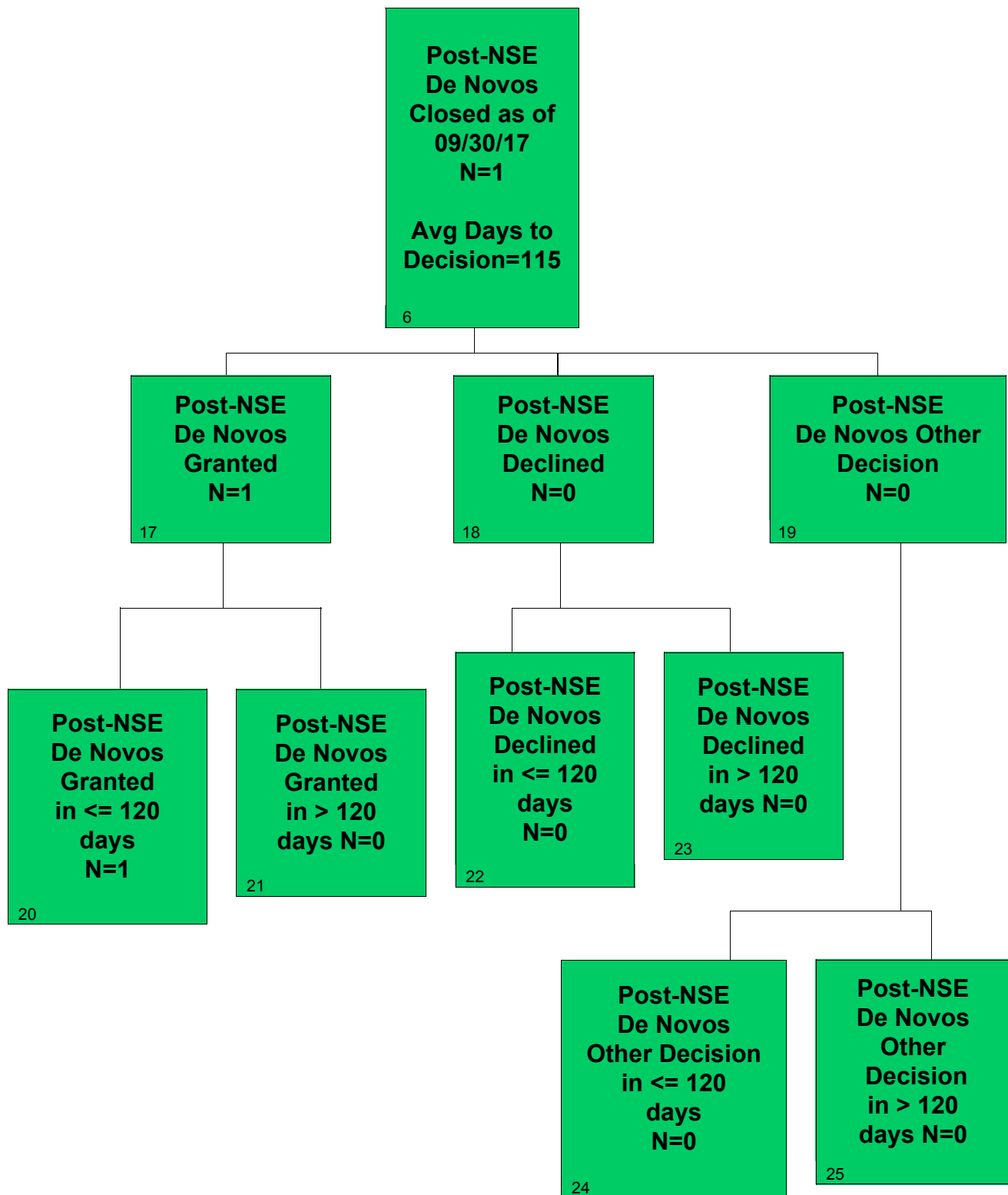
CDRH De Novos - FY 2015

As of 9/30/17



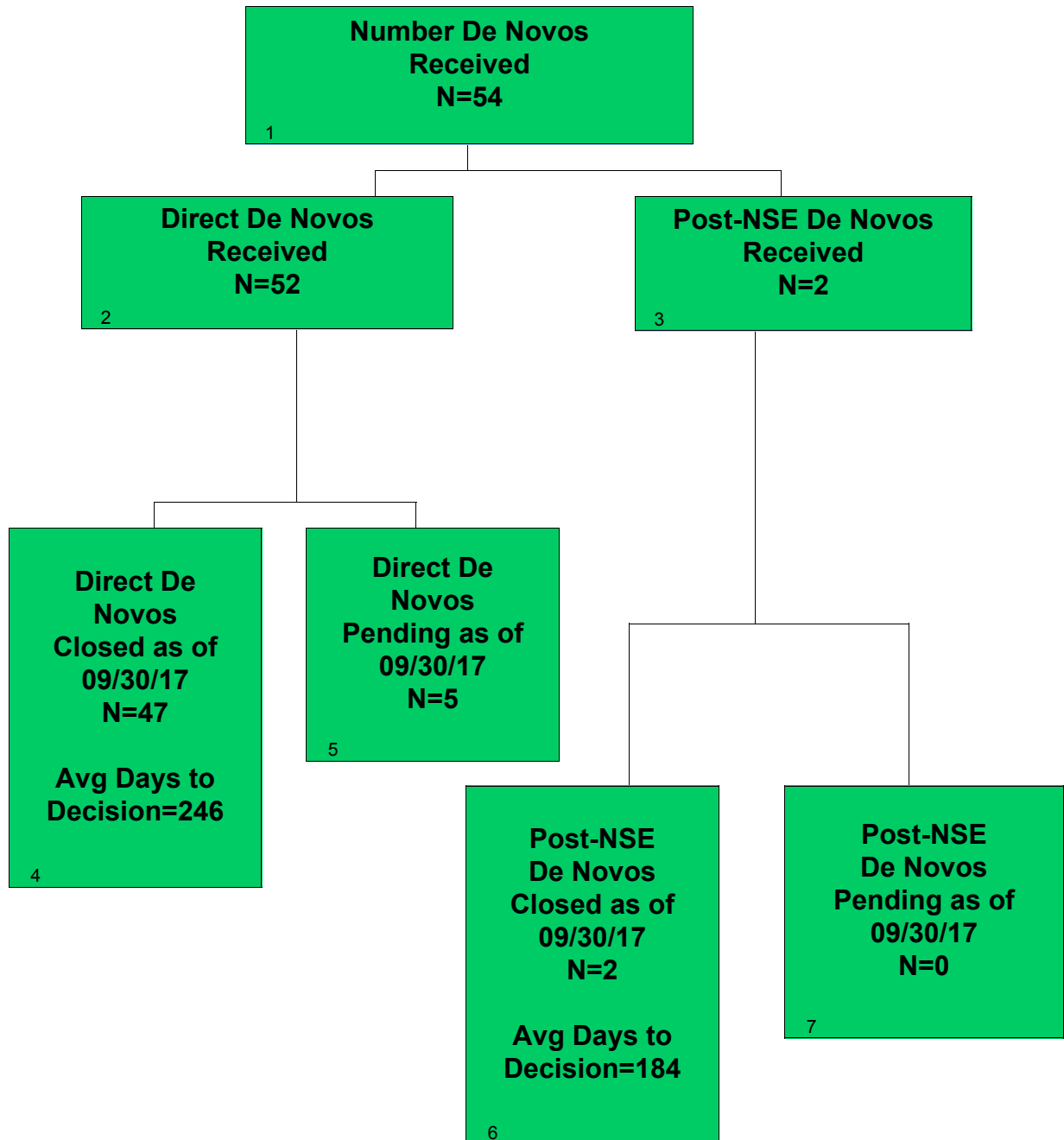
CDRH De Novos - FY 2015

As of 9/30/17



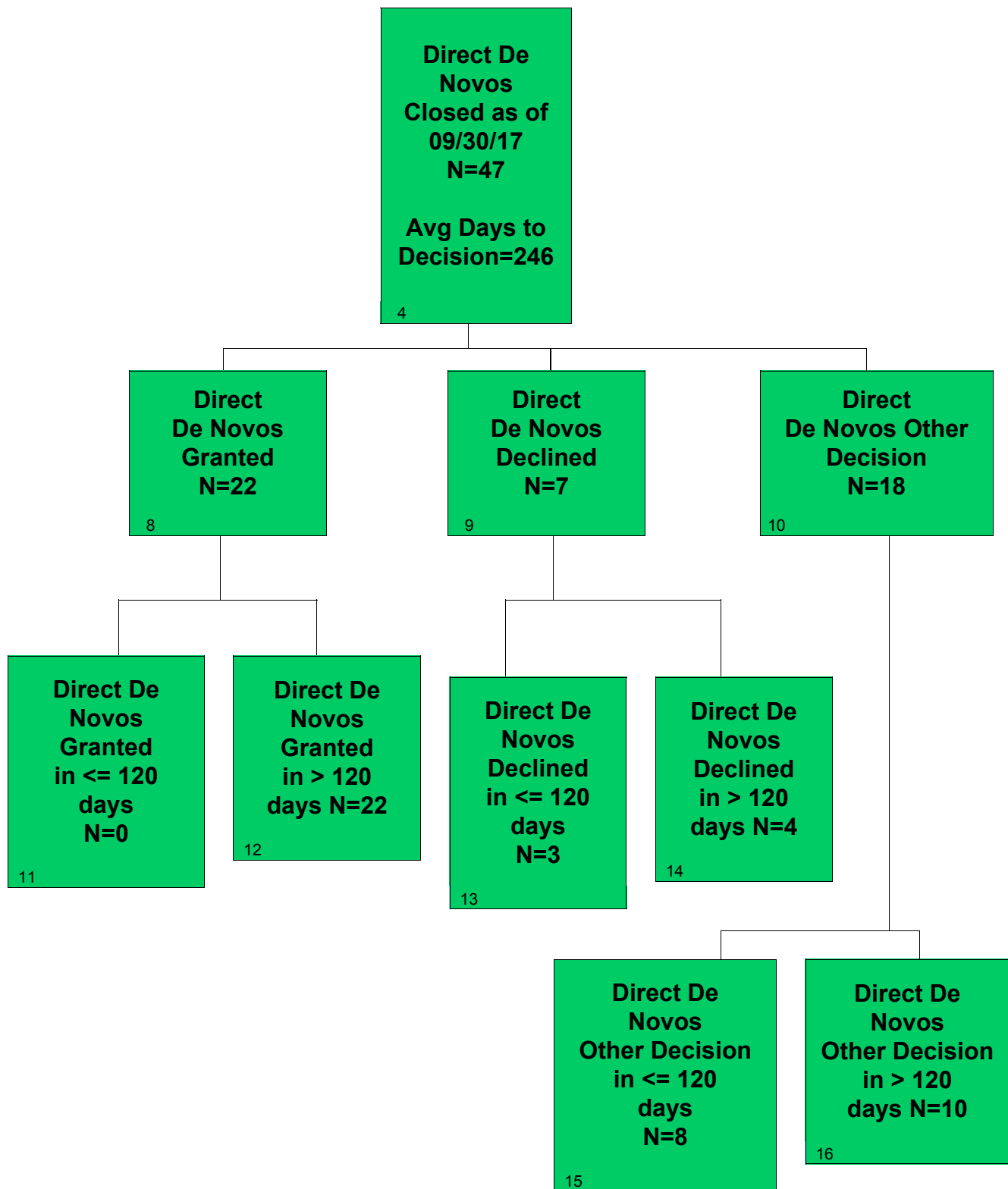
CDRH De Novos - FY 2016

As of 9/30/17



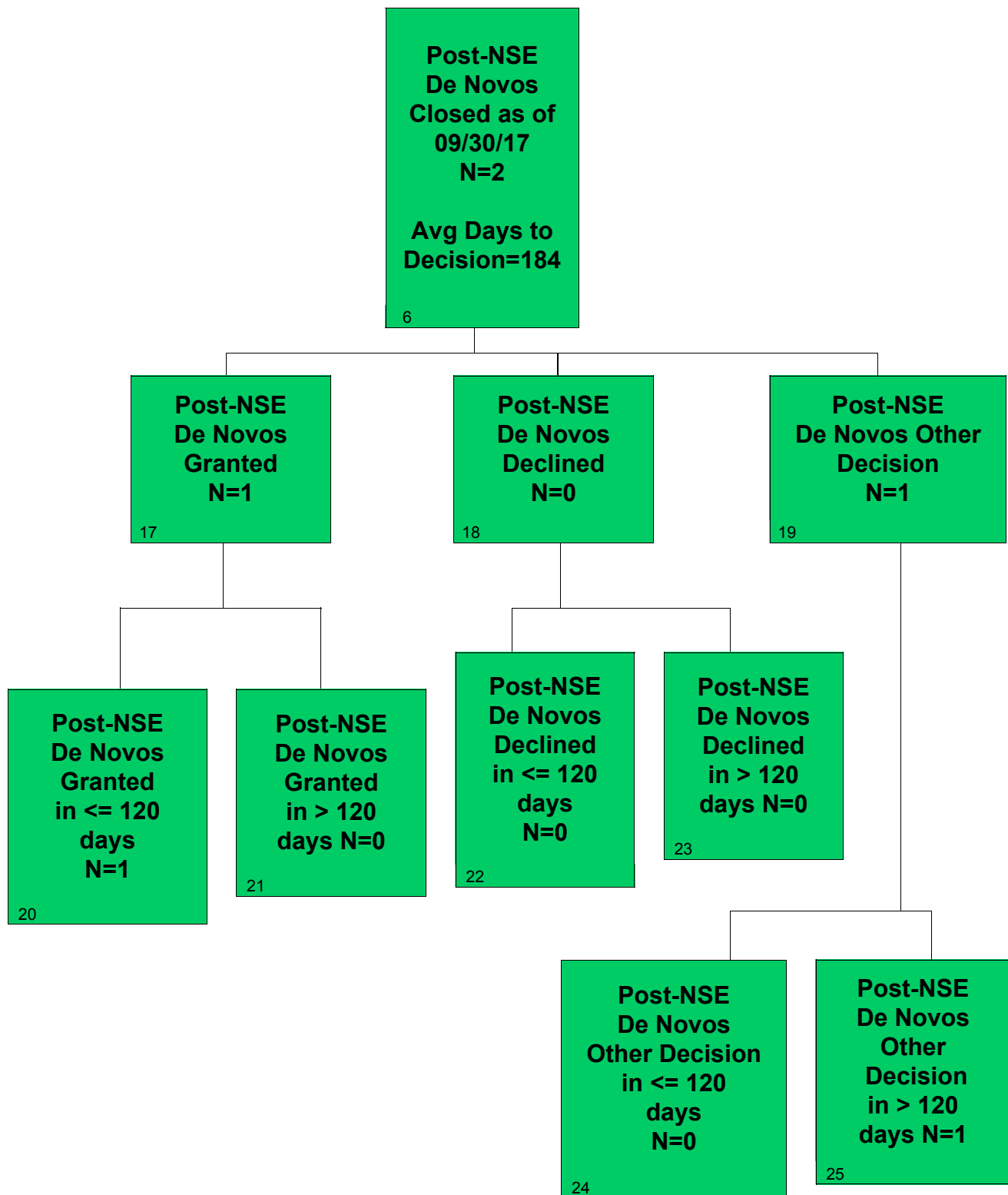
CDRH De Novos - FY 2016

As of 9/30/17



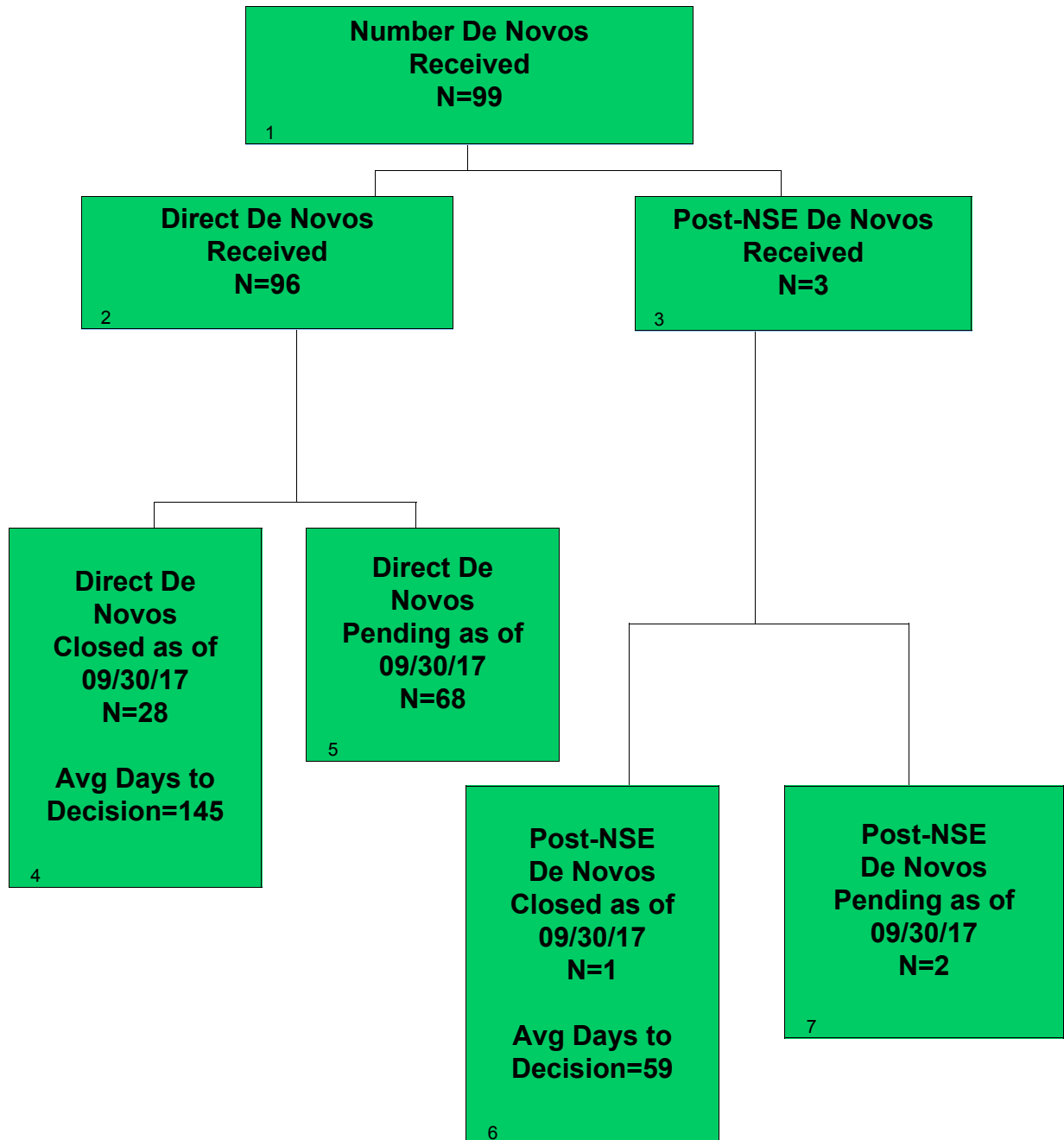
CDRH De Novos - FY 2016

