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

July 30, 2015
10:00 A.M.

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- *Paul Gadiock, CDRH-OCD.*

FDA MDUFA Performance — Actions through June 30, 2015

- Report on decisions goals for 3rd Quarter of FY 2015.
    - CDRH: *Barbara Zimmerman, CDRH.*
    - CBER: *Sheryl Kochman, CBER.*

Qualitative Update on Finances – 3rd Quarter of FY 2015

- User fee receipts through the 3rd Quarter of FY 2015 – *Maurille Beheton and David Miller, FDA-OFM.*

CDRH Registration and Listing

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

Independent Assessment

- Progress and update- *Raphaela (Madonna) Simon*, *FDA-OC*.

CDRH Staff Training Update

- *Jacqueline Woodard, CDRH-OCE.*

Other

- RTA Update–*CDRH-ODE*
- CDRH Staffing update

Set date for next meeting, following close of Q4 FY 2015 -Target Date: **TBD**

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Medical Device Guidance Documents
(Issued in FY 2015)

(April 1, 2015 through June 30, 2015) (Quarter 3)

39. Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings—Draft Guidance for Industry and Food and Drug Administration Staff (6-30-15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm452804.pdf
38. Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance Environment for Multi-Configuration Passive Medical Devices—Draft Guidance for Industry and Food and Drug Administration Staff (6-29-15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm452644.pdf
37. Unique Device Identification: Direct Marking of Devices—Draft Guidance for Industry and Food and Drug Administration Staff (6-26-15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm452262.pdf
36. Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions—Draft Guidance for Investigational Device Sponsors, Sponsor-Investigators, and Food and Drug Administration Staff (6-18-15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm448520.pdf
35. Content and Format of Abbreviated 510(k)s for Early Growth Response 1 Gene Fluorescence In-Situ Hybridization Test System for Specimen Characterization Devices—Guidance for Industry and Food and Drug Administration Staff (6-17-15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm416131.pdf
34. Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures—Guideline for Industry and Food and Drug Administration Staff (5-27-15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm448520.pdf
33. Patient Preference Information—Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Device Labeling—Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders (5/18/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm446680.pdf
32. Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff (5/18/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm446729.pdf
31. Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices– Draft Guidance for Industry and Food and Drug Administration Staff

(5/6/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm444591.pdf

30. Acceptance of Medical Device Clinical Data From Studies Conducted Outside the United States– Draft Guidance for Industry and Food and Drug Administration Staff (4/21/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm443133.pdf
29. Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval– Guidance for Industry and Food and Drug Administration Staff (4/13/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm393994.pdf
28. Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions– Guidance for Industry and Food and Drug Administration Staff (4/13/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm393978.pdf
27. Procedures for Meetings of the Medical Devices Advisory Committee– Draft Guidance for Industry and Food and Drug Administration Staff (4/1/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm440348.pdf

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

26. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling– Guidance for Industry and Food and Drug Administration Staff (3/17/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm253010.pdf
25. Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices – Draft Guidance for Industry and Food and Drug Administration Staff (2/25/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm435355.pdf
24. Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors – Guidance for Industry and Food and Drug Administration Staff (2/18/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm434502.pdf
23. Safety Considerations To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications – Guidance for Industry and Food and Drug Administration Staff (2/11/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313385.pdf
22. Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices – Draft Guidance for Industry and Food and Drug Administration Staff

(2/11/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm433165.pdf

21. Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices - Guidance for Industry and Food and Drug Administration Staff (2/9/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm401996.pdf
20. Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff (2/9/15) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf
19. Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails – Draft Guidance for Industry and Food and Drug Administration Staff (1/27/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm431312.pdf
18. General Wellness: Policy for Low Risk Devices – Draft Guidance for Industry and Food and Drug Administration Staff (1/20/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429674.pdf
17. Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types – Draft Guidance for Industry and Food and Drug Administration Staff (1/20/15) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf
16. Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes – Draft Guidance for Industry and Food and Drug Administration Staff (1/20/15) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm430550.pdf

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

15. Radiation Biodosimetry Devices - Draft Guidance for Industry and Food and Drug Administration Staff (12/30/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM427866.pdf
14. Transfer of a Premarket Notification (510(k)) Clearance: Questions and Answers - Draft Guidance for Industry and Food and Drug Administration Staff (12/22/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM427385.pdf
13. Minimizing Risk for Children's Toy Laser Products - Guidance for Industry and Food and Drug Administration Staff (12/19/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM363731.pdf
12. Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR)

Environment - Guidance for Industry and Food and Drug Administration Staff (12/11/14) (L2) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM107708.pdf

11. Infusion Pumps Total Product Life Cycle - Guidance for Industry and Food and Drug Administration Staff (12/02/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209337.pdf
10. Recommendations for Labeling Medical Products To Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex - Guidance for Industry and Food and Drug Administration Staff (12/02/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM342872.pdf
9. Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators - Guidance for Industry and Food and Drug Administration Staff (11/25/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf
8. Design Considerations for Devices Intended for Home Use – Guidance for Industry and Food and Drug Administration Staff (11/24/14) (L2) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM331681.pdf
7. Combined Functionality for Molecular Diagnostic Instruments – Guidance for Industry and Food and Drug Administration Staff (11/12/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM346553.pdf
6. Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex and Genetic Mutations Associated with Antibiotic Resistance in Respiratory Specimens – Guideline for Industry and Food and Drug Administration Staff (10/22/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM419468.pdf
5. Distinguishing Medical Device Recalls From Medical Device Enhancements - Guidance for Industry and Food and Drug Administration Staff (10/15/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM418469.pdf
4. Flow Cytometric Devices – Draft Guidance for Industry and Food and Drug Administration Staff (10/14/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM418205.pdf
3. Food and Drug Administration Notification and Medical Device Reporting for Laboratory Developed Tests – Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories (10/03/14)

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416684.pdf

2. Framework for Regulatory Oversight of Laboratory Developed Tests - Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories (10/03/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416685.pdf
1. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff (10/02/14) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf

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Quarterly Update on
Medical Device Performance Goals
----MDUFA III CDRH Performance Data ----
Action through 30 June 2015

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Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Act
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology Devices
DIHD	Division of Immunology and Hematology Devices
DMD	Division of Microbiology Devices
DMGP	Division of Molecular Genetics and Pathology
DNPMD	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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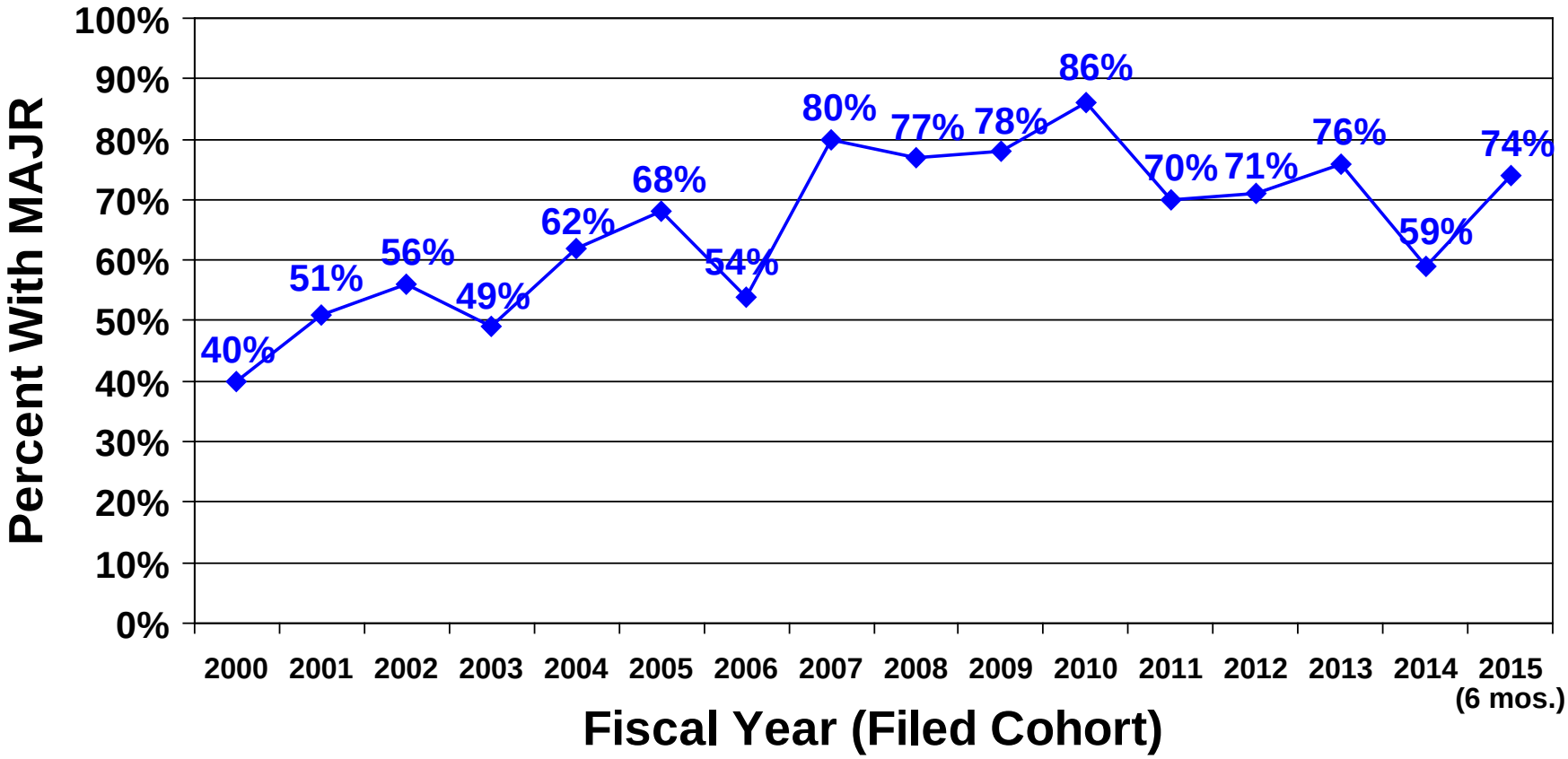
PMAs