As of 9/30/17



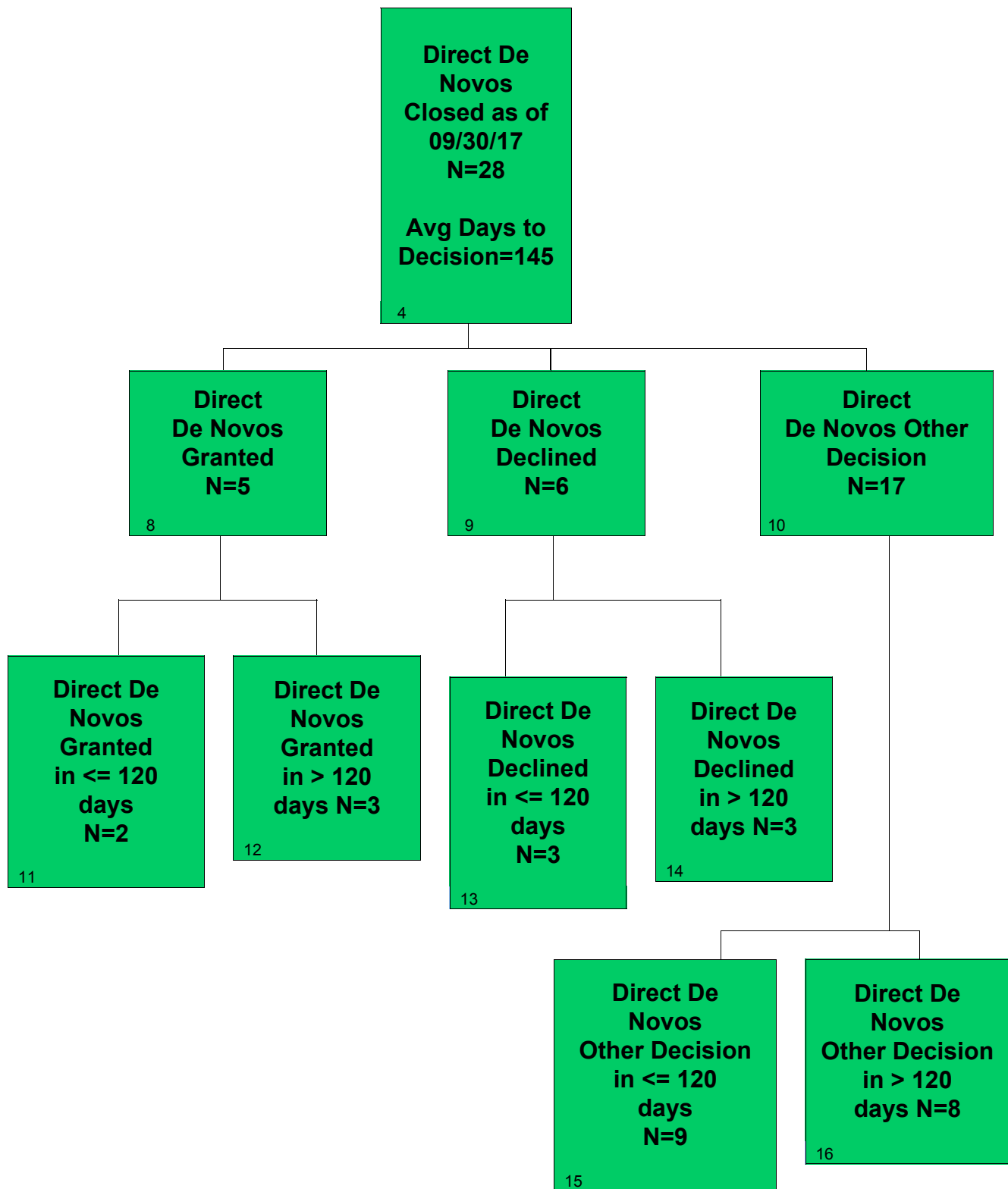
CDRH De Novos - FY 2017

As of 9/30/17



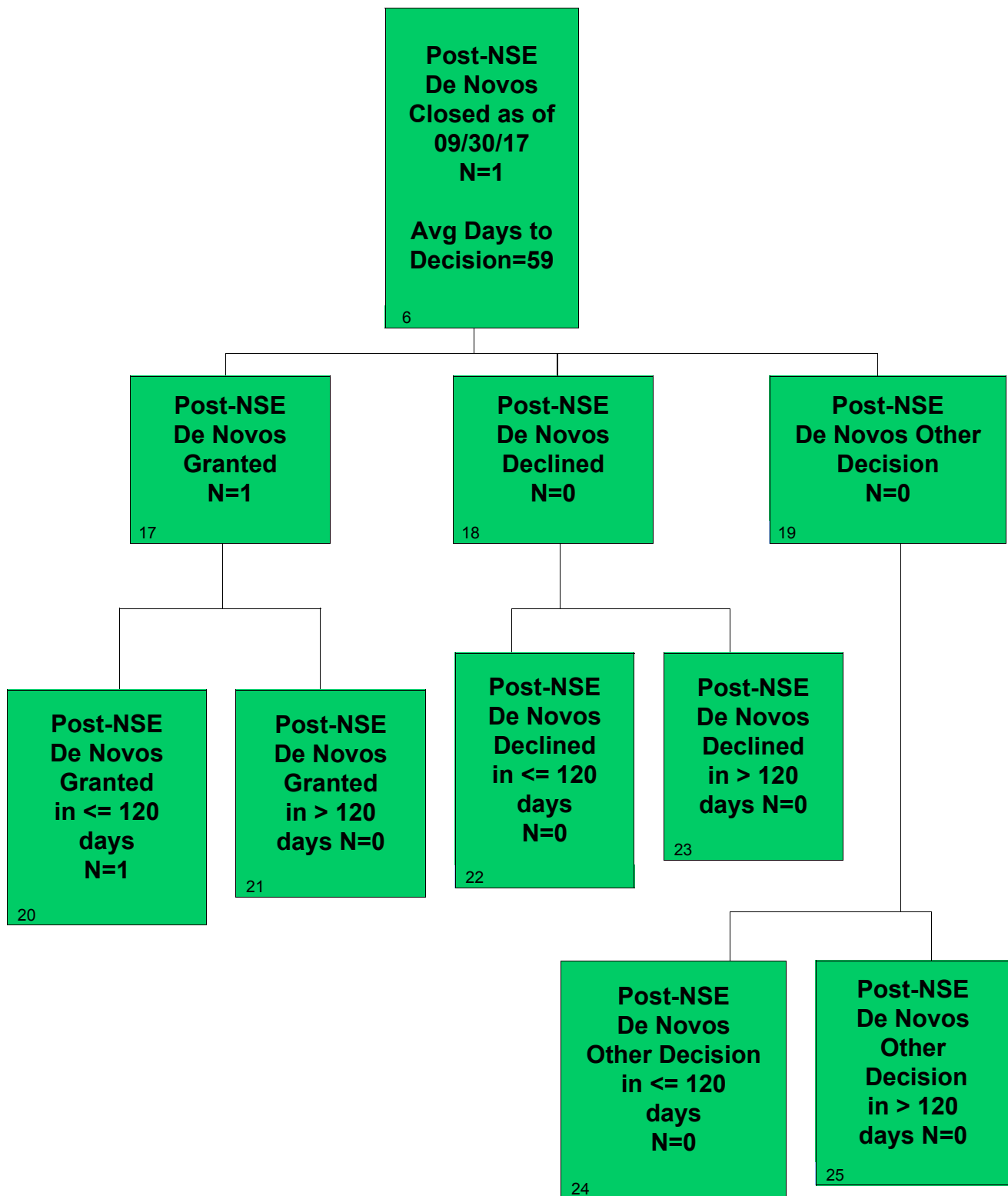
CDRH De Novos - FY 2017

As of 9/30/17



CDRH De Novos - FY 2017

As of 9/30/17



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Section 8 De Novo Requests

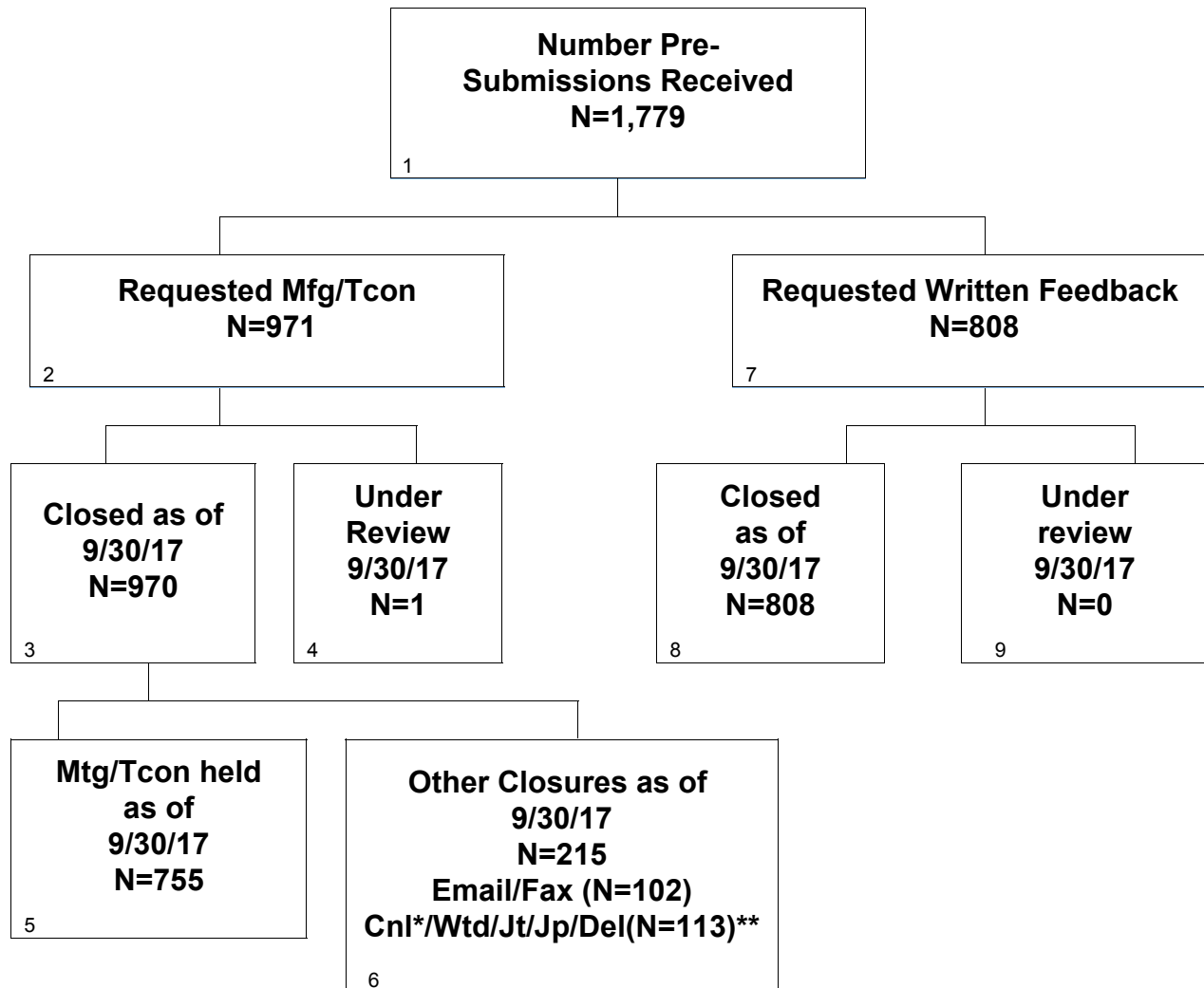
Table 8.1 CDRH – Annual General Metric Report for De Novo Requests

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	49	29
Number of De Novo Requests with Decision Pending	0	0	0	5	70
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 9/30/17

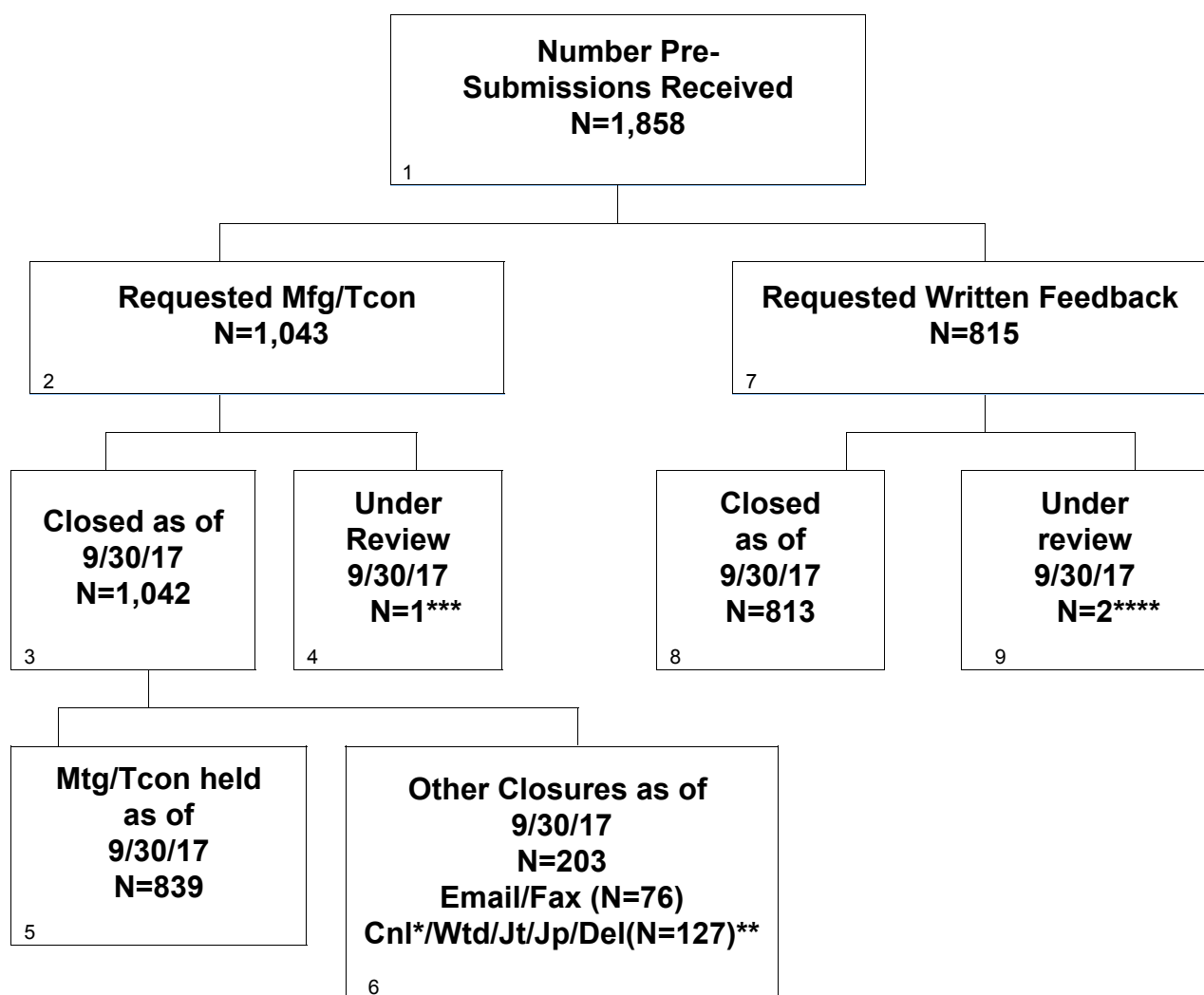


*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient

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

CDRH Pre-Submissions - FY 2014

As of 9/30/17



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

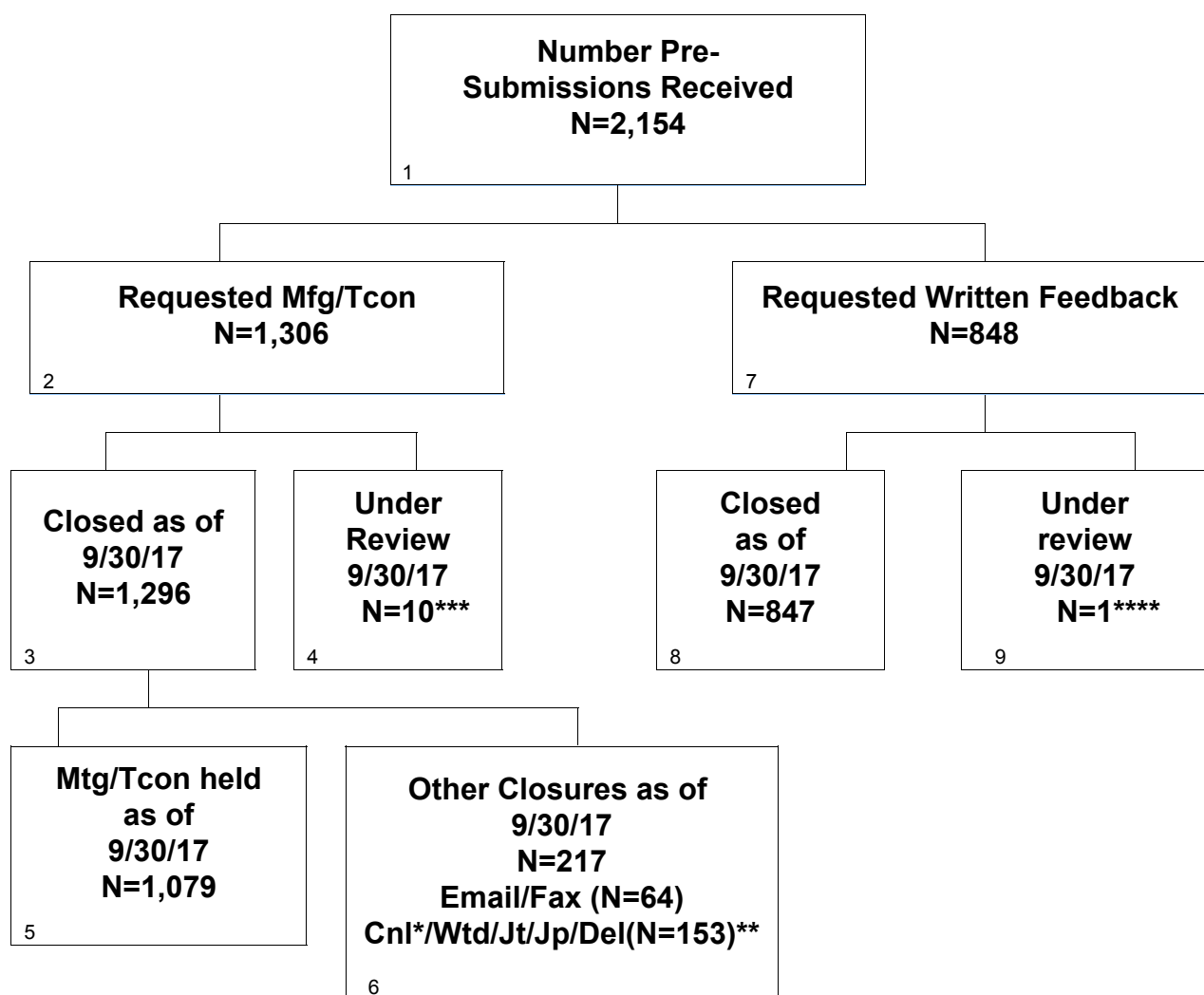
**Cnl/Wtd/Jt/Jp/Del= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending / Deleted Due to No RTA Response

***Includes 1 Pre-Submission on RTA Hold as of 9/30/2017

****Includes 2 Pre-Submissions on RTA Hold as of 9/30/2017

CDRH Pre-Submissions - FY 2015

As of 9/30/17



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

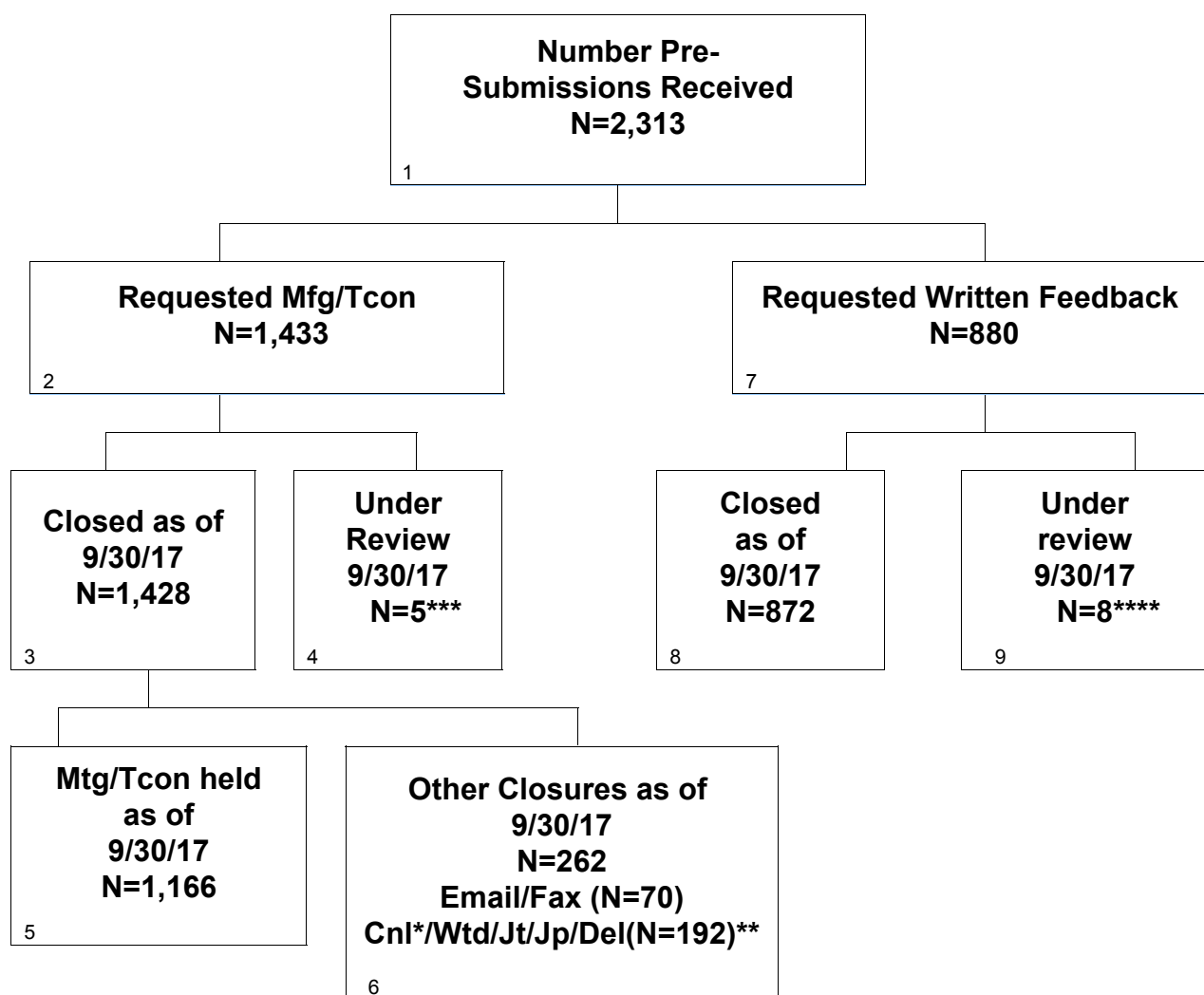
**Cnl/Wtd/Jt/Jp/Del= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending / Deleted Due to No RTA Response