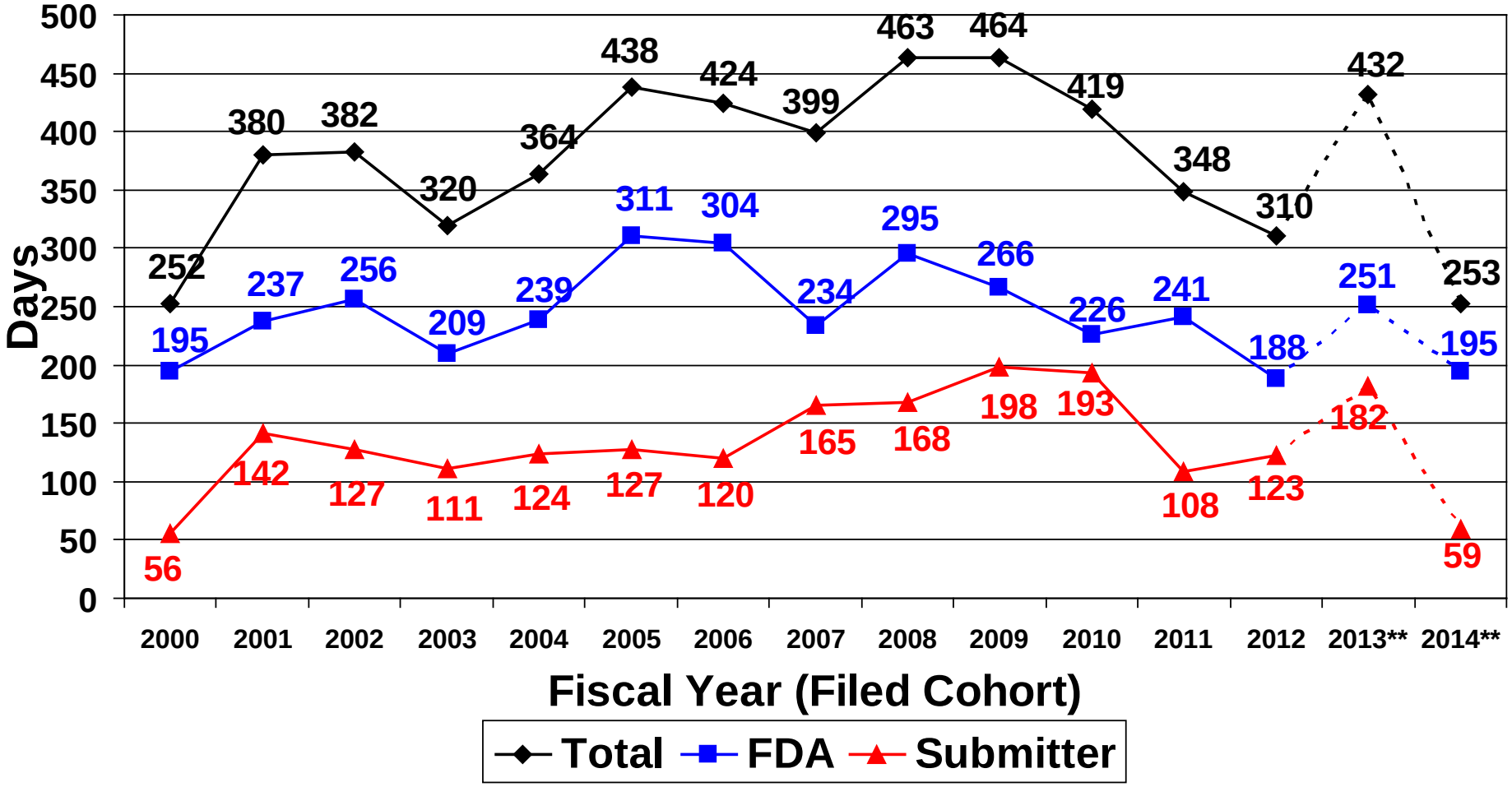
Percent of PMAs With Major Deficiency Letter (MAJR) on 1st FDA Review Cycle*



*Includes original PMAs only; FY 2013 - FY 2015 are receipt cohorts including PMAs filed as of 03/31/2015, prior cohorts are filed cohorts; FY 2014 and FY 2015 (6 mos.) exclude 1 PMA and 3 PMAs, respectively, for which the 1st cycle was incomplete as of 06/30/2015, data for FY 2014 and FY 2015 will change

Average Time to MDUFA Decision: PMAs*

(As of June 30, 2015)

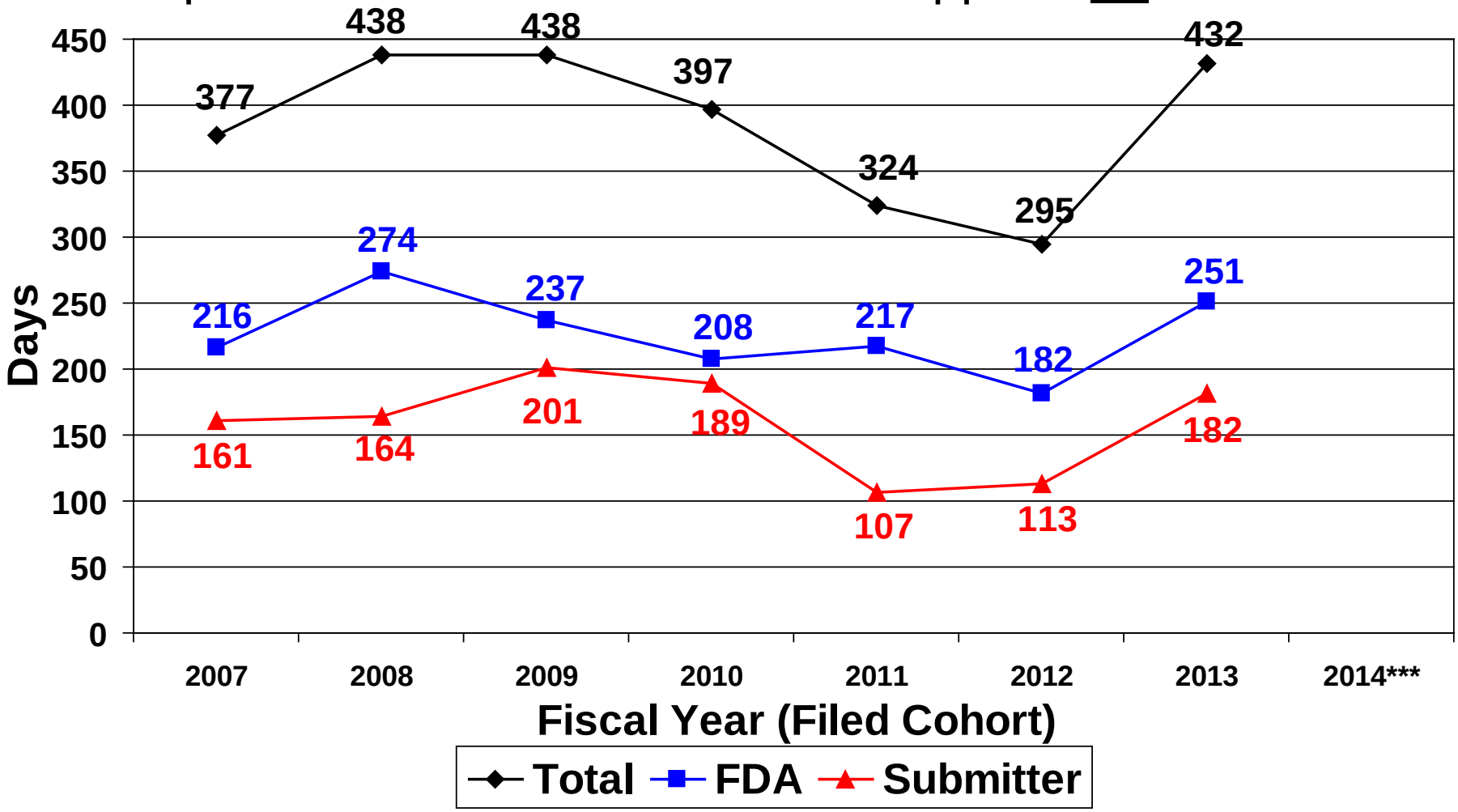


*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 06/30/2015, prior cohorts are filed cohorts; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY13 = 97% (28/29); FY14 = 79% (22/28)

Average Time to MDUFA Decision: PMAs*

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



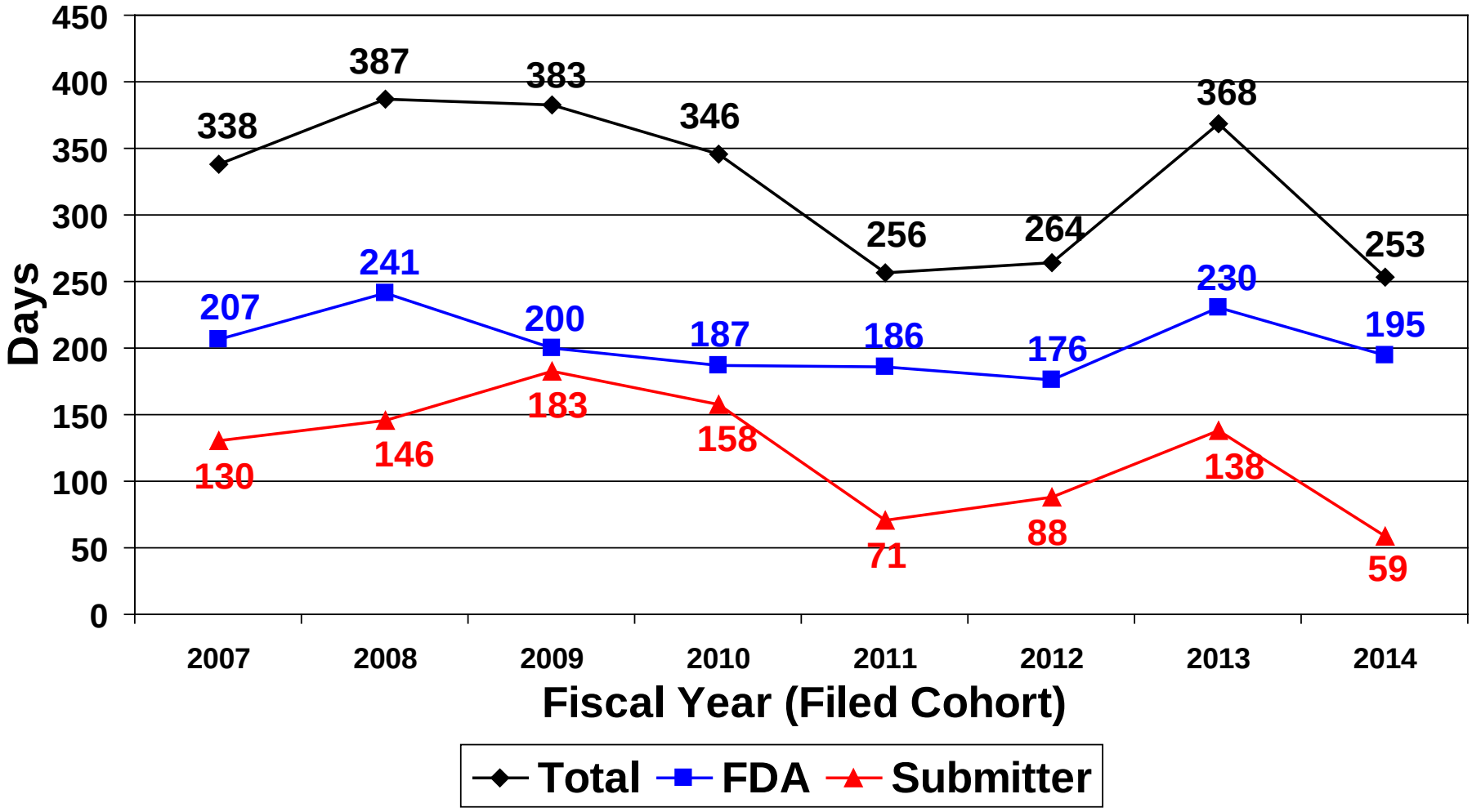
*Includes original PMAs only; times may not add to total due to rounding

**Proportion of cohort closed (MDUFA decision) in this comparison:
FY07 = 34/35; FY08 = 29/30; FY09 = 31/32; FY10 = 42/43; FY11 = 42/43; FY12 = 23/24; FY13 = 28/29