***Includes 4 Pre-Submissions on RTA Hold as of 9/30/2017

****Includes 1 Pre-Submissions on RTA Hold as of 9/30/2017

CDRH Pre-Submissions - FY 2016

As of 9/30/17



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

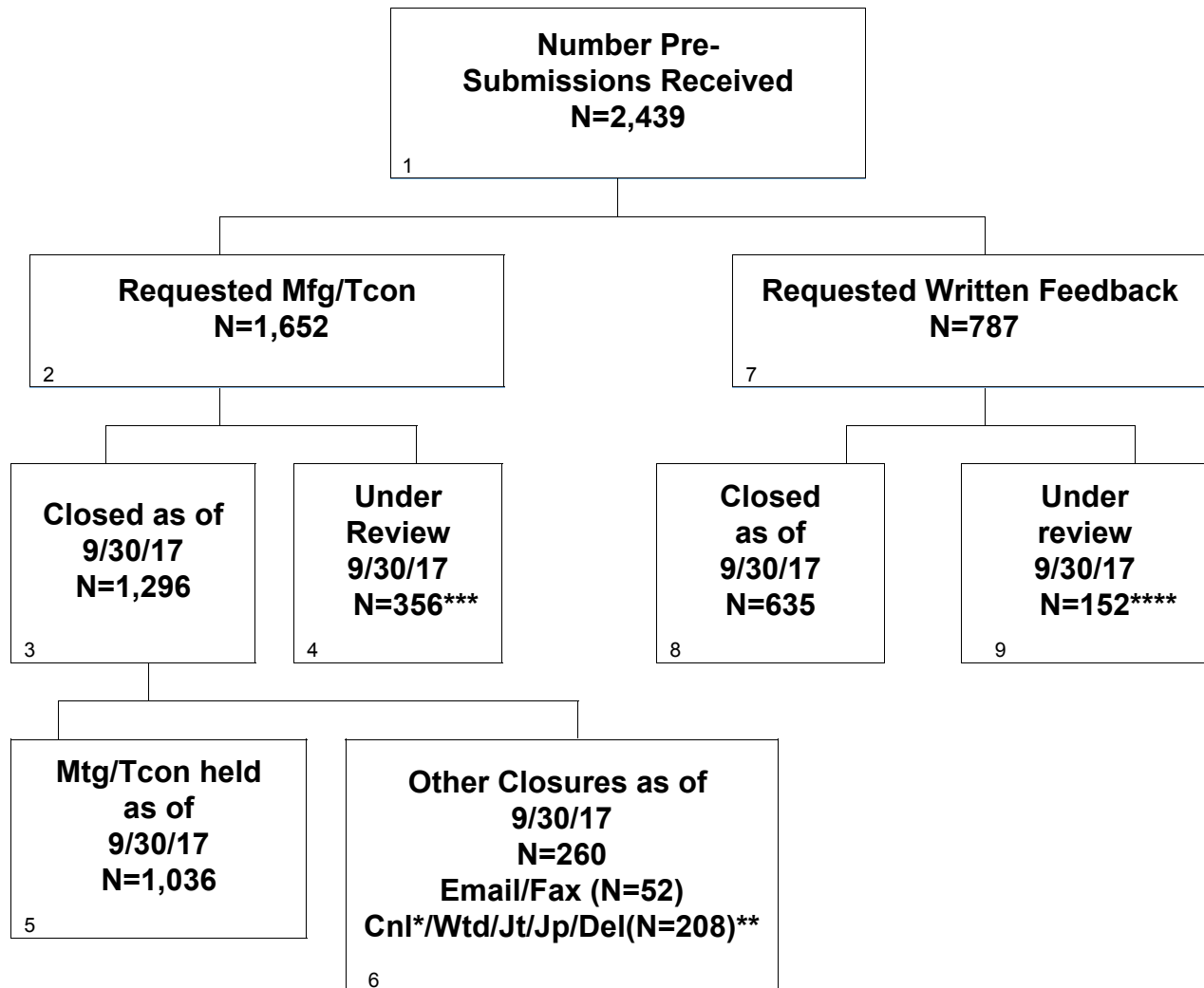
**Cnl/Wtd/Jt/Jp/Del= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending / Deleted Due to No RTA Response

***Includes 2 Pre-Submissions on RTA Hold as of 9/30/2017

****Includes 5 Pre-Submissions on RTA Hold as of 9/30/2017

CDRH Pre-Submissions - FY 2017

As of 9/30/17



*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 9/30/2017

****Includes 14 Pre-Submissions on RTA Hold as of 9/30/2017

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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	2,439
Number requesting a meeting or teleconference	971	1,043	1,306	1,433	1,652
Number with meetings or teleconferences held	755	839	1,079	1,166	1,036
Average days to meeting	59.2	65.0	65.7	69.1	68.4
20th Percentile days to meeting	38	48	51	55	55
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	80
Maximum days to meeting	183	243	249	221	191

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	1,139	1,350	1,473	1,590
Number requesting a meeting or teleconference	611	696	859	944	1,091
Number with meetings or teleconferences held	455	554	693	761	655
Average days to meeting	61.8	67.8	68.7	71.3	70.3
20th Percentile days to meeting	40	49	52	54	55
40th Percentile days to meeting	57	63	66	67	67
60th Percentile days to meeting	67	72	72	74	73
80th Percentile days to meeting	79	83	82	84	84
Maximum days to meeting	183	243	249	221	191

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	719	804	840	849
Number requesting a meeting or teleconference	360	347	447	489	561
Number with meetings or teleconferences held	300	285	386	405	381
Average days to meeting	55.4	59.5	60.2	64.9	65.2
20th Percentile days to meeting	37	46	51	56	55
40th Percentile days to meeting	53	60	62	65	64
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	156	204	231	307	305
Number requesting a meeting or teleconference	82	110	137	178	192
Number with meetings or teleconferences held	58	82	106	144	107
Average days to meeting	68.3	70.7	74.9	79.4	76.8
20th Percentile days to meeting	52	54	64	66	62
40th Percentile days to meeting	65	65	70	73	71
60th Percentile days to meeting	75	75	77	82	79
80th Percentile days to meeting	83	86	86	92	90
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	308	372	389	446	467
Number requesting a meeting or teleconference	215	236	263	290	299
Number with meetings or teleconferences held	174	200	222	229	199
Average days to meeting	56.1	59.3	57.1	59.9	59.7
20th Percentile days to meeting	35	44	43	44	43
40th Percentile days to meeting	49	54	52	54	54
60th Percentile days to meeting	62	65	63	63	64
80th Percentile days to meeting	74	74	71	73	74
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	76	115	154	131	166
Number requesting a meeting or teleconference	48	70	108	106	133
Number with meetings or teleconferences held	30	48	92	80	75
Average days to meeting	70.5	88.8	81.7	83.0	85.1
20th Percentile days to meeting	44	65	65	64	69
40th Percentile days to meeting	63	78	74	73	75
60th Percentile days to meeting	77	90	84	83	85
80th Percentile days to meeting	91	113	94	97	104
Maximum days to meeting	163	243	249	179	139

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	100	107	128	115	121
Number requesting a meeting or teleconference	63	72	85	81	78
Number with meetings or teleconferences held	40	63	67	68	42
Average days to meeting	60.7	75.5	70.7	71.5	74.6
20th Percentile days to meeting	45	62	59	58	67
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	87	72	108	115	148
Number requesting a meeting or teleconference	49	46	75	74	115
Number with meetings or teleconferences held	35	34	55	63	70
Average days to meeting	66.4	75.4	74.1	77.7	75.8
20th Percentile days to meeting	53	66	65	70	68
40th Percentile days to meeting	64	69	73	75	71
60th Percentile days to meeting	70	73	77	83	76
80th Percentile days to meeting	83	86	83	87	85
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	131	134	160	169	189
Number requesting a meeting or teleconference	76	82	90	95	129
Number with meetings or teleconferences held	60	65	72	78	77
Average days to meeting	60.0	59.5	70.6	67.8	67.4
20th Percentile days to meeting	47	44	56	55	58
40th Percentile days to meeting	60	57	68	67	66
60th Percentile days to meeting	67	66	73	73	70
80th Percentile days to meeting	71	74	83	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	123	135	180	190	194
Number requesting a meeting or teleconference	78	80	101	120	145
Number with meetings or teleconferences held	58	62	79	99	85
Average days to meeting	67.5	71.8	71.0	74.7	69.3
20th Percentile days to meeting	41	62	59	61	58
40th Percentile days to meeting	64	69	68	69	68
60th Percentile days to meeting	73	77	70	73	72
80th Percentile days to meeting	85	90	80	84	77
Maximum days to meeting	183	111	189	162	118

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	179	231	228	239
Number requesting a meeting or teleconference	108	100	151	146	177
Number with meetings or teleconferences held	91	88	137	128	137
Average days to meeting	51.3	57.0	55.4	62.5	64.5
20th Percentile days to meeting	36	42	37	52	54
40th Percentile days to meeting	49	55	57	62	64
60th Percentile days to meeting	59	65	65	68	70
80th Percentile days to meeting	68	70	70	72	73
Maximum days to meeting	90	112	97	203	146

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	129	128	120	137	123
Number requesting a meeting or teleconference	66	72	66	87	90
Number with meetings or teleconferences held	54	67	66	76	60
Average days to meeting	61.1	65.0	67.3	72.2	75.8
20th Percentile days to meeting	39	56	61	64	66
40th Percentile days to meeting	64	67	66	71	71
60th Percentile days to meeting	70	71	70	74	73
80th Percentile days to meeting	83	73	73	80	82
Maximum days to meeting	99	113	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	94
Number with meetings or teleconferences held	49	28	44	59	48
Average days to meeting	52.6	60.4	61.1	63.8	65.1
20th Percentile days to meeting	42	43	52	56	60
40th Percentile days to meeting	51	56	63	67	67
60th Percentile days to meeting	62	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	147	154	171	185	194
Number requesting a meeting or teleconference	83	90	118	119	141
Number with meetings or teleconferences held	70	70	102	99	94
Average days to meeting	63.0	58.1	61.6	65.6	64.5
20th Percentile days to meeting	44	40	50	57	56
40th Percentile days to meeting	56	60	63	64	63
60th Percentile days to meeting	66	68	69	70	69
80th Percentile days to meeting	83	72	72	75	74
Maximum days to meeting	138	115	94	121	92

Table 9.1.DRH - OIR - Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	70	54	69	76	81
Number requesting a meeting or teleconference	45	37	49	57	59
Number with meetings or teleconferences held	36	32	37	43	42
Average days to meeting	46.7	57.5	61.0	59.0	54.1
20th Percentile days to meeting	31	47	54	45	46
40th Percentile days to meeting	43	59	61	56	51
60th Percentile days to meeting	57	68	65	65	57
80th Percentile days to meeting	63	72	70	70	66
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	3
SI over 90 FDA days	0	0	0	0	0
SI pending within 90 FDA days	0	0	0	0	1
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	3
Average number of FDA days to Substantive Interaction	73.5	69.9	77.5	81.9	88.7
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	89
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	5
MDUFA III Decisions within 180 FDA Days	3	14	11	9	5
CLIA Waiver Applications pending MDUFA III Decision	0	0	0	0	2
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

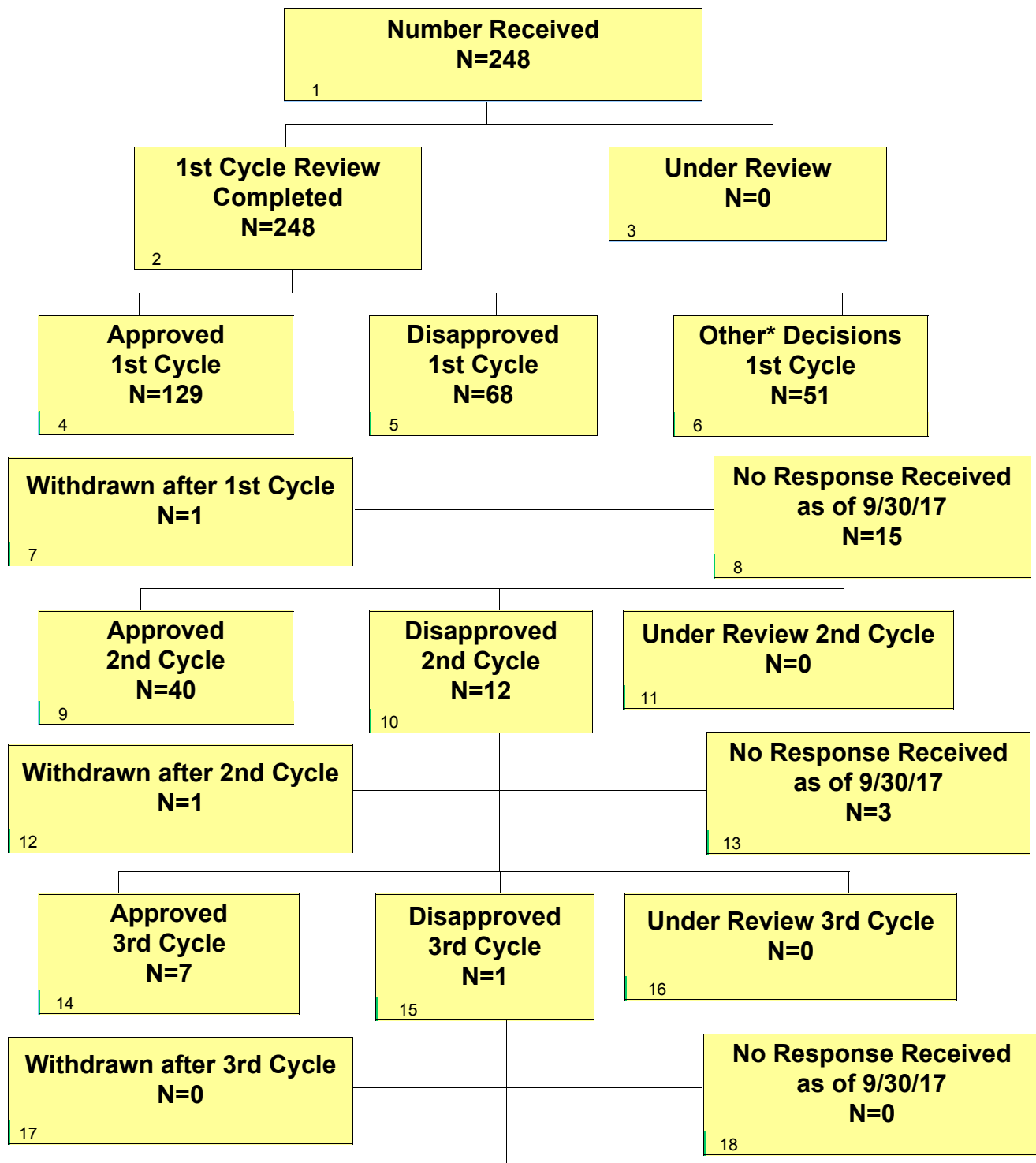
Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	3	14	11	9	5
Average FDA days to MDUFA III decision	102.7	118.6	122.4	118.4	92.6
20th Percentile FDA days to MDUFA III decision	66	80	58	83	63
40th Percentile FDA days to MDUFA III decision	71	104	104	88	83
60th Percentile FDA days to MDUFA III decision	94	135	171	121	106
80th Percentile FDA days to MDUFA III decision	133	177	173	180	132
Maximum FDA days to MDUFA III decision	173	179	180	180	145
Average Industry days to MDUFA III decision	59.0	46.1	88.1	64.0	12.8
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	12.8
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	105.4
20th Percentile Total days to MDUFA III decision	66	80	104	83	63
40th Percentile Total days to MDUFA III decision	71	131	171	139	83
60th Percentile Total days to MDUFA III decision	129	177	238	238	112
80th Percentile Total days to MDUFA III decision	240	197	278	268	155
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