***FY14 cohort is not yet 97% closed (as of 06/30/2015)

Average Time to MDUFA Decision: PMAs*

- Comparison of Filed Cohorts When Approx. 79% Closed** -

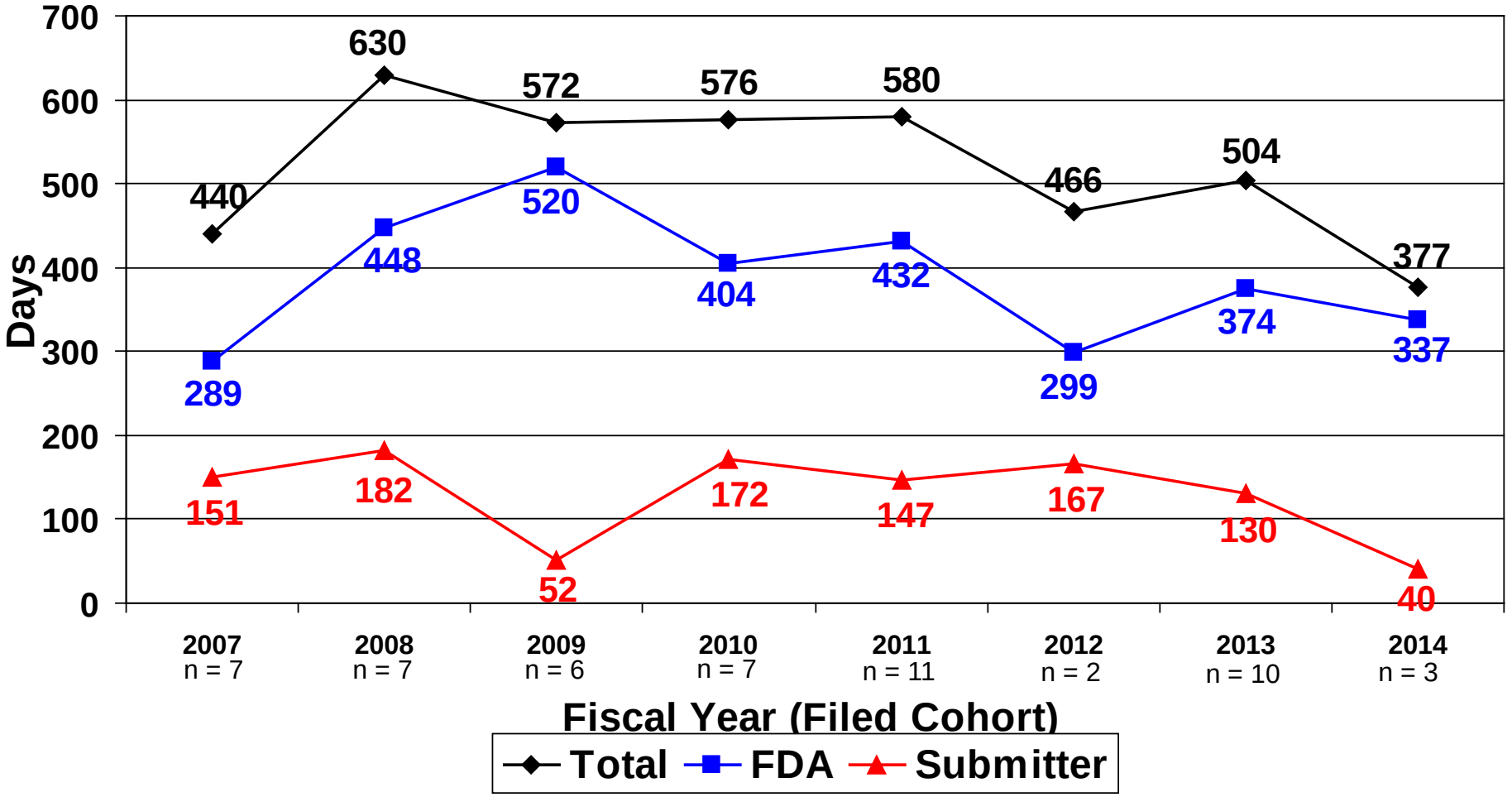


*Includes original PMAs only; times may not add to total due to rounding

**Proportion of cohort closed (MDUFA decision) in this comparison:
FY07 = 28/35; FY08 = 25/30; FY09 = 25/32; FY10 = 34/43; FY11 = 34/43; FY12 = 19/24;
FY13 = 23/29; FY14 = 22/28

Average Time to MDUFA Decision: PMAs With Panel Review*

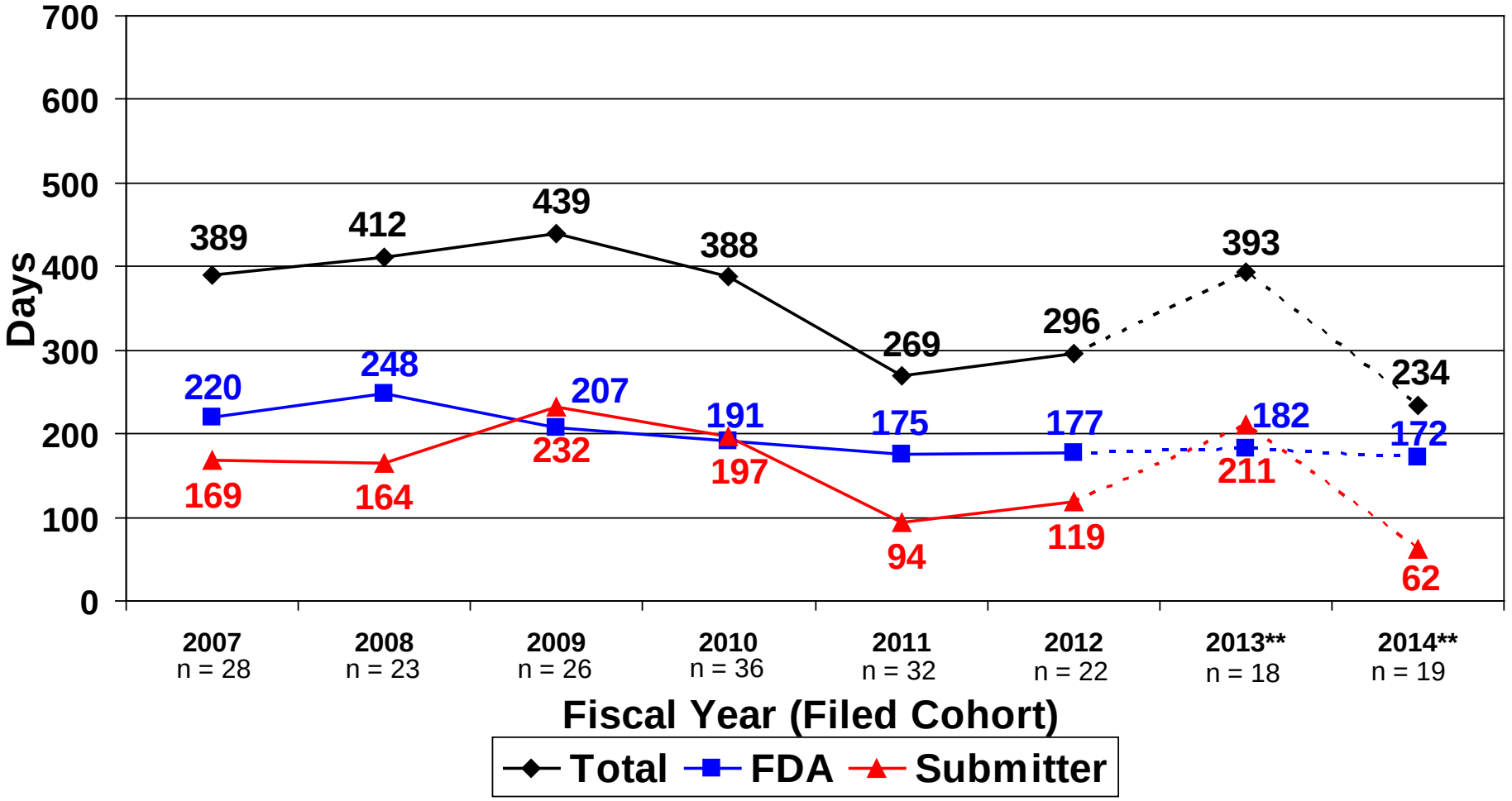
(As of June 30, 2015)



***Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 06/30/2015, prior cohorts are filed cohorts; times may not add to total due to rounding; all cohorts are closed (MDUFA decision) as of 06/30/2015**

Average Time to MDUFA Decision: PMAs Without Panel Review*

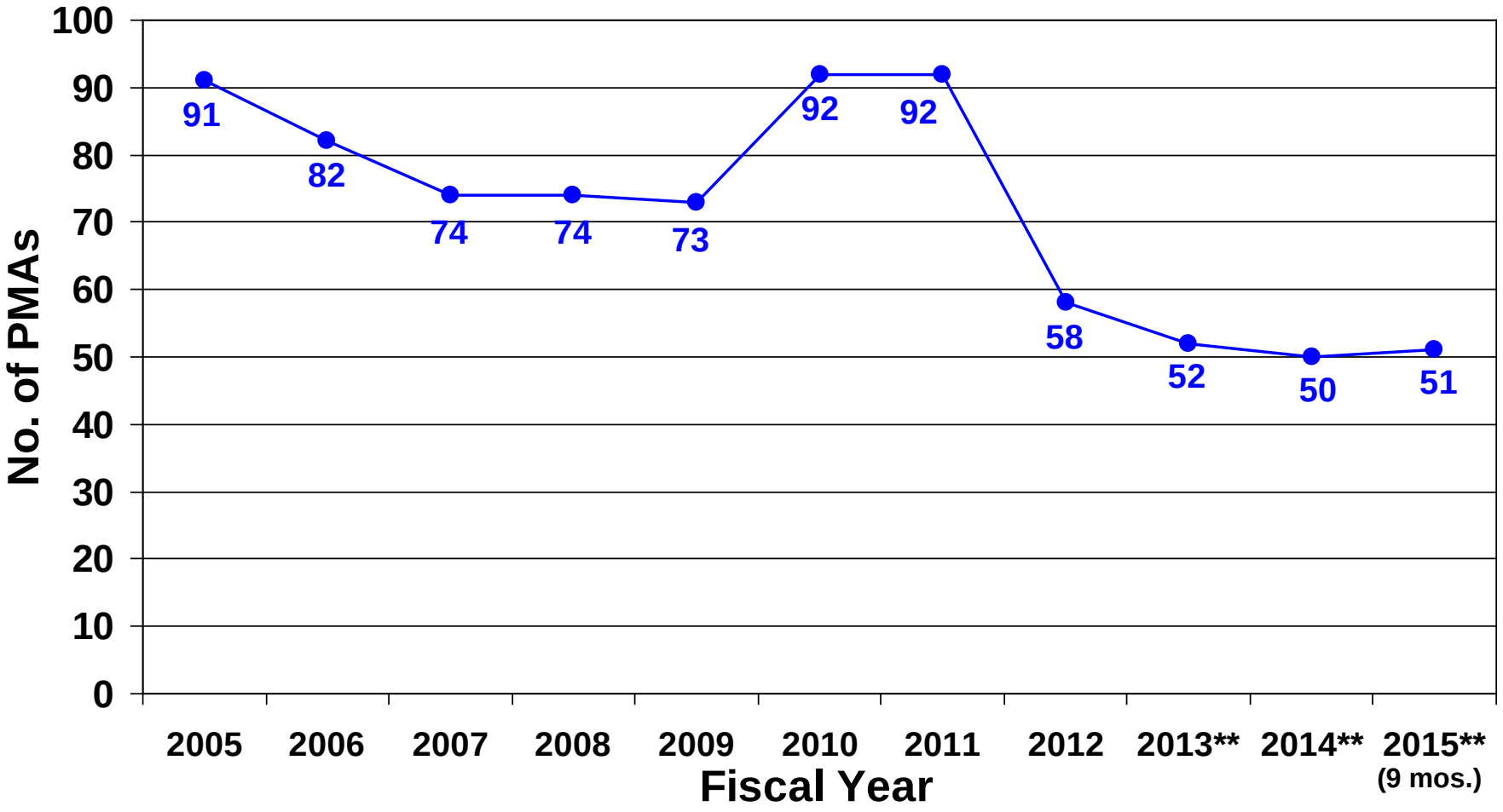
(As of June 30, 2015)



*Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of 06/30/2015, prior cohorts are filed cohorts; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY13 = 95% (18/19); FY14 = 76% (19/25)

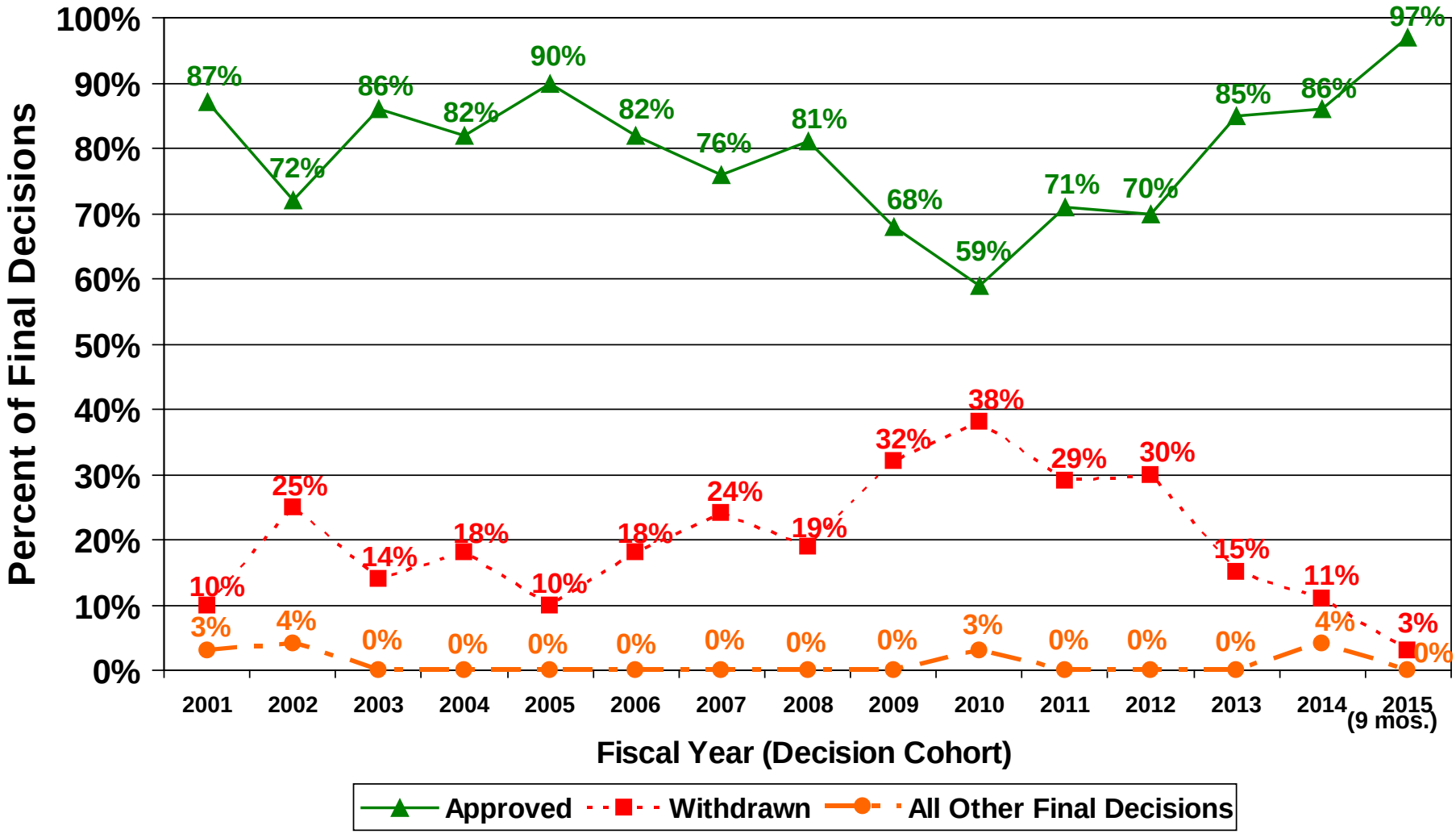
PMAs Pending* at End of Year



*Original PMAs under review or on hold; FY 2015 is as of 06/30/2015

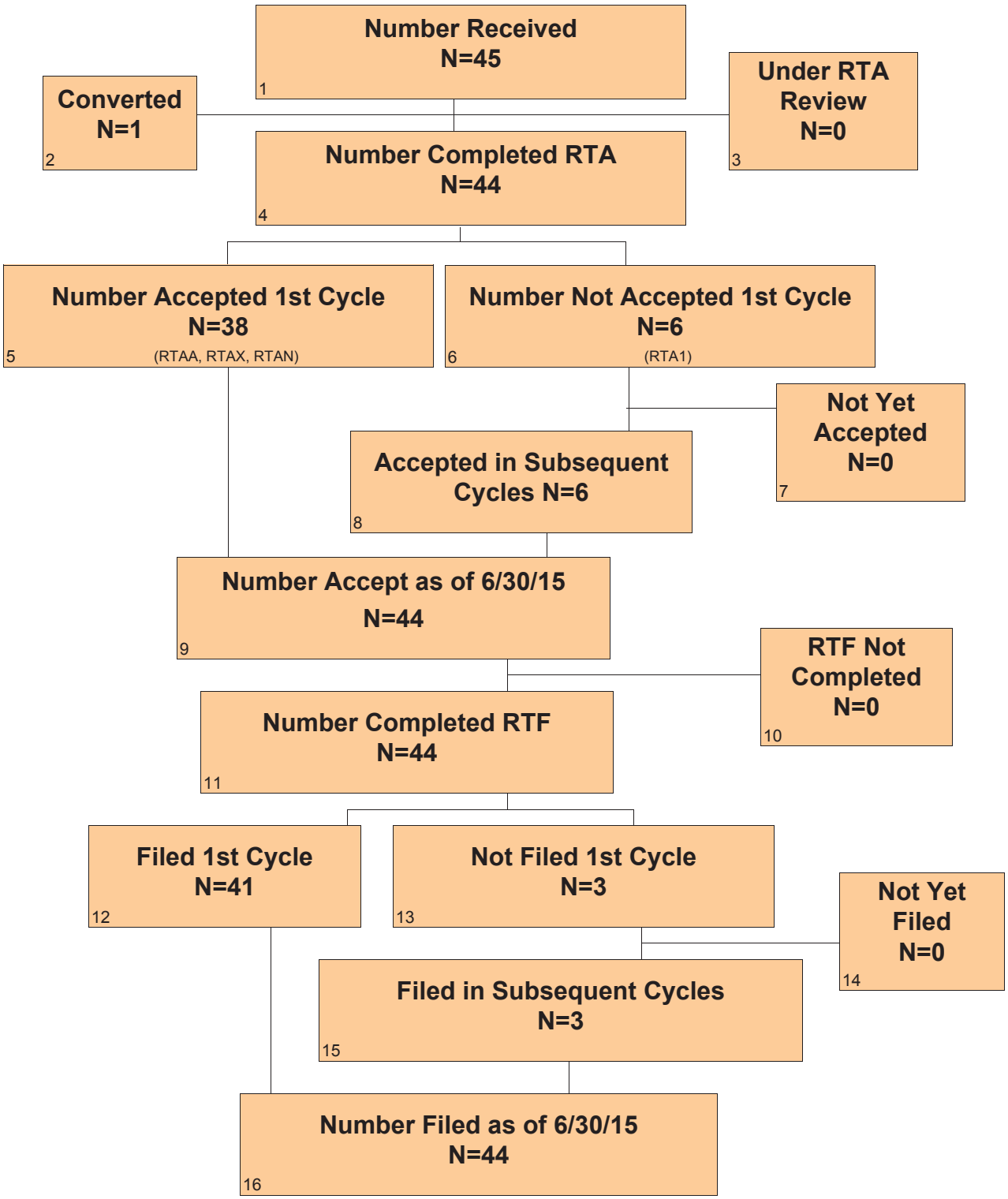
**Excludes FY 2013 - FY 2015 receipts that were not accepted for review at year's end; FY 2015 increase reflects increase in filed PMAs (40 PMA annual rate compared to 24, 29, and 28 for FY 2012 – FY 2014, respectively)

Percent of PMAs Approved*

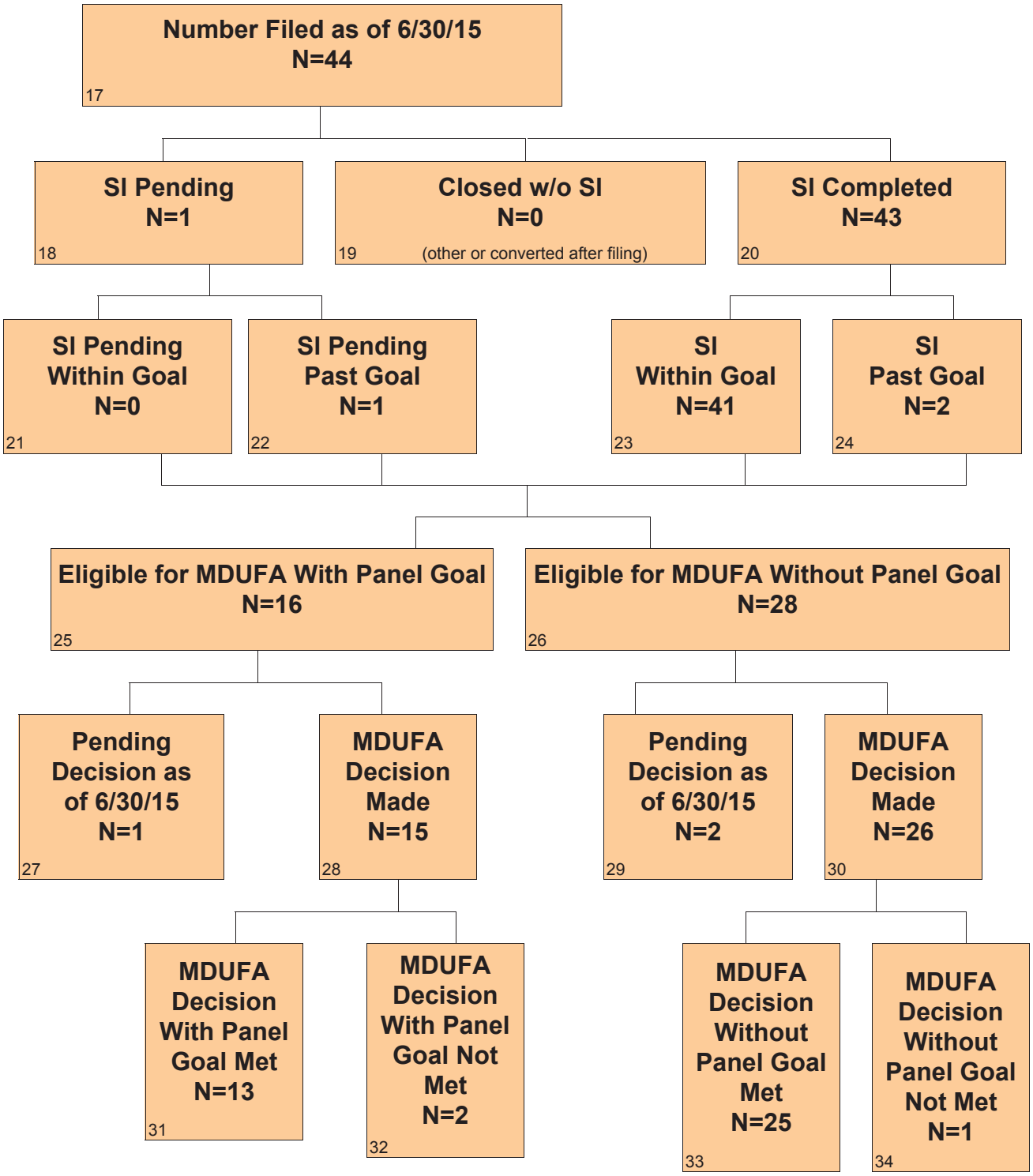


*Based on original PMAs that were accepted for filing as of 06/30/2015; percentages may not add to 100% due to rounding

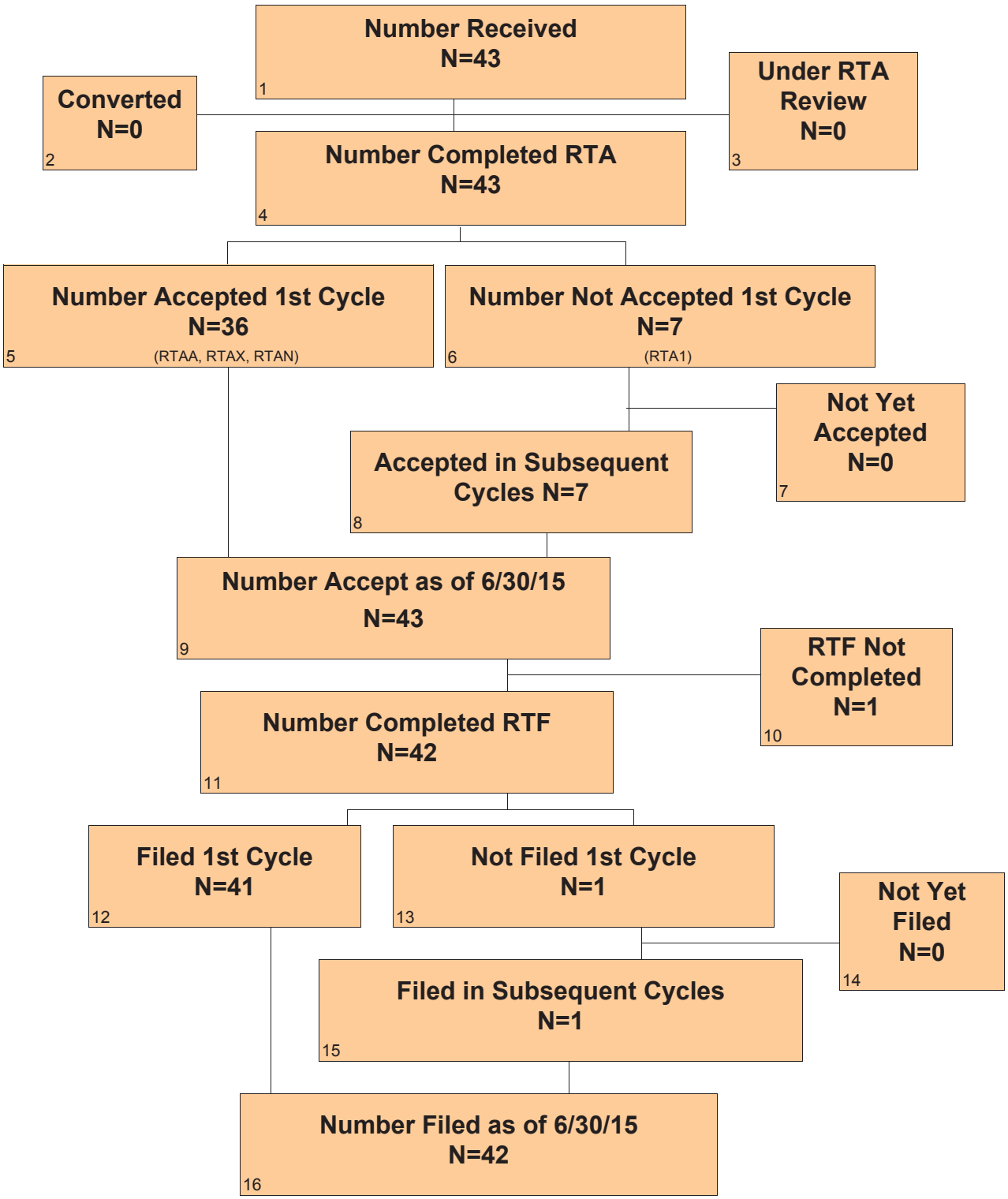
CDRH PMA Original and Panel Track Supplements - FY 2013 As of 6/30/15



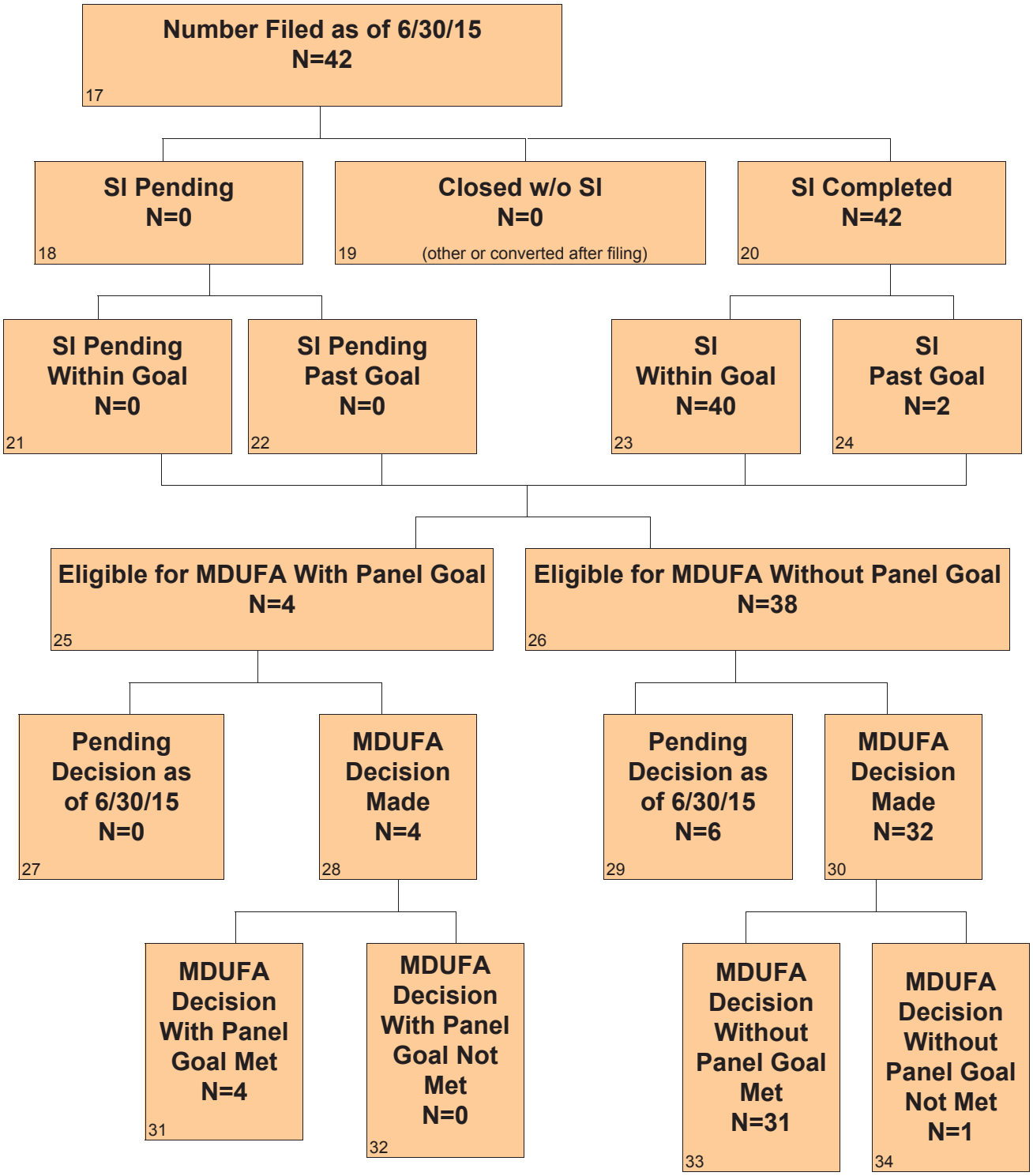
CDRH PMA Original and Panel Track Supplements - FY 2013 As of 6/30/15 Continued