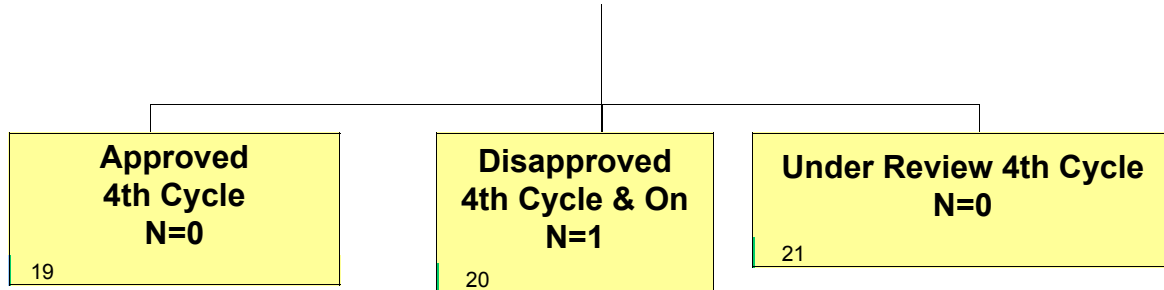
As of 9/30/17



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

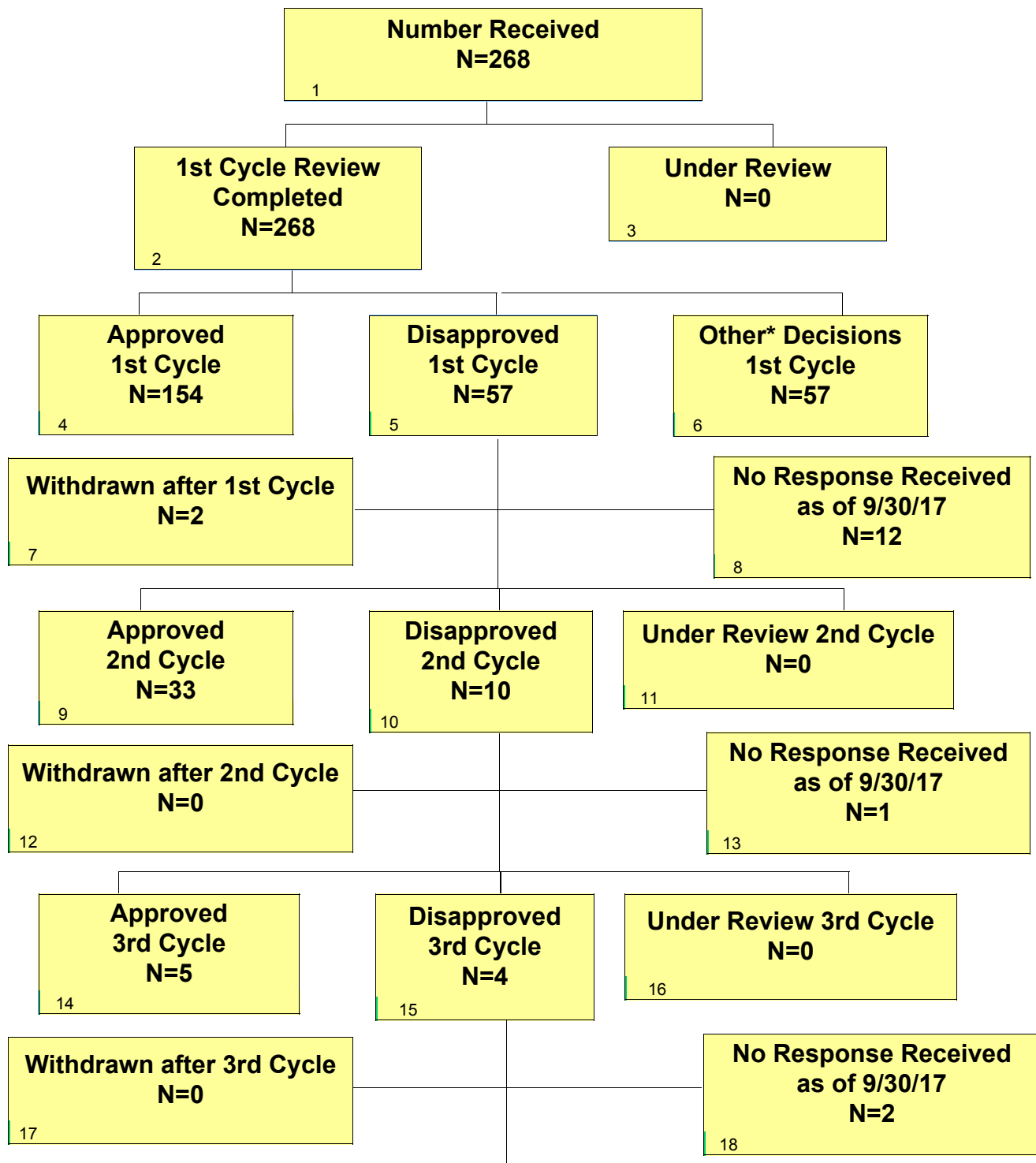
CDRH IDEs - FY 2014

As of 9/30/17



CDRH IDEs - FY 2015

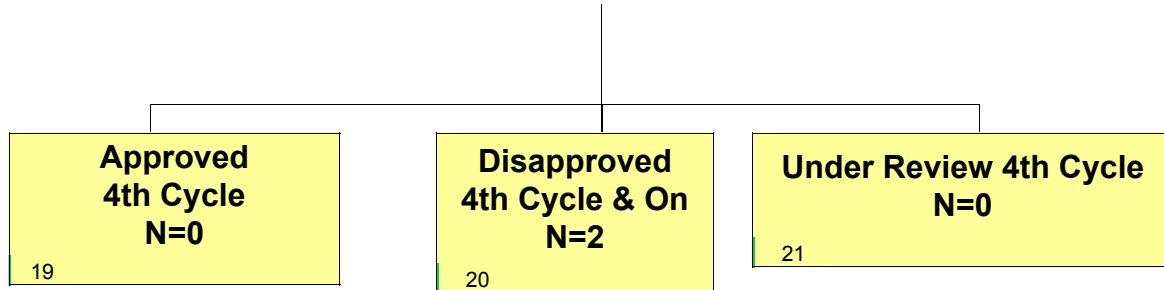
As of 9/30/17



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

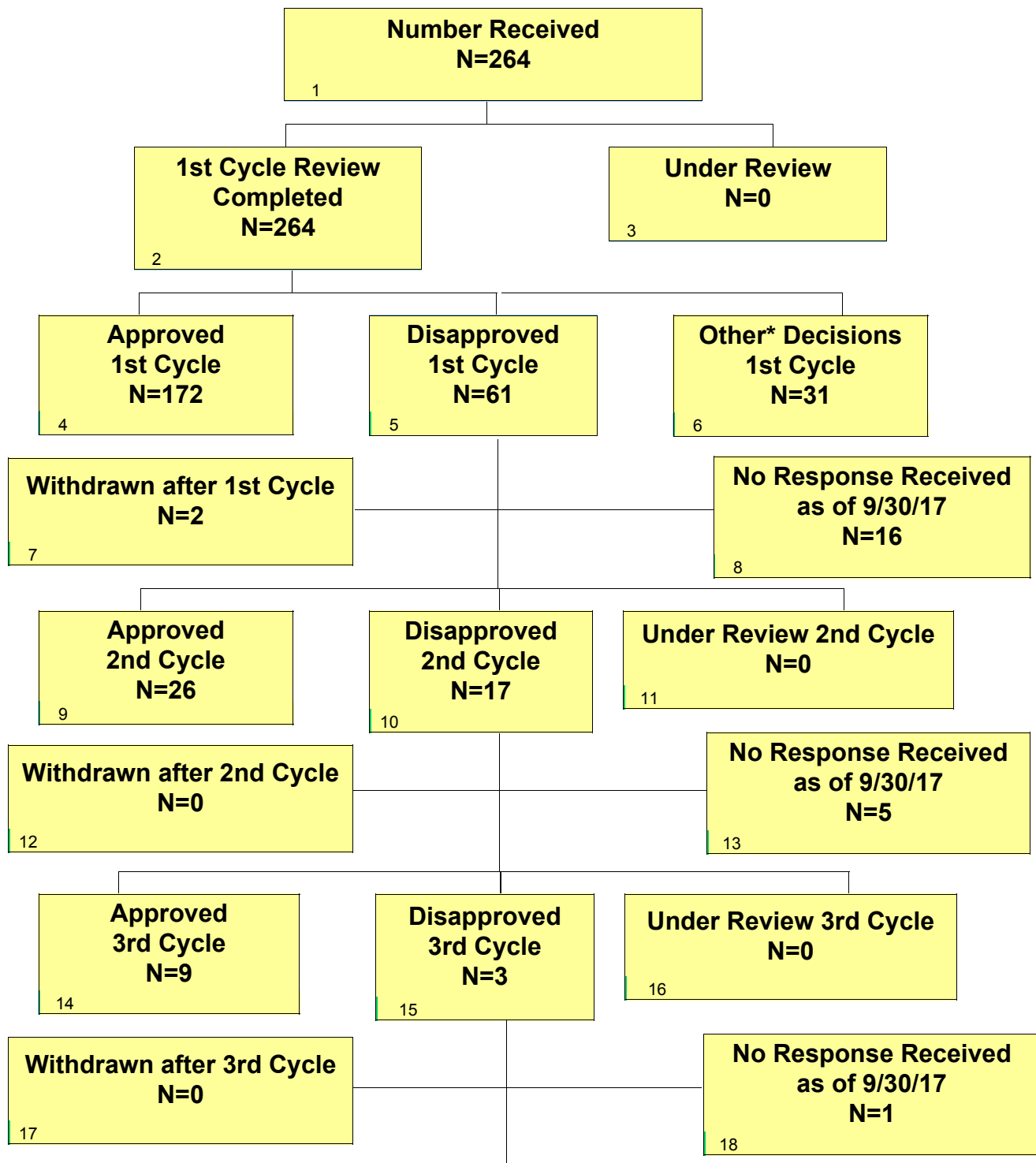
CDRH IDEs - FY 2015

As of 9/30/17



CDRH IDEs - FY 2016

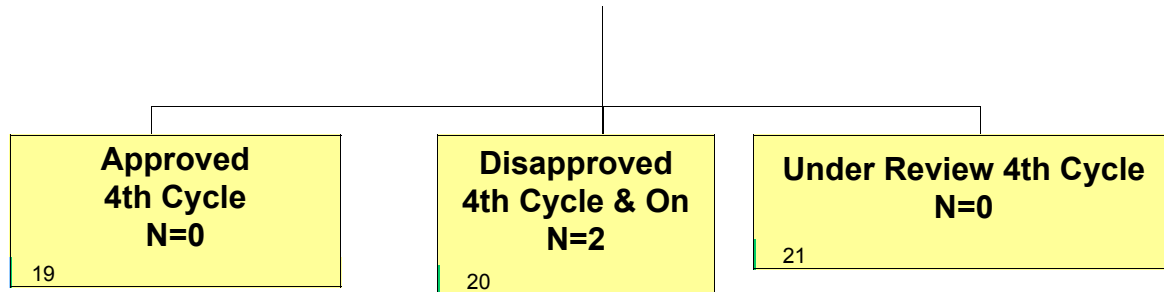
As of 9/30/17



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

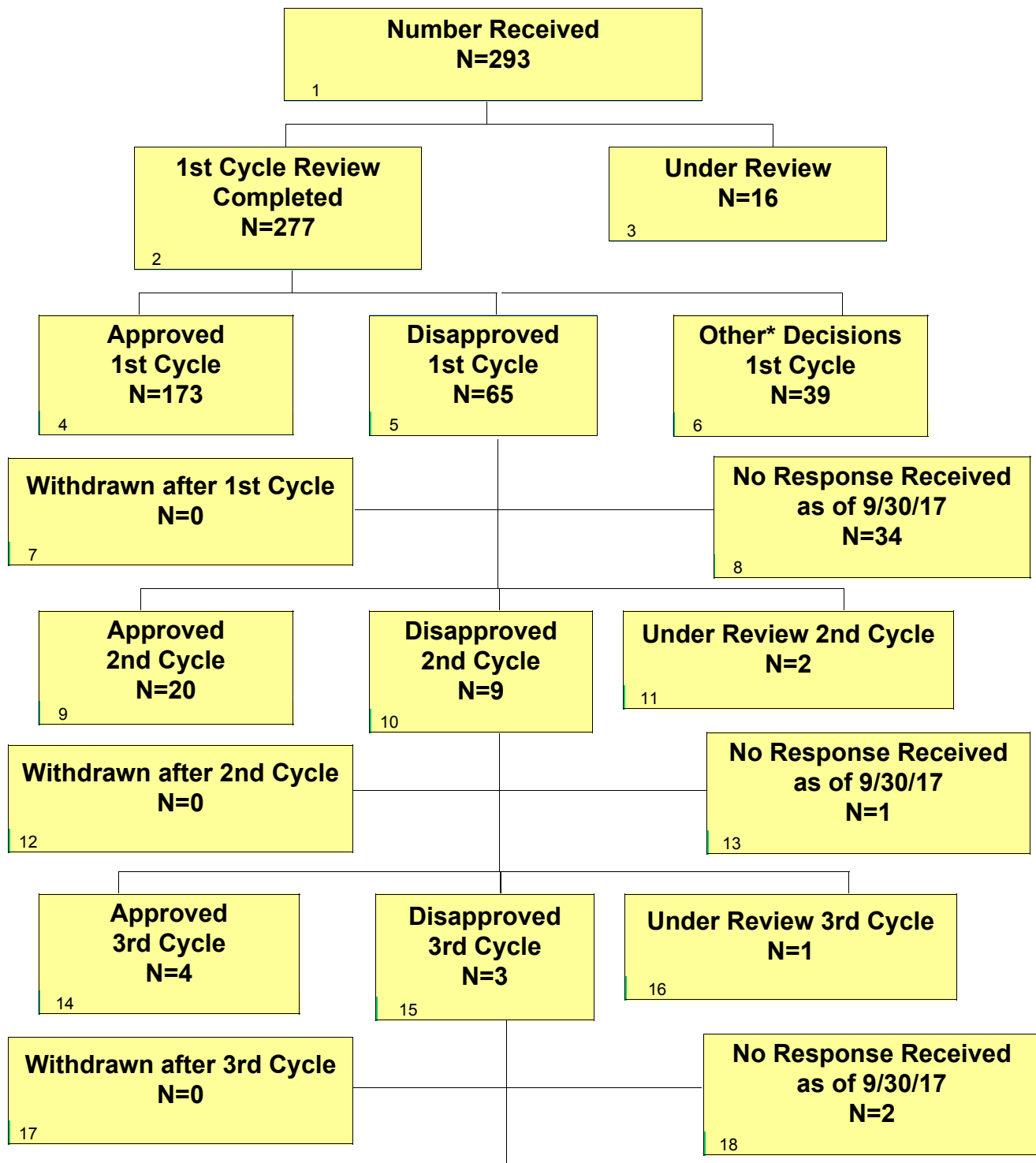
CDRH IDEs - FY 2016

As of 9/30/17



CDRH IDEs - FY 2017

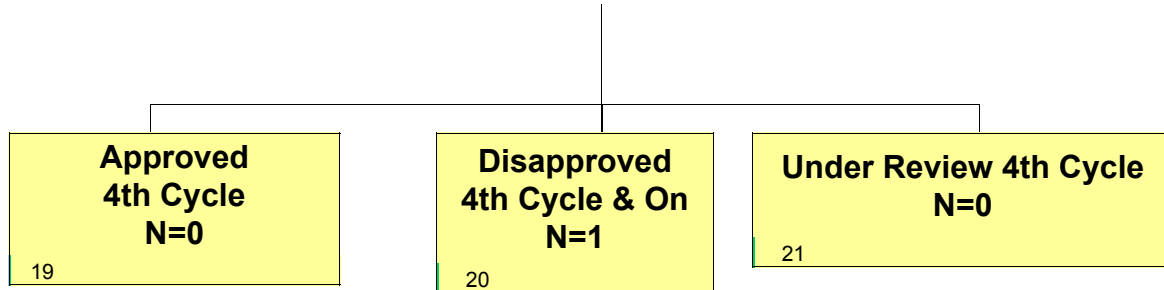
As of 9/30/17



* Other decisions include withdrawn (N=8), withdrawn and converted (N=23), RTA (N=0), nonsignificant risk device (N=6), exempt (N=0), product jurisdiction pending (N=0), product jurisdiction transferred (N=1), or Basic Physiological Research (N=1).

CDRH IDEs - FY 2017

As of 9/30/17



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	1.3	1.3	1.3	1.2
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0.3	0.3	0.2

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	1.4	1.3	1.3	1.2
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.4	0.3	0.3	0.2

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	1.1	1.1	1.1	1.0
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.1	0.1	0.1	0.0

Section 11 IDEs - Division Level Metrics

Table 11.1.DAGRID - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	8	19	13	20
Average number of cycles to approval or conditional approval of the IDE	N/A	1.7	1.2	1.3	1.0
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.7	0.2	0.3	0

Table 11.1.DCD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	58	58	70	77
Average number of cycles to approval or conditional approval of the IDE	N/A	1.5	1.4	1.5	1.4
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.5	0.4	0.5	0.4

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	33	38	48	54
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.2	1.1	1.2
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0.2	0.1	0.2

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	1.2	1.2	1.1	1.0
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.2	0.1	0

Table 11.1.DOED - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	18	26	14	24
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.1	1.6	1.1
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.1	0.6	0.1

Table 11.1.DRGUD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	31	43	36	38
Average number of cycles to approval or conditional approval of the IDE	N/A	1.5	1.5	1.3	1.2
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.5	0.5	0.3	0.2

Table 11.1.DSD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	25	33	21	27
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.3	1.1	1.1
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.3	0.1	0.1

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	1.0	1.1	1.1	1.0
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0.1	0.1	0

Table 11.1.DIHD - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	2	2	0	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	1.0	1.0	1.0	1.0
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	1.0	1.0	1.0	1.0
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	1.6	1.5	1.4	1.0
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.6	0.5	0.4	0

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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	5
SI over 90 FDA days	N/A	0	0	0	0
SI pending within 90 FDA days	N/A	0	0	0	1
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	5
Average number of FDA days to Substantive Interaction	N/A	87.0	87.0	77.0	87.6
20th Percentile FDA days to Substantive Interaction	N/A	N/A	86	N/A	86
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	88
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	0
MDUFA III Decisions with in 210 FDA Days	N/A	1	3	1	0
CLIA Waiver Applications pending MDUFA III Decision	N/A	0	0	0	6
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	0
Average FDA days to MDUFA III decision	N/A	169.0	167.7	131.0	N/A
20th Percentile FDA days to MDUFA III decision	N/A	N/A	134	N/A	N/A
40th Percentile FDA days to MDUFA III decision	N/A	N/A	184	N/A	N/A
60th Percentile FDA days to MDUFA III decision	N/A	N/A	209	N/A	N/A
80th Percentile FDA days to MDUFA III decision	N/A	N/A	210	N/A	N/A
Maximum FDA days to MDUFA III decision	N/A	169	210	131	N/A
Average Industry days to MDUFA III decision	N/A	0.0	119.7	96.0	N/A
20th Percentile Industry days to MDUFA III decision	N/A	N/A	72	N/A	N/A
40th Percentile Industry days to MDUFA III decision	N/A	N/A	143	N/A	N/A
60th Percentile Industry days to MDUFA III decision	N/A	N/A	179	N/A	N/A
80th Percentile Industry days to MDUFA III decision	N/A	N/A	180	N/A	N/A
Maximum Industry days to MDUFA III decision	N/A	0	180	96	N/A
Average Total days to MDUFA III decision	N/A	169.0	287.3	227.0	N/A
20th Percentile Total days to MDUFA III decision	N/A	N/A	231	N/A	N/A
40th Percentile Total days to MDUFA III decision	N/A	N/A	253	N/A	N/A
60th Percentile Total days to MDUFA III decision	N/A	N/A	289	N/A	N/A
80th Percentile Total days to MDUFA III decision	N/A	N/A	339	N/A	N/A
Maximum Total days to MDUFA III decision	N/A	169	389	227	N/A

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

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

Table 1.1 and Tables 1.1.x PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year (see definition for the Received cohort above).
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number with accepted RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer.
4	Number without RTA Review and > 15 Days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number without RTA Review and <= 15 Days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of submissions not accepted for filing review	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

Table 1.2 and Tables 1.2.x**PMA Original and Panel Track Supplements – Filing Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year (see definition for the Received cohort above).
2	Number Accepted [#]	Number Received (line 1) that got "RTA Accepted" (RTAA), RTAX, or RTAN decision in the first RTA review cycle entered by reviewer.
3	Number with completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013

Table 1.3 and Tables 1.3.x**PMA Originals & Panel Track Supplements Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under with no SI past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 1.4 and Tables 1.4.x**PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 1.5 and Tables 1.5.x PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision Past Goal	Number of submissions pending MDUFA III Decision (line 5) past goal. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.6 and Tables 1.6.x**PMA Originals & Panel Track Supplements (with Panel Review)
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision Past Goal	Number of submissions pending MDUFA III Decision (line 5) past goal. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

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

#	Measure	Description
1	Number with MDUFA III Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

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

#	Measure	Description
1	Number with MDUFA III Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

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

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

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

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

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

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

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

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

Section 2 PMA 180 Day Supplements

Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goals - Definitions

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year. See definition of the received cohort above.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or NON-MDUFA decision but without an SI.
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA Decision Performance Goals - Definitions

#	Measure	Description
1	Supplements filed	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA III Decisions	Supplements received (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMa).
3	MDUFA III Decisions	Supplements received (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	Supplements pending MDUFA III Decision	Number of supplements received (line 1) that do not have a MDUFA III decision or a final decision.
6	Supplements pending MDUFA III Decision Past Goal	Number of supplements pending MDUFA III Decision (line 5) past goal. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 2.3 and Tables 2.3.x**PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable - Definitions**

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

Table 2.4 and Tables 2.4.x**PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

Section 3 PMA Real Time Supplements

Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions

#	Measure	Description
1	Supplements received	Number of Real Time PMA supplements that were received in this fiscal year. See the Received cohort definition above.
2	Non-MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) within goal.
5	Supplements pending MDUFA III Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA III decision and are not closed with a final decision.
6	Supplements pending MDUFA III Decision Past Goal	Number of supplements pending MDUFA III Decision (line 5) past goal. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – Rate of Not Approvable - Definitions

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

Table 3.3 and Tables 3.3.x**Real Time PMA Supplements Performance Metrics – Submissions
Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

Section 5 PMA Annual Metrics and Goals

Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non-Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements (No Panel) – Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

Table 5.2 **PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number with a decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY closed	Number with a decision (line 2) divided by Number Filed (line 1).

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

#	Measure	Description
1	Number with MDUFA decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number with MDUFA decision after trimming the upper and lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA III decision and 5% of submissions with the highest number of Total Days to MDUFA III decision.
3	Three-year Rolling Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

Section 6 510(k) MDUFA III Performance

Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision - Definitions

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year. See definition for received cohort above. Third party reviews shall be excluded from this table.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	RTA Review not done and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN or RTAS) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	RTA Review not done and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" decision in the first RTA review cycle.
7	Rate of submissions not accepted	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goals - Definitions

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions with RTA review accepted in this fiscal year (RTAA, RTAX, RTAN, or RTAS.). Third party 510(k) submissions are excluded from SI performance report.
2	510(k) withdrawn or deleted prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made before or on the cutoff date and before any SI action: WD, DD, DE, HD, K4, NR, RC, RD .
3	SI within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI pending within 60 FDA days	Submissions that are under review for not more than 60 FDA days and that do not have an SI.
6	SI pending over 60 FDA days	Submissions that are under review over 60 FDA days and that do not have an SI.
7	510(k)s NSE without SI	Number of 510(k) submissions that are closed with an NSE decision (or with an AN, DN, or ON decision where Date Received does not equal Date Final Decision) and did not have an SI.
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

Table 6.3 and Tables 6.3.x**510(k) Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of 510(k) submissions accepted in this fiscal year that had an SI. Third party 510(k) submissions shall be excluded from this report.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all 510(k) submissions with SI (line 1).
3	20 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1).

Tables 6.4 and Tables 6.4.x 510(k) MDUFA Decision Performance Goals - Definitions

#	Measure	Description
1	510(k)s accepted	Number of 510(k) submissions accepted in this fiscal year. Third party 510(k) shall also be included into this report.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not SE or NSE).
3	MDUFA III Decisions (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA III decision (SE or NSE).
4	MDUFA III Decisions within 90 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA III Decision over 90 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 90 FDA Days	Number of submissions with MDUFA III Decisions within 90 FDA Days (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA Decision - Definitions

#	Measure	Description
1	Average review cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA III Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

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

#	Measure	Description
1	Number Accepted	Number of 510(k) submissions accepted in this fiscal year. See definition for Accepted cohort above.
2	Number with MDUFA decision	Number submissions accepted (line 1) that also had a MDUFA decision.
3	Number of SE decisions	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE decisions	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) and closed with Withdrawal (WD) final decision.
6	Number deleted	Number of submissions accepted (line 1) and closed with Delete (DE) final decision.
7	Rate of SE decisions	Number of SE decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of NSE decisions	Number of NSE decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number Received (line 1).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number Received (line 1).

Table 6.7 and Tables 6.7.x**510(k) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days. Third Party 510(k) submissions shall also be included into this report.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

Section 7 510(k) Annual General Metrics

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

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. Third party 510(k) submissions shall also be included into this count.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

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

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. Third-party 510(k) submissions shall also be included into this report.
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA III Decision	Total number of 510(k) submissions accepted (line 1) that had a MDUFA III decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) divided by the total of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA III decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA III Decision (line 4) excluding 2% of submissions with the lowest number of Total Days to MDUFA III decision and 2% of submissions with the highest number of Total Days to MDUFA III decision.
7	Average Total Time to MDUFA III decision	Average Total Time (FDA and Industry) to MDUFA decision. If the cohort is not closed (less than 99% of 510(k) submissions have a decision) "N/A" shall be displayed instead.

Section 8 Annual Metrics for De Novo Requests

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

#	Measure	Description
1	Number of <i>De Novo</i> Requests Received	Total number of <i>de novo</i> requests received in this fiscal year as of the report cutoff date.
2	Number of <i>De Novo</i> Requests with Decision	Number of <i>de novo</i> requests received in this fiscal year (line 1) which have also received a final decision as of the report cutoff date.
3	Number of <i>De Novo</i> Requests with Decision Pending	Number <i>de novo</i> requests received in this fiscal year (line 1) which have not received a final decision as of the report cutoff date.
4	Average Number of Days to Decision	Average total number of days to decision (days between <i>De Novo</i> Date Received and <i>De Novo</i> Decision Date) for <i>de novo</i> requests with decision (line 2).

Section 9 Pre-Submissions

Table 9.1 and Tables 9.1.x Pre-Submissions Performance Metrics - Definitions

#	Measure	Description
1	Number of all qualified Pre-Submissions received	Number of all qualified Pre-Submissions received. This include those with a type="pre-sub" either with a meeting request or written feedback requested in the fiscal year.
2	Number requesting a meeting or teleconference	Number of qualified Pre-submission received (line 1) with the Sub-Type of "Pre-Sub Meeting Request".
3	Number with meetings or teleconferences held	Number requesting a meeting or teleconference (line 2) with Actual Meeting Date populated with a value prior to the cutoff date.
4	Days to meeting	Table shall show average days from Date FDA Initial Clock Start to Actual Meeting Date as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for days to meeting days, Industry days, and Total days. The calculation includes meetings where the Actual Meeting Date is greater than the Date FDA Initial Clock Start and the Actual Meeting Date is prior to as of the cutoff date.

Section 10 CLIA Waiver Annual Metrics

Table 10.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Withdrawn prior to SI	Number of submissions with MDUFA Decision WTDR within 90 FDA days
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days
5	SI pending within 90 FDA days	Number of submissions that are under review for not more than 90 FDA days and with no SI
6	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no SI
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within 90 FDA days (line 3) divided by the total number of submissions Eligible for SI (line 1), except those withdrawn before an SI was made or due (line 2)

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

Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications filed in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all CLIA Waivers with SI (line 1).
3	20 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1).

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

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year, and did not have a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 180 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 180 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 180 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 180 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA III Decisions within 180 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

Table 10.4 CLIA Waiver (with Panel Review) MDUFA Decision Performance Goals) – Definitions

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year, and had a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 330 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 330 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

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

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

Table 10.6 CLIA Waiver (with Panel Review) Time to MDUFA Decision - Definitions

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

Section 11 IDE Performance Metrics

Table 11.1 IDE Performance Metrics

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.