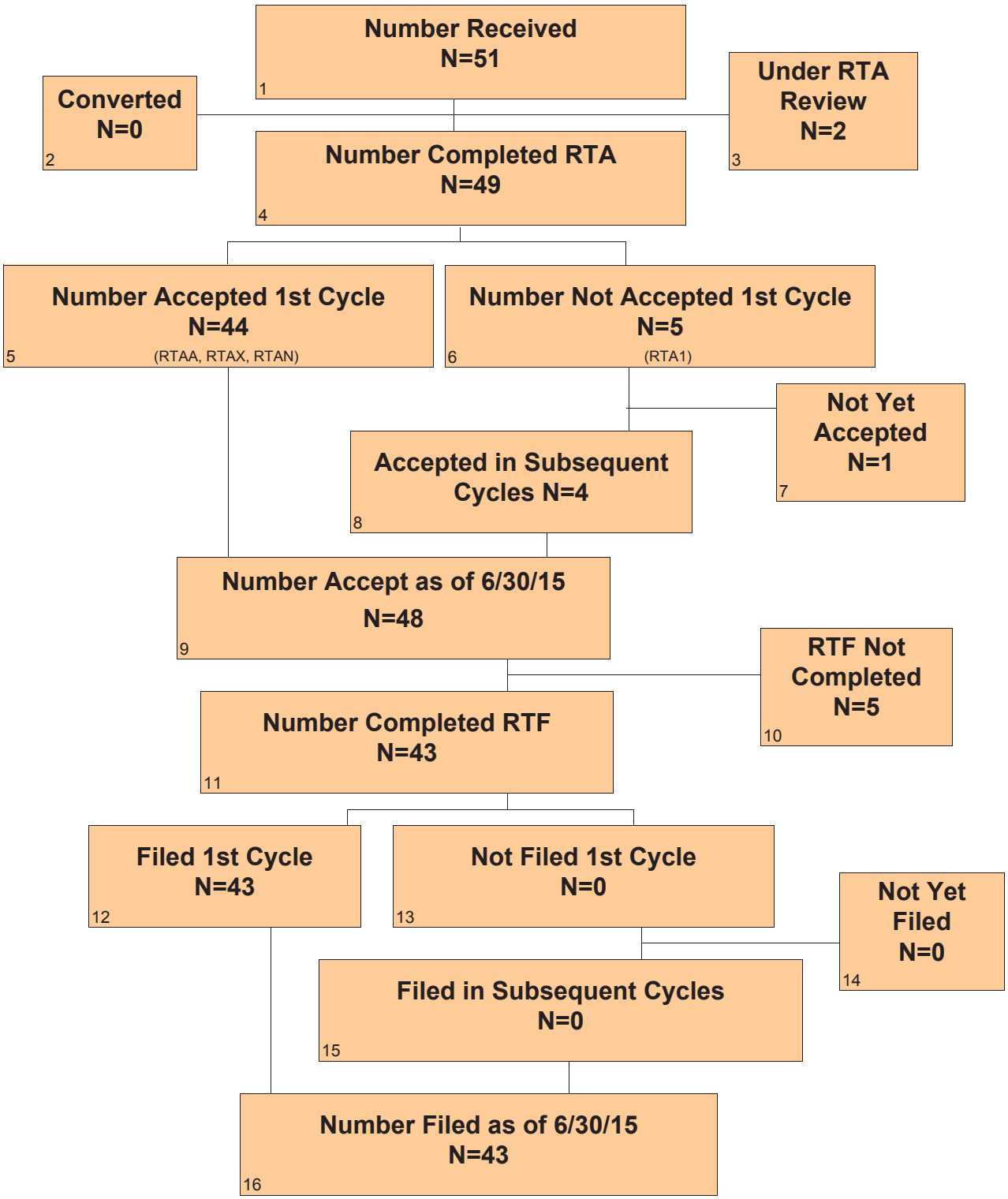
CDRH PMA Original and Panel Track Supplements - FY 2014 As of 6/30/15



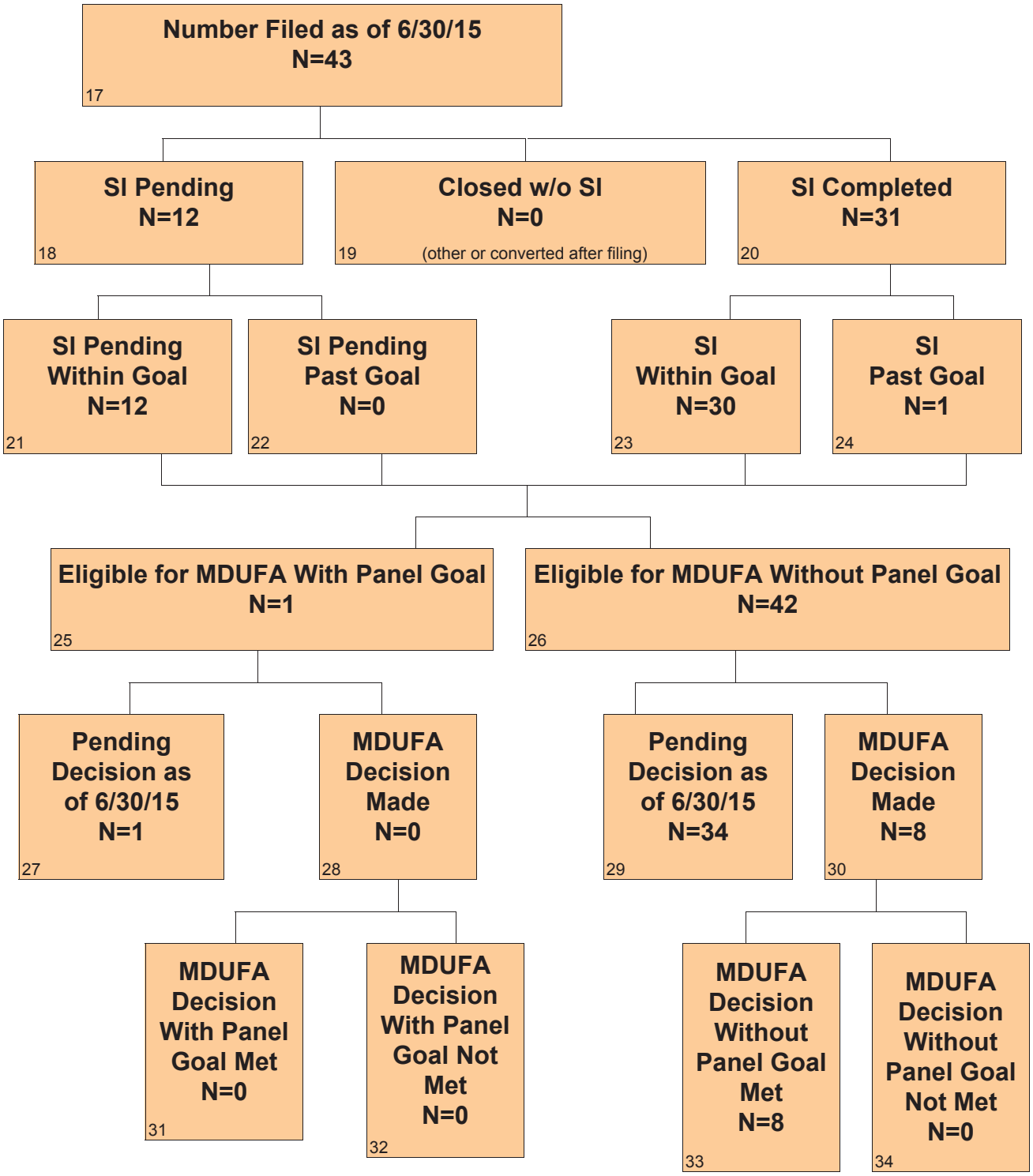
CDRH PMA Original and Panel Track Supplements - FY 2014 As of 6/30/15 Continued



CDRH PMA Original and Panel Track Supplements - FY 2015 As of 6/30/15



CDRH PMA Original and Panel Track Supplements - FY 2015 As of 6/30/15 Continued



Section 1 PMA Original and Panel Track Supplements - Center Level

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	35	43	51		
Closed before RTA action	1	0	0		
Number with accepted RTA review	27	35	42		
Number without a RTA Review and > 15 Days since Date Received	1	1	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	2		
Number Not Accepted for Filing Review	6	7	5		
Rate of submissions not accepted for filing review	17.6%	16.3%	10.2%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	45	43	51		
Number Accepted	38	36	44		
Completed RTF	44	42	43		
Number Not Filed	3	1	0		
Rate of submissions Not Filed	6.8%	2.4%	0%		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	44	42	43		
SI Goal Met	41	40	30		
SI Goal Not Met	2	2	1		
SI Pending Within Goal	0	0	12		
SI Pending Past Goal	1	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	93.2%	95.2%	96.8%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	43	42	31		
Average number of FDA days to Substantive Interaction	88.3	90.0	89.0		
20th Percentile FDA days to Substantive Interaction	86	87	84		
40th Percentile FDA days to Substantive Interaction	88	88	87		
60th Percentile FDA days to Substantive Interaction	90	89	88		
80th Percentile FDA days to Substantive Interaction	90	90	90		
Maximum FDA days to Substantive Interaction	117	136	168		

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	28	38	42		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	26	32	8		
MDUFA III Decisions Goal Met	25	31	8		
PMAs pending MDUFA III Decision	2	5	34		
PMAs pending MDUFA III Decision Past Goal	1	0	0		
Current Performance Percent Goal Met	92.6%	96.9%	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	16	4	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	15	4	0		
MDUFA III Decisions Goal Met	13	4	0		
PMAs pending MDUFA III Decision	1	0	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	86.7%	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	26	32	8		
Average FDA days to MDUFA III decision	177.2	172.6	159.6		
20th Percentile FDA days to MDUFA III decision	175	176	143		
40th Percentile FDA days to MDUFA III decision	177	178	168		
60th Percentile FDA days to MDUFA III decision	180	179	177		
80th Percentile FDA days to MDUFA III decision	180	180	177		
Maximum FDA days to MDUFA III decision	291	201	180		
Average Industry days to MDUFA III decision	170.1	46.3	22.6		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	81	0	0		
60th Percentile Industry days to MDUFA III decision	118	46	8		
80th Percentile Industry days to MDUFA III decision	356	87	54		
Maximum Industry days to MDUFA III decision	563	168	78		
Average Total days to MDUFA III decision	347.3	219.0	182.3		
20th Percentile Total days to MDUFA III decision	180	179	177		
40th Percentile Total days to MDUFA III decision	248	180	177		
60th Percentile Total days to MDUFA III decision	307	230	183		
80th Percentile Total days to MDUFA III decision	531	263	204		
Maximum Total days to MDUFA III decision	743	358	237		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	15	4	0		
Average FDA days to MDUFA III decision	339.6	332.8	0		
20th Percentile FDA days to MDUFA III decision	276	316	0		
40th Percentile FDA days to MDUFA III decision	314	318	0		
60th Percentile FDA days to MDUFA III decision	316	320	0		
80th Percentile FDA days to MDUFA III decision	360	344	0		
Maximum FDA days to MDUFA III decision	668	379	0		
Average Industry days to MDUFA III decision	98.9	74.8	0		
20th Percentile Industry days to MDUFA III decision	0	12	0		
40th Percentile Industry days to MDUFA III decision	17	36	0		
60th Percentile Industry days to MDUFA III decision	119	85	0		
80th Percentile Industry days to MDUFA III decision	187	132	0		
Maximum Industry days to MDUFA III decision	295	178	0		
Average Total days to MDUFA III decision	438.5	407.5	0		
20th Percentile Total days to MDUFA III decision	312	367	0		
40th Percentile Total days to MDUFA III decision	338	402	0		
60th Percentile Total days to MDUFA III decision	454	412	0		
80th Percentile Total days to MDUFA III decision	577	448	0		
Maximum Total days to MDUFA III decision	805	498	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	28	38	42		
Number with MDUFA decision	26	32	8		
Number of Withdrawals	1	0	0		
Number of Not Approvable	4	2	0		
Rate of Withdrawals	3.8%	0%	0%		
Rate of Not Approvable	15.4%	6%	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	16	4	1		
Number with MDUFA decision	15	4	0		
Number of Withdrawals	1	0	0		
Number of Not Approvable	3	0	0		
Rate of Withdrawals	6.7%	0%	N/A		
Rate of Not Approvable	20.0%	0%	N/A		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	1	0		
Mean FDA days for submissions that missed goal	576	201	0		
Mean industry days for submissions that missed goal	57	43	0		

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	28	37	38		
Closed before RTA action	1	0	0		
Number with accepted RTA review	20	30	30		
Number without a RTA Review and > 15 Days since Date Received	1	1	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	1		
Number Not Accepted for Filing Review	6	6	5		
Rate of submissions not accepted for filing review	22.2%	16.2%	13.5%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	35	37	38		
Number Accepted	28	31	32		
Completed RTF	34	36	32		
Number Not Filed	3	1	0		
Rate of submissions Not Filed	8.8%	2.8%	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	32		
SI Goal Met	31	34	23		
SI Goal Not Met	2	2	1		
SI Pending Within Goal	0	0	8		
SI Pending Past Goal	1	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	91.2%	94.4%	95.8%		

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	33	36	24		
Average number of FDA days to Substantive Interaction	88.2	90.6	91		
20th Percentile FDA days to Substantive Interaction	86	87	85		
40th Percentile FDA days to Substantive Interaction	88	88	87		
60th Percentile FDA days to Substantive Interaction	89	89	88		
80th Percentile FDA days to Substantive Interaction	90	90	90		
Maximum FDA days to Substantive Interaction	117	136	168		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	22	32	31		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	20	27	4		
MDUFA III Decisions Goal Met	19	26	4		
PMAs pending MDUFA III Decision	2	5	27		
PMAs pending MDUFA III Decision Past Goal	1	0	0		
Current Performance Percent Goal Met	90.5%	96.3%	100%		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	12	4	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	11	4	0		
MDUFA III Decisions Goal Met	10	4	0		
PMAs pending MDUFA III Decision	1	0	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	90.9%	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	20	27	4		
Average FDA days to MDUFA III decision	184.8	175.0	159.5		
20th Percentile FDA days to MDUFA III decision	177	176	148		
40th Percentile FDA days to MDUFA III decision	180	178	177		
60th Percentile FDA days to MDUFA III decision	180	179	177		
80th Percentile FDA days to MDUFA III decision	180	180	178		
Maximum FDA days to MDUFA III decision	291	201	180		
Average Industry days to MDUFA III decision	175.7	46.6	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	75	7	0		
60th Percentile Industry days to MDUFA III decision	145	46	0		
80th Percentile Industry days to MDUFA III decision	357	81	0		
Maximum Industry days to MDUFA III decision	563	168	0		
Average Total days to MDUFA III decision	360.4	221.5	159.5		
20th Percentile Total days to MDUFA III decision	180	179	148		
40th Percentile Total days to MDUFA III decision	255	186	177		
60th Percentile Total days to MDUFA III decision	381	230	177		
80th Percentile Total days to MDUFA III decision	533	259	178		
Maximum Total days to MDUFA III decision	743	358	180		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	11	4	0		
Average FDA days to MDUFA III decision	359.2	332.8	0		
20th Percentile FDA days to MDUFA III decision	290	316	0		
40th Percentile FDA days to MDUFA III decision	315	318	0		
60th Percentile FDA days to MDUFA III decision	316	320	0		
80th Percentile FDA days to MDUFA III decision	501	344	0		
Maximum FDA days to MDUFA III decision	668	379	0		
Average Industry days to MDUFA III decision	108.1	74.8	0		
20th Percentile Industry days to MDUFA III decision	0	12	0		
40th Percentile Industry days to MDUFA III decision	28	36	0		
60th Percentile Industry days to MDUFA III decision	141	85	0		
80th Percentile Industry days to MDUFA III decision	186	132	0		
Maximum Industry days to MDUFA III decision	295	178	0		
Average Total days to MDUFA III decision	467.3	407.5	0		
20th Percentile Total days to MDUFA III decision	316	367	0		
40th Percentile Total days to MDUFA III decision	348	402	0		
60th Percentile Total days to MDUFA III decision	490	412	0		
80th Percentile Total days to MDUFA III decision	610	448	0		
Maximum Total days to MDUFA III decision	805	498	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	22	32	31		
Number with MDUFA decision	20	27	4		
Number of Withdrawals	1	0	0		
Number of Not Approvable	3	2	0		
Rate of Withdrawals	5.0%	0%	0%		
Rate of Not Approvable	15.0%	7%	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	12	4	1		
Number with MDUFA decision	11	4	0		
Number of Withdrawals	1	0	0		
Number of Not Approvable	2	0	0		
Rate of Withdrawals	9.1%	0%	N/A		
Rate of Not Approvable	18.2%	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	0		
Mean FDA days for submissions that missed goal	576	201	0		
Mean industry days for submissions that missed goal	57	43	0		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	6	13		
Closed before RTA action	0	0	0		
Number with accepted RTA review	7	5	12		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	1		
Number Not Accepted for Filing Review	0	1	0		
Rate of submissions not accepted for filing review	0.0%	16.7%	0.0%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	6	13		
Number Accepted	10	5	12		
Completed RTF	10	6	11		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0.0%	0.0%	0%		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	10	6	11		
SI Goal Met	10	6	7		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	90.9%	100%	100%		

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	7		
Average number of FDA days to Substantive Interaction	88.8	86.3	81.4		
20th Percentile FDA days to Substantive Interaction	86	85	74		
40th Percentile FDA days to Substantive Interaction	90	86	86		
60th Percentile FDA days to Substantive Interaction	90	87	89		
80th Percentile FDA days to Substantive Interaction	90	88	90		
Maximum FDA days to Substantive Interaction	112	89	90		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	6	6	11		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	6	5	4		
MDUFA III Decisions Goal Met	6	5	4		
PMAs pending MDUFA III Decision	0	1	7		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	4	0	0		
MDUFA III Decisions Goal Met	3	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	75.0%	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	5	4		
Average FDA days to MDUFA III decision	152.0	160.0	159.8		
20th Percentile FDA days to MDUFA III decision	116	159	149		
40th Percentile FDA days to MDUFA III decision	167	178	161		
60th Percentile FDA days to MDUFA III decision	174	179	168		
80th Percentile FDA days to MDUFA III decision	177	179	173		
Maximum FDA days to MDUFA III decision	179	179	177		
Average Industry days to MDUFA III decision	151.7	45.2	45.3		
20th Percentile Industry days to MDUFA III decision	81	0	24		
40th Percentile Industry days to MDUFA III decision	107	0	45		
60th Percentile Industry days to MDUFA III decision	118	42	58		
80th Percentile Industry days to MDUFA III decision	133	109	69		
Maximum Industry days to MDUFA III decision	400	120	78		
Average Total days to MDUFA III decision	303.7	205.2	205.0		
20th Percentile Total days to MDUFA III decision	217	160	188		
40th Percentile Total days to MDUFA III decision	248	179	199		
60th Percentile Total days to MDUFA III decision	284	221	207		
80th Percentile Total days to MDUFA III decision	307	286	221		
Maximum Total days to MDUFA III decision	579	299	237		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	4	0	0		
Average FDA days to MDUFA III decision	285.8	0	0		
20th Percentile FDA days to MDUFA III decision	261	0	0		
40th Percentile FDA days to MDUFA III decision	301	0	0		
60th Percentile FDA days to MDUFA III decision	311	0	0		
80th Percentile FDA days to MDUFA III decision	319	0	0		
Maximum FDA days to MDUFA III decision	325	0	0		
Average Industry days to MDUFA III decision	73.5	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	21	0	0		
60th Percentile Industry days to MDUFA III decision	84	0	0		
80th Percentile Industry days to MDUFA III decision	139	0	0		
Maximum Industry days to MDUFA III decision	189	0	0		
Average Total days to MDUFA III decision	359.3	0	0		
20th Percentile Total days to MDUFA III decision	261	0	0		
40th Percentile Total days to MDUFA III decision	324	0	0		
60th Percentile Total days to MDUFA III decision	403	0	0		
80th Percentile Total days to MDUFA III decision	460	0	0		
Maximum Total days to MDUFA III decision	504	0	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	6	6	11		
Number with MDUFA decision	6	5	4		
Number of Withdrawals	0	0	0		
Number of Not Approvable	1	0	0		
Rate of Withdrawals	0%	0%	0%		
Rate of Not Approvable	16.7%	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	0		
Number with MDUFA decision	4	0	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	1	0	0		
Rate of Withdrawals	0%	N/A	N/A		
Rate of Not Approvable	25.0%	N/A	N/A		

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

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

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

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

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

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

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

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

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

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

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

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

Table 1.4.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	1		
Average number of FDA days to Substantive Interaction	85.0	87.0	168.0		
20th Percentile FDA days to Substantive Interaction	84	87	168		
40th Percentile FDA days to Substantive Interaction	85	87	168		
60th Percentile FDA days to Substantive Interaction	85	87	168		
80th Percentile FDA days to Substantive Interaction	86	87	168		
Maximum FDA days to Substantive Interaction	87	87	168		

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

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	1	0		
Average FDA days to MDUFA III decision	180.0	179.0	0		
20th Percentile FDA days to MDUFA III decision	180	179	0		
40th Percentile FDA days to MDUFA III decision	180	179	0		
60th Percentile FDA days to MDUFA III decision	180	179	0		
80th Percentile FDA days to MDUFA III decision	180	179	0		
Maximum FDA days to MDUFA III decision	180	179	0		
Average Industry days to MDUFA III decision	360.0	0	0		
20th Percentile Industry days to MDUFA III decision	360	0	0		
40th Percentile Industry days to MDUFA III decision	360	0	0		
60th Percentile Industry days to MDUFA III decision	360	0	0		
80th Percentile Industry days to MDUFA III decision	360	0	0		
Maximum Industry days to MDUFA III decision	360	0	0		
Average Total days to MDUFA III decision	540.0	179.0	0		
20th Percentile Total days to MDUFA III decision	540	179	0		
40th Percentile Total days to MDUFA III decision	540	179	0		
60th Percentile Total days to MDUFA III decision	540	179	0		
80th Percentile Total days to MDUFA III decision	540	179	0		
Maximum Total days to MDUFA III decision	540	179	0		

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

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

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	17	17	19		
Closed before RTA action	1	0	0		
Number with accepted RTA review	15	15	16		
Number without a RTA Review and > 15 Days since Date Received	1	1	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	1		
Number Not Accepted for Filing Review	0	1	2		
Rate of submissions not accepted for filing review	0%	5.9%	11.1%		

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

Table 1.2.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	19		
Number Accepted	19	16	16		
Completed RTF	19	17	18		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	19	17	18		
SI Goal Met	17	16	14		
SI Goal Not Met	1	1	1		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	1	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	89.5%	94.1%	93.3%		