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

Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year
2	Withdrawn prior to SI	Number of submissions that were withdrawn or deleted prior to 90 days
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days
5	SI pending within 90 FDA days	Number of submissions that are under review for not more than 90 FDA days and with no SI
6	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no SI
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within 90 FDA days (line 3) divided by the total number of submissions Eligible for SI (line 1), except those withdrawn before an SI was made or due (line 2)

Table 12.2 Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications filed in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1).

Table 12.3 Dual 510(k) and CLIA Waiver (without panel review) MDUFA Decision Performance Goals – Definitions

#	Measure	Description
1	Dual 510(k) and CLIA Waiver Applications accepted	Number of Dual 510(k) and CLIA Waiver by Applications that were filed in this fiscal year, and did not have a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 210 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 210 FDA days
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision over 210 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 210 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 210 FDA Days	Number of submissions with MDUFA III Decisions within 210 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA Decision Performance Goals – Definitions

#	Measure	Description
1	Dual 510(k) and CLIA Waiver Applications accepted	Number of Dual 510(k) and CLIA Waiver by Applications that were filed in this fiscal year, and had a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 210 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 210 FDA days
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA Decision – Definitions

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA Decision – Definitions

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

**Quarterly Update on
Medical Device Performance Goals
----MDUFA III CBER Performance Data ----
Action through 30 Sep 2017**

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	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	1
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	1
SI within 90 FDA days	0	6	3	2	1
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%	100%	100%	100%	100%

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	1
Average number of FDA days to Substantive Interaction	101.00	88.00	87.00	87.50	87.00
20th Percentile FDA days to Substantive Interaction	101	87	85	87	87
40th Percentile FDA days to Substantive Interaction	101	88	86	87	87
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	1
Non-MDUFA III Decisions	0	0	0	0	0
MDUFA III Decisions	0	6	3	2	0
MDUFA III Decisions within 180 FDA Days	0	6	3	2	0
PMAs pending MDUFA III Decision	0	0	0	0	1
PMAs pending MDUFA III Decision over 180 FDA days	0	0	0	0	0
Current Performance Percent within 180 FDA Days	0%	100%	100%	100%	0%

**Table 1.5 CBER – PMA Originals & Panel-Track Supplements (with Panel Review) MDUFA
Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0	0	0	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%

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	0
Average FDA days to MDUFA III decision	0	173.00	165.00	165.00	0.00
20th Percentile FDA days to MDUFA III decision	0	170	159	152	0
40th Percentile FDA days to MDUFA III decision	0	172	165	152	0
60th Percentile FDA days to MDUFA III decision	0	176	165	177	0
80th Percentile FDA days to MDUFA III decision	0	177	171	177	0
Maximum FDA days to MDUFA III decision	0	180	171	177	0
Average Industry days to MDUFA III decision	0	137.00	120.00	207.00	0.00
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	0	41	56	0	0
60th Percentile Industry days to MDUFA III decision	0	178	56	207	0
80th Percentile Industry days to MDUFA III decision	0	284	305	207	0
Maximum Industry days to MDUFA III decision	0	317	305	207	0
Average Total days to MDUFA III decision	0	310.00	285.00	268.00	0.00
20th Percentile Total days to MDUFA III decision	0	172	171	152	0
40th Percentile Total days to MDUFA III decision	0	218	221	152	0
60th Percentile Total days to MDUFA III decision	0	358	221	384	0
80th Percentile Total days to MDUFA III decision	0	460	464	384	0
Maximum Total days to MDUFA III decision	0	479	464	384	0

Table 1.7 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	0	0	0	0
Average FDA days to MDUFA III decision	303.00	0.00	0.00	0.00	0.00
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	41.00	0.00	0.00	0.00	0.00
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	344.00	0.00	0.00	0.00	0.00
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	1
Number with MDUFA decision	0	6	3	2	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 1.9 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	4
SI over 90 FDA days	0	0	1	1	0
SI pending within 90 FDA days	0	0	0	0	1
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	0	0
MDUFA III Decisions	2	1	4	3	2
MDUFA III Decisions within 180 FDA Days	2	1	4	3	2
Supplements pending MDUFA III Decision	0	0	0	2	3
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%	100.0%

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	3	2
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0.0%	0.0%	0.0%	0.0%	0.0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0	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 - 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	3
MDUFA III Decisions within 90 FDA Days	3	2	5	3	3
Supplements pending MDUFA III Decision	0	0	0	0	1
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	3
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	1
Number with a decision (MDUFA or Non-MDUFA)	1	6	3	2	0
% of FY closed	100.0%	100.0%	100.0%	100.0%	0.0%

Section 6 510(k) Center Level Metrics

Table 6.1 CBER – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	57	56	44	53
Closed before RTA action	1	1	0	1	3
Number Accepted	40	35	37	31	39
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	3
Number Not Accepted	19	21	19	12	6
Rate of submissions not accepted for review	32.2%	37.5%	33.9%	27.9%	12.8%

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	46
SI within 60 FDA days	41	49	49	42	41
SI over 60 FDA days	6	2	1	0	0
SI pending within 60 FDA days	0	0	0	0	5
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	87.2%	96.1%	98.0%	100.0%	100.0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	47	51	50	42	41
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	56
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	46
Non-MDUFA III Decisions	8	5	10	5	2
MDUFA III Decisions (SE/NSE)	39	46	41	34	22
MDUFA III Decisions within 90 FDA Days	37	46	41	34	22
510(k)s pending MDUFA III Decision	0	0	1	3	22
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0	0	0
Current Performance Percent within 90 FDA Days	94.9%	100.0%	100.0%	100.0%	100.0%

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	1.62	1.27
Number with MDUFA III decision	39	46	41	34	22
Average FDA days to MDUFA III decision	71	113	80	69	63
20th Percentile FDA days to MDUFA III decision	30	37	30	30	29
40th Percentile FDA days to MDUFA III decision	81	67	76	77	60
60th Percentile FDA days to MDUFA III decision	87	88	84	83	86
80th Percentile FDA days to MDUFA III decision	89	90	88	87	88
Maximum FDA days to MDUFA III decision	94	588	308	90	90
Average Industry days to MDUFA III decision	76	87	65	62	9
20th Percentile Industry days to MDUFA III decision	0	0	0	0	0
40th Percentile Industry days to MDUFA III decision	19	0	0	18	0
60th Percentile Industry days to MDUFA III decision	83	44	29	57	0
80th Percentile Industry days to MDUFA III decision	150	182	123	130	17
Maximum Industry days to MDUFA III decision	370	381	399	292	74
Average Total days to MDUFA III decision	147	201	145	131	72
20th Percentile Total days to MDUFA III decision	30	40	58	72	29
40th Percentile Total days to MDUFA III decision	108	81	79	83	60
60th Percentile Total days to MDUFA III decision	171	126	110	125	89
80th Percentile Total days to MDUFA III decision	244	272	207	216	101
Maximum Total days to MDUFA III decision	460	958	707	371	160

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	46
Number with MDUFA decision	39	46	41	34	22
Number of SE decisions	36	43	37	30	22
Number of NSE decisions	3	3	4	4	0
Number of Withdrawals	8	5	10	5	2
Number deleted	0	0	0	0	0
Rate of SE decisions	92.3%	93.5%	90.2%	88.2%	100.0%
Rate of NSE decisions	7.7%	6.5%	9.8%	11.8%	0.0%
Rate of Withdrawals	17.0%	9.8%	19.2%	11.9%	4.3%
Rate of Deleted	0.0%	0.0%	0.0%	0.0%	0.0%

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0	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	46
Number of Traditional submissions	34	42	40	35	36
Number of Special submissions	9	9	12	7	9
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	46
Currently Under Review	0	0	1	3	22
Number with Non-MDUFA Decision	8	5	10	5	2
Number with MDUFA III Decision	39	46	41	34	22
Percent of cohort closed	100.0%	100.0%	97.6%	91.9%	50.0%
Number with MDUFA III decision after trimming the upper and lower 2%	37	44	39	32	20
Average Total Time to MDUFA III decision	147	201	145	131	72

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	1
Number of De Novo Petitions with Decision Pending	0	0	0	0	1
Average Number of Days to Decision	577	0	314	0	120

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	42
Number with meetings or teleconferences granted	29	41	45	39	42
Number with meeting granted and industry cancelled	13	7	12	13	11
Number with meeting granted and FDA cancelled	0	1	1	1	0
Number with meeting granted and pending within timeframe	0	0	0	0	9
Number with meeting granted and pending outside timeframe	0	0	0	0	1
Number with meetings or teleconferences held	15	33	32	25	21
Average days to meeting	65	68	68	77	79
20th Percentile days to meeting	55	44	58	62	68
40th Percentile days to meeting	58	62	68	79	76
60th Percentile days to meeting	61	78	76	83	79
80th Percentile days to meeting	70	92	83	86	89
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	2
Number of Standard BLA First Actions less than or equal to 10 months	9	10	2	26	0
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	0
Number of Priority BLA First Actions greater than 10 months	0	0	0	0	0
Number of Priority BLAs Pending	0	0	0	0	1

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	0
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0	17	1	1	0
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	37
Number of Standard PAS Supplements First Actions less than or equal to 4months	20	6	19	47	32
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	5

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	12
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	28

IDEs

CBER – Annual General Metric Report for IDEs

#	Measure	Description	FY13	FY14	FY15	FY16	FY17 (01Oct16-30Sep17)
1	Number of IDEs received	Number of IDEs received in the fiscal year.	14*	23	17	20	14
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	1.25 (15/12)
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)	0.33 (4/12)

FY 2017 Medical Device User Fee Collections
as of September 30th, 2017
Excludes Unearned Fees

	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$91,986,338	\$482,921	\$91,503,417		
Application Fees	\$44,997,703	\$791,801	\$44,205,902		
Total	\$136,984,041	\$1,274,722	\$135,709,319	\$126,083,000	108%

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

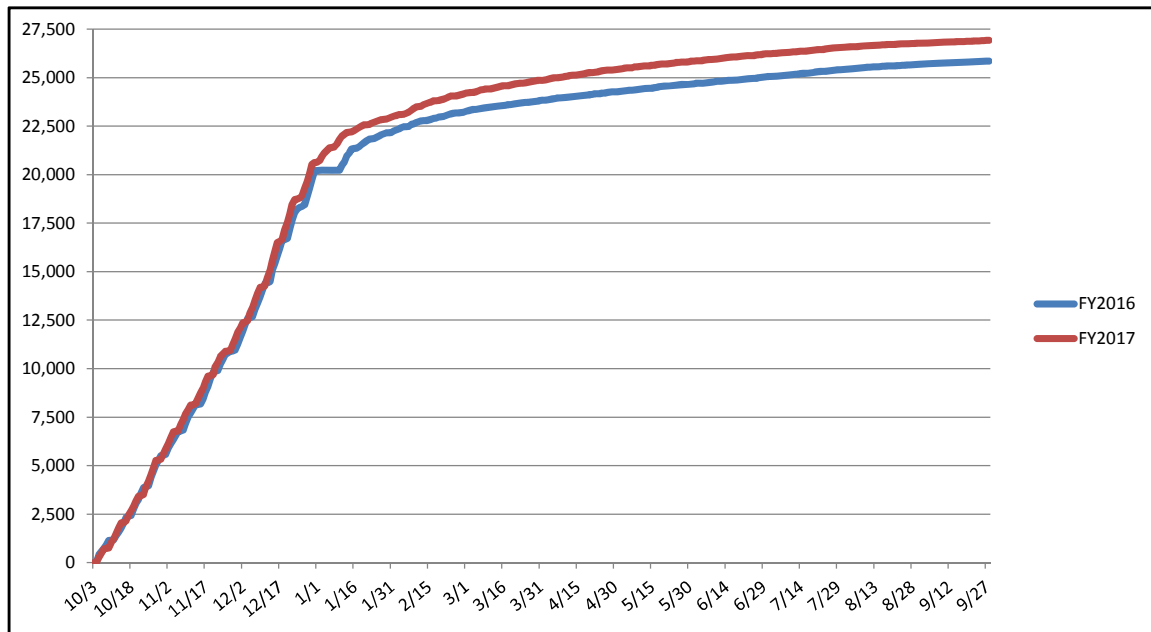
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
MD I	\$21,620,549	\$26,281,779	\$31,790,187	\$34,417,751	\$27,847,812
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
MD II	\$47,720,674	\$57,418,055	\$63,876,407	\$70,063,039	\$65,691,665
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
MD III	\$101,085,001	\$121,013,993	\$134,492,926	\$146,057,769	\$135,709,319

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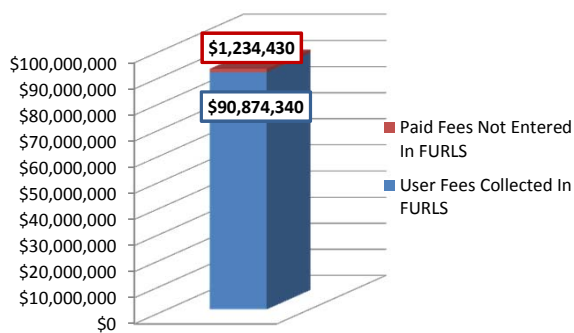
MDUFA III, Registrations, Fourth Quarter Summary FY2017

Registrations by Type Est Type	FY17 Year End Active Totals			FY16 Year End Active Totals			FY17 vs FY16
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,135	9,611	15,746	6,067	9,150	15,217	103.48%
Contract Manufacturer	1,074	1,441	2,515	1,010	1,345	2,355	106.79%
Contract Sterilizer	71	132	203	75	129	204	99.51%
Specification Developer	1,737	518	2,255	1,703	469	2,172	103.82%
Reprocessor of Single Use Devices	29	1	30	32	1	33	90.91%
U.S. Manufacturer of Export Only Devices	128	0	128	120	0	120	106.67%
Repackager/Relabeler	1,159	202	1,361	1,165	177	1,342	101.42%
Remanufacturer	23	10	33	21	10	31	106.45%
Foreign Exporter/Private Label Distributor	0	921	921	0	774	774	118.99%
Initial Importer	3,327	0	3,327	3,294	0	3,294	101.00%
Unknown	16	12	28	15	12	27	103.70%
Total:	13,699	12,848	26,547	13,502	12,067	25,569	103.82%

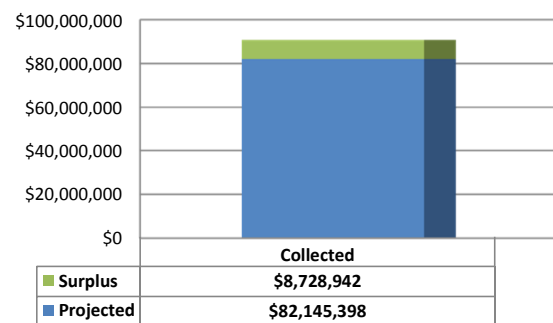
Registration Progress - FY2016 Versus FY2017



User Fees Collected Versus User Fees Paid



**User Fee Progress
Goals - \$82,145,398 fees; 24,289 Registrations**



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Center for Devices and Radiological Health Internal Training Summary Report

Q4 FY17

October 2016 – September 2017

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

As of: 10/10/2017

The FDA continues to invest in internal and external training opportunities supporting the medical device review process. The Division of Employee Training and Development (DETD) is CDRH's internal resource for scientific, regulatory, leadership training, career development programs, and customized learning opportunities. We help further the Center's mission of regulating medical devices and radiation-emitting products by championing employee growth across the Center's eight offices. Our approach to improving performance combines classroom, experiential, and online learning with mentoring, self-study initiatives, and specialty programs. We are committed to providing CDRH employees with the knowledge and skills needed to maximize their organizational and individual potential.