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	18	17	15		
Average number of FDA days to Substantive Interaction	88.3	87.7	88.9		
20th Percentile FDA days to Substantive Interaction	84	87	85		
40th Percentile FDA days to Substantive Interaction	88	88	88		
60th Percentile FDA days to Substantive Interaction	90	89	88		
80th Percentile FDA days to Substantive Interaction	90	90	90		
Maximum FDA days to Substantive Interaction	117	91	113		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	16	16	18		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	14	15	3		
MDUFA III Decisions Goal Met	13	14	3		
PMAs pending MDUFA III Decision	2	1	15		
PMAs pending MDUFA III Decision Past Goal	1	0	0		
Current Performance Percent Goal Met	86.7%	93.3%	100%		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	14	15	3		
Average FDA days to MDUFA III decision	187.4	173.9	153.7		
20th Percentile FDA days to MDUFA III decision	177	177	133		
40th Percentile FDA days to MDUFA III decision	180	178	162		
60th Percentile FDA days to MDUFA III decision	180	179	178		
80th Percentile FDA days to MDUFA III decision	180	180	179		
Maximum FDA days to MDUFA III decision	291	201	180		
Average Industry days to MDUFA III decision	165.7	31.3	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	70	0	0		
60th Percentile Industry days to MDUFA III decision	103	7	0		
80th Percentile Industry days to MDUFA III decision	329	52	0		
Maximum Industry days to MDUFA III decision	563	161	0		
Average Total days to MDUFA III decision	353.1	205.2	153.7		
20th Percentile Total days to MDUFA III decision	180	179	133		
40th Percentile Total days to MDUFA III decision	250	180	162		
60th Percentile Total days to MDUFA III decision	284	186	178		
80th Percentile Total days to MDUFA III decision	527	248	179		
Maximum Total days to MDUFA III decision	743	338	180		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	3	1	0		
Average FDA days to MDUFA III decision	433.3	318.0	0		
20th Percentile FDA days to MDUFA III decision	316	318	0		
40th Percentile FDA days to MDUFA III decision	316	318	0		
60th Percentile FDA days to MDUFA III decision	386	318	0		
80th Percentile FDA days to MDUFA III decision	527	318	0		
Maximum FDA days to MDUFA III decision	668	318	0		
Average Industry days to MDUFA III decision	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
Average Total days to MDUFA III decision	433.3	318.0	0		
20th Percentile Total days to MDUFA III decision	316	318	0		
40th Percentile Total days to MDUFA III decision	316	318	0		
60th Percentile Total days to MDUFA III decision	386	318	0		
80th Percentile Total days to MDUFA III decision	527	318	0		
Maximum Total days to MDUFA III decision	668	318	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	16	16	18		
Number with MDUFA decision	14	15	3		
Number of Withdrawals	1	0	0		
Number of Not Approvable	2	0	0		
Rate of Withdrawals	7.1%	0%	0%		
Rate of Not Approvable	14.3%	0%	0%		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	1	0		
Mean FDA days for submissions that missed goal	576	201	0		
Mean industry days for submissions that missed goal	57	45	0		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	3	4		
Closed before RTA action	0	0	0		
Number with accepted RTA review	0	2	4		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	1	1	0		
Rate of submissions not accepted for filing review	100%	33.3%	0%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	3	4		
Number Accepted	0	2	4		
Completed RTF	1	3	4		
Number Not Filed	0	1	0		
Rate of submissions Not Filed	0%	33.3%	0%		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	1	3	4		
SI Goal Met	0	2	1		
SI Goal Not Met	1	1	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	0%	66.7%	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	1		
Average number of FDA days to Substantive Interaction	92.0	90.3	87.0		
20th Percentile FDA days to Substantive Interaction	92	90	87		
40th Percentile FDA days to Substantive Interaction	92	90	87		
60th Percentile FDA days to Substantive Interaction	92	90	87		
80th Percentile FDA days to Substantive Interaction	92	91	87		
Maximum FDA days to Substantive Interaction	92	91	87		

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

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	3	0		
Average FDA days to MDUFA III decision	180.0	182.3	0		
20th Percentile FDA days to MDUFA III decision	180	178	0		
40th Percentile FDA days to MDUFA III decision	180	179	0		
60th Percentile FDA days to MDUFA III decision	180	182	0		
80th Percentile FDA days to MDUFA III decision	180	186	0		
Maximum FDA days to MDUFA III decision	180	190	0		
Average Industry days to MDUFA III decision	0	91.7	0		
20th Percentile Industry days to MDUFA III decision	0	48	0		
40th Percentile Industry days to MDUFA III decision	0	69	0		
60th Percentile Industry days to MDUFA III decision	0	97	0		
80th Percentile Industry days to MDUFA III decision	0	132	0		
Maximum Industry days to MDUFA III decision	0	168	0		
Average Total days to MDUFA III decision	180.0	274.0	0		
20th Percentile Total days to MDUFA III decision	180	227	0		
40th Percentile Total days to MDUFA III decision	180	246	0		
60th Percentile Total days to MDUFA III decision	180	276	0		
80th Percentile Total days to MDUFA III decision	180	317	0		
Maximum Total days to MDUFA III decision	180	358	0		

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 1.2.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	5		
Number Accepted	2	4	3		
Completed RTF	2	4	4		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

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

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

Table 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	2		
Average number of FDA days to Substantive Interaction	86.0	100.0	89.0		
20th Percentile FDA days to Substantive Interaction	86	89	88		
40th Percentile FDA days to Substantive Interaction	86	89	89		
60th Percentile FDA days to Substantive Interaction	86	90	89		
80th Percentile FDA days to Substantive Interaction	86	107	90		
Maximum FDA days to Substantive Interaction	86	133	90		

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

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	1	3	4		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	2	0		
MDUFA III Decisions Goal Met	1	2	0		
PMAs pending MDUFA III Decision	0	1	4		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	N/A		

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

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	1	1	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	1	0		
MDUFA III Decisions Goal Met	1	1	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	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	0		
Average FDA days to MDUFA III decision	175.0	179.5	0		
20th Percentile FDA days to MDUFA III decision	175	179	0		
40th Percentile FDA days to MDUFA III decision	175	179	0		
60th Percentile FDA days to MDUFA III decision	175	180	0		
80th Percentile FDA days to MDUFA III decision	175	180	0		
Maximum FDA days to MDUFA III decision	175	180	0		
Average Industry days to MDUFA III decision	356.0	79.0	0		
20th Percentile Industry days to MDUFA III decision	356	78	0		
40th Percentile Industry days to MDUFA III decision	356	79	0		
60th Percentile Industry days to MDUFA III decision	356	79	0		
80th Percentile Industry days to MDUFA III decision	356	80	0		
Maximum Industry days to MDUFA III decision	356	81	0		
Average Total days to MDUFA III decision	531.0	258.5	0		
20th Percentile Total days to MDUFA III decision	531	258	0		
40th Percentile Total days to MDUFA III decision	531	258	0		
60th Percentile Total days to MDUFA III decision	531	259	0		
80th Percentile Total days to MDUFA III decision	531	259	0		
Maximum Total days to MDUFA III decision	531	260	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	1	0		
Average FDA days to MDUFA III decision	219.0	314.0	0		
20th Percentile FDA days to MDUFA III decision	219	314	0		
40th Percentile FDA days to MDUFA III decision	219	314	0		
60th Percentile FDA days to MDUFA III decision	219	314	0		
80th Percentile FDA days to MDUFA III decision	219	314	0		
Maximum FDA days to MDUFA III decision	219	314	0		
Average Industry days to MDUFA III decision	186.0	101.0	0		
20th Percentile Industry days to MDUFA III decision	186	101	0		
40th Percentile Industry days to MDUFA III decision	186	101	0		
60th Percentile Industry days to MDUFA III decision	186	101	0		
80th Percentile Industry days to MDUFA III decision	186	101	0		
Maximum Industry days to MDUFA III decision	186	101	0		
Average Total days to MDUFA III decision	405.0	415.0	0		
20th Percentile Total days to MDUFA III decision	405	415	0		
40th Percentile Total days to MDUFA III decision	405	415	0		
60th Percentile Total days to MDUFA III decision	405	415	0		
80th Percentile Total days to MDUFA III decision	405	415	0		
Maximum Total days to MDUFA III decision	405	415	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	3	4		
Number with MDUFA decision	1	2	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	1	1	0		
Rate of Withdrawals	0%	0%	N/A		
Rate of Not Approvable	100%	50.0%	N/A		

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

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

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

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1	2		
Closed before RTA action	0	0	0		
Number with accepted RTA review	4	1	2		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	1	0	0		
Rate of submissions not accepted for filing review	20.0%	0%	0%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	1	2		
Number Accepted	5	1	2		
Completed RTF	6	1	1		
Number Not Filed	1	0	0		
Rate of submissions Not Filed	16.7%	0%	0%		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	6	1	1		
Average number of FDA days to Substantive Interaction	88.5	81.0	79.0		
20th Percentile FDA days to Substantive Interaction	88	81	79		
40th Percentile FDA days to Substantive Interaction	88	81	79		
60th Percentile FDA days to Substantive Interaction	89	81	79		
80th Percentile FDA days to Substantive Interaction	90	81	79		
Maximum FDA days to Substantive Interaction	90	81	79		

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

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	2	1	1		
Average FDA days to MDUFA III decision	178.5	170.0	177.0		
20th Percentile FDA days to MDUFA III decision	178	170	177		
40th Percentile FDA days to MDUFA III decision	178	170	177		
60th Percentile FDA days to MDUFA III decision	179	170	177		
80th Percentile FDA days to MDUFA III decision	179	170	177		
Maximum FDA days to MDUFA III decision	180	170	177		
Average Industry days to MDUFA III decision	108.5	0	0		
20th Percentile Industry days to MDUFA III decision	43	0	0		
40th Percentile Industry days to MDUFA III decision	87	0	0		
60th Percentile Industry days to MDUFA III decision	130	0	0		
80th Percentile Industry days to MDUFA III decision	174	0	0		
Maximum Industry days to MDUFA III decision	217	0	0		
Average Total days to MDUFA III decision	287.0	170.0	177.0		
20th Percentile Total days to MDUFA III decision	221	170	177		
40th Percentile Total days to MDUFA III decision	265	170	177		
60th Percentile Total days to MDUFA III decision	309	170	177		
80th Percentile Total days to MDUFA III decision	353	170	177		
Maximum Total days to MDUFA III decision	397	170	177		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	3	0	0		
Average FDA days to MDUFA III decision	328.0	0	0		
20th Percentile FDA days to MDUFA III decision	225	0	0		
40th Percentile FDA days to MDUFA III decision	268	0	0		
60th Percentile FDA days to MDUFA III decision	334	0	0		
80th Percentile FDA days to MDUFA III decision	423	0	0		
Maximum FDA days to MDUFA III decision	512	0	0		
Average Industry days to MDUFA III decision	144.7	0	0		
20th Percentile Industry days to MDUFA III decision	56	0	0		
40th Percentile Industry days to MDUFA III decision	113	0	0		
60th Percentile Industry days to MDUFA III decision	171	0	0		
80th Percentile Industry days to MDUFA III decision	232	0	0		
Maximum Industry days to MDUFA III decision	293	0	0		
Average Total days to MDUFA III decision	472.7	0	0		
20th Percentile Total days to MDUFA III decision	303	0	0		
40th Percentile Total days to MDUFA III decision	316	0	0		
60th Percentile Total days to MDUFA III decision	419	0	0		
80th Percentile Total days to MDUFA III decision	612	0	0		
Maximum Total days to MDUFA III decision	805	0	0		

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	4	5	1		
Average number of FDA days to Substantive Interaction	88.5	97.8	86.0		
20th Percentile FDA days to Substantive Interaction	88	88	86		
40th Percentile FDA days to Substantive Interaction	88	88	86		
60th Percentile FDA days to Substantive Interaction	88	89	86		
80th Percentile FDA