Table X provides a summary of internal training conducted in CDRH between October 1, 2016 and September 30, 2017. DETD offered 574 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and program activities.

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Table X - FY17 CDRH Internal Training Conducted by DETD:*October 1, 2016 - September 30, 2017*

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA III	5	94	157
	ELP	23	303	3656
	Other LAW	233	18699	17409
<i>LAW Subtotal:</i>		<i>261</i>	<i>19096</i>	<i>21222</i>
Leadership Development Training (LED)	LEAD: Leadership for Managers	77	853	3176
	Leadership for Non-Managers	21	266	1911
	Other LED	18	328	2015
<i>LED Subtotal:</i>		<i>116</i>	<i>1447</i>	<i>7102</i>
Professional Development (PRO) Training	New Employee Orientation (NEO)	4	109	750
	Other PRO	72	1174	9542
<i>PRO Subtotal:</i>		<i>76</i>	<i>1283</i>	<i>10292</i>
Science (SCI) Training	All SCI	<i>100</i>	<i>2527</i>	<i>4813</i>
Center-Specific Information Technology (CIT) Training	All CIT	<i>21</i>	<i>517</i>	<i>587</i>
Grand Total:		574	24870	44016

Premarket Reviewer Training - RCP

Reviewer Certification Program (RCP) Refresh:

RCP was revised in June 2016, condensed into a 27-hour program consisting of both online and classroom courses that are essential to new reviewers in their first 60 days of hire. While the goals and missions are consistent with the earlier version of RCP, the condensed course design means reviewers will get the most salient core knowledge in a more timely fashion. After completion of the 27 hours of learning, reviewers will enroll in advanced courses designed to further enhance their skills. In this updated format, the components include:

- 15 classroom courses, including a program Orientation and Capstone, totaling 22.5 hours of training
- 5 online courses, totaling 4.5 hours
- 7 Advanced courses, to be taken within a year of employment
- Practical activities and hands-on exercises
- Knowledge assessments

RCP Refresh Training by Cohort: *October 1, 2016 – September 30, 2017*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall I 2016 Cohort	15	5	ODE	15	238	305
			OIR	2	35	44
			OSEL	13	202	259
Fall II 2016 Cohort	15	5	ODE	14	88	108
			OIR	3	31	37
			OSEL	5	52	65
Spring 1 2017 Cohort	11	9	ODE	21	410	492
			OIR	2	42	50
			OSEL	6	102	123
Spring 2 2017 Cohort	11	10	OC	17	308	366
			ODE	3	61	72
			OSEL	4	80	94
Summer 1 2017 Cohort	11	10	OC	15	290	362
			ODE	3	48	61
			OIR	1	15	20
			OSB	5	102	127
Summer 2 2017 Cohort	11	10	OC	2	37	44
			OCE	6	91	110
			OIR	4	79	93
Total:	74	49	-	141	2311	2832

Premarket Reviewer Training - ELP

Experiential Learning Program (ELP):

CDRH offers an innovative learning opportunity for new and experienced review staff. The Experiential Learning Program (ELP) is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the premarket review of the resulting medical devices. The program fosters the premarket reviewers' understanding of how medical devices are developed, clinically tested, manufactured, and utilized.

ELP Training Completed: *October 1, 2016 – September 30, 2017*

Office	# of Site Visits	# of Attendees	Total Training Hours	Example Focus Areas
ODE	17	225	2608	<ul style="list-style-type: none">• Non-clinical testing – animal model• Reprocessing and Sterilization• Cardiac Electrophysiology• Neurostimulators• Standards Conformity
OIR	5	61	776	<ul style="list-style-type: none">• NGS• IVD Reagent Manufacturer• Antimicrobial susceptibility testing• Biocompatibility testing – IHC reagents
OSEL	1	17	272	<ul style="list-style-type: none">• Production and Calibration of Innovative Manufacturing Methods
Total:	23	303	3656	-

Leadership Training - LEAD

Leadership Enhancement and Development (LEAD) Program:

The LEAD Program is a Mandatory Supervisory Training Program targeting all CDRH Supervisors, Managers, and Non-Bargaining Unit Team Leaders. The LEAD curriculum supports the CDRH Management Competencies and addresses the supervisory training requirements as mandated in 5 CFR 412.

LEAD Training Completed: *October 1, 2016 – September 30, 2017*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	77	853	3176	<ul style="list-style-type: none"> • Coaching to Win Big • Crucial Accountability • Meetings that Work • Managing Former Peers • Facilitating Virtual Meetings

LEAD Training for ODE and OIR Completed: *October 1, 2016 – September 30, 2017*

Office	Total # of Managers/Supervisors	# of Training Participants	Training Hours Completed	Training Hours Required*	% of Required Training Hours Completed
ODE	72	52	812	1152	70%
OIR	43	26	288	688	42%
Total:	115	78	1100	1840	56%

*This data is based on the 16 hour minimum annual management training requirement for managers with more than 3 years of experience. New managers have an additional 24 hour training requirement, for a total of 40 hours. The total number of managers/supervisors was calculated at the beginning of the fiscal year (October 1, 2016) to serve as a baseline.

Leadership Training - LRP

Leadership Readiness Program (LRP):

The Leadership Readiness Program (LRP) is a one-year learning opportunity for employees considering a supervisory career path. The program facilitates learning in the areas of mentoring, self-study, classroom-based courses, and other practical activities. The target audience for this program is highly motivated non-managers at the GS 12, 13, and non-supervisory 14 levels or equivalent Commissioned Corps Officers rank, with a minimum of two years of FDA experience. Participants are selected for the one-year cohort program through a competitive process. They remain in their current position and participate in the LRP as a collateral activity.

LRP Participant Data:

LRP Program Year	Office	# of Enrolled Participants	# of Participant Completions
2006 – 2007	OIVD	3	3
	ODE	13	12
2008 – 2009	OIVD	3	3
	ODE	10	10
	Other	17	16
2010 – 2011	OIVD	3	3
	ODE	9	8
	Other	8	8
2012 – 2013	OIR	3	3
	ODE	6	6
	Other	11	11
2014 – 2015	OIR	2	2
	ODE	6	6
	Other	12	12
2016-2017	OIR	3	3
	ODE	9	9
	Other	8	8
Total:		126	123

CDRH Training Courses by Category:

The following section contains a sampling of DETD courses that occurred through FY15.

Regulatory and Law (LAW) Training:

Basic Food and Drug Law	This interactive course is designed to provide CDRH employees with a focused, in-depth knowledge of the Food, Drug, and Cosmetic Act and court precedents that govern the Agency's activities.
Benefit-Risk Guidance – Online	This online course outlines the factors to consider when making benefit-risk determinations in medical device Premarket Approval (PMA) application and De novo petitions.
FOI for Reviewers – Online	This course provides an overview of the Freedom of Information Act (FOIA) and provides additional information regarding the exemptions that apply when interacting with industry, consumers, and other domestic and foreign government agencies.
How to Write Deficiencies in Four-Part Harmony	This course provides staff with instruction regarding how to write deficiencies that are clear, concise and in the appropriate format. Through instructor- and coach-led lecture and interactive exercises, participants explore use of the 4-Part Harmony as addressed in the Guidance document.
How to Write Effective Pre-market Consulting Reviews	High quality consulting reviews are essential for communicating and documenting the pre-market review of medical devices. This course is led by experienced reviewers who describe the content required in pre-market consulting reviews and share best practices.
Humanitarian Use Devices and Humanitarian Device Exemption	This half-day seminar provides information on the Humanitarian Use Device (HUD) designation process and Humanitarian Device Exemption (HDE) review requirements, including an update on changes in legislation and guidance documents related to HUDs/HDEs in the FDA Safety and Innovation Act (FDASIA).
Mastering Technical Writing: A Plain Writing Workshop	This course teaches participants the basic elements of plain writing and how to use them to write succinct, well-written technical documents. It is based on best practices used by professional writers and features interactive exercises and peer feedback.

Investigational Device Exemption (IDE) Overview- Online	This course describes what an IDE is, how to obtain it, and how to address it in AIMS.
MDUFA III - Module 1: 510(k)s webcast – Online	Module 1: 510(k)s provides Center staff with an overview of the MDUFA III changes to the 510(k) program with respect to Refuse to Accept (RTA), Substantive Interaction (SI) Communication, Interactive Review (IR), MDUFA Performance Goals, and Missed MDUFA Decision (MMD) Communication.
MDUFA III - Module 2: PMAs webcast – Online	Module 2: PMAs provides Center staff with an overview of the MDUFA III changes to the PMA program with respect to Refuse to Accept (RTA), Refuse to File (RTF), Substantive Interaction (SI) Communication, Interactive Review (IR), MDUFA Performance Goals, and Missed MDUFA Decision (MMD) Communication.
MDUFA III - Module 3: Pre-Submissions webcast – Online	Module 3: Pre-Submissions provides Center staff with training on the draft Pre-Submission guidance document and MDUFA III commitments, including a description of the types of Pre-Submissions and the tracking process.
MDUFA III - Module 4: Electronic Workload Management webcast – Online	Module 4: Electronic Workload Management Enhancements provides Center staff with instruction on the new eCopy program, the DocMan/Alfresco management tool, digital signatures and the Center Tracking System (CTS) Dashboards.
MDUFA III - Module 5: CLIA Waivers webcast – Online	Module 5: CLIA Waivers provides Center staff with instruction on the new program and processing procedures, Substantive Interactive (SI) Communication, and MDUFA Performance Goals.
Signal Management Program - Online	This module provides an overview of the Signal Management Program (SMP), which is a Center-wide program for finding, reporting, and resolving signals associated with marketed medical devices. Viewers will discover why CDRH has a consistent, systematic approach to handling signals and how their contribution can impact medical device safety.
Distinguishing Medical Device Recalls from Medical Device Enhancements	This course provides CDRH staff with instruction on the distinctions between medical device recalls and medical device enhancements.

Leadership Development Training for Managers and Non-Managers:

Handling People with Diplomacy & Tact	Employees will learn the critically important big-picture mentality of their work, a blueprint for mega productivity, and a brand new sense of unity. Participants will also learn techniques to empower their team, and make each team member responsible and accountable for their actions.
LEAD: CDRH Customer Service Training	Customer service is one of CDRH's 2014-2015 Strategic Priorities. Providing excellent customer service improves our interactions with stakeholders and colleagues and supports better regulatory outcomes, which improves public health. As part of this strategic priority implementation, CDRH has adopted Standards of Excellence.
LEAD: CDRH Manager Orientation Program	To provide managers with detailed resources to access professional development and HR information for themselves as well as the employees they supervise.
LEAD: Crucial Conversations	This course teaches participants the skills and tools necessary for stepping up to and holding conversations that occur when stakes are high, opinions differ, and emotions run strong.
LEAD: The Successful Mentor	This workshop provides the participants with a learning experience that will enable them to maximize the mentoring experience.
LEAD: Time Management for Leaders	This training provides managers with the skills needed to monitor where their time goes, set priorities, manage tasks, and distinguish urgent from important activities in order to achieve their goals.

Professional Development (PRO) Training:

Briefing and Public Speaking Skills	This workshop will review a systematic approach to planning and delivering effective, focused presentations to small or large groups. It will cover techniques for establishing objectives, remaining on target, and responding to difficult questions or challenges.
Critical Thinking and Problem Solving	This one-day workshop develops critical thinking skills for practical everyday use. Participants learn to assist work teams in understanding complex problems, methods for evaluating the possibilities of various decisions and increase their productivity and confidence for the constructive resolution of problems.

Critical TOP Thinking	This training provides an overview and tools for Thought Optimized Processing (TOP) Thinking. Participants will learn how to get more accomplished in a better and pragmatic way while maintaining precision and accuracy. Instruction will also address the ability to think creatively and critically and ensure that reasoning is objective.
Emotional Intelligence	This training provides participants with a proven set of skills in four areas of competency: self-awareness, self-management, social awareness, and social adeptness.
Event-Driven Leadership	This course supports organizational leadership in developing the competencies to deal with ongoing changes and events that impact the professional environment.
Influencing Other for High Impact	This seminar focuses on the skills and strategies necessary to increase the likelihood that others will say "yes". Instruction includes the opportunity to translate theory into practice.
Sparkling Creativity and Innovation	This course offers strategies and techniques to help the participant harness innovative thinking, find solutions to problems and enhance their own and others' ability to think more clearly and make better decisions.

Science (SCI) Training:

Basics of Flow Cytometry	Flow cytometry is used as a powerful technique in many fields, including diagnosis of hematological malignancy, detection of minimal residual disease (MRD), determination of CD4/CD8 ratio in HIV, and nanotechnology.
Basics of Human Factors Engineering and Device Design	Human factors engineering is a discipline that blends engineering design with human psychology, kinesiology, and biomechanics. The goal is to apply knowledge of human cognition and physical limitations to the design of systems, such as tools, tasks, devices, software, work areas, etc.
CDRH Laboratory Waste Management – online	This course gives an overview of the requirements for waste handling in CDRH laboratories, as well as a brief description of Emergency Procedures for the laboratory. These requirements are in place to establish regulatory compliance with entities such as EPA, Maryland Department of the Environment (MDE), and Montgomery County.

Regenerative Medicine Series	The Regenerative Medicine Seminar Series offers a variety of thought-provoking seminars that examine restoration and function of the human form within the context of translational research involving medical devices and biologics.
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Center-Specific IT (CIT) Training

Learning about SharePoint	This training provides participants with a basic overview of SharePoint, examples of how it is used in CDRH and how to find additional resources. The relationship between SharePoint and Knowledge Management is also discussed.
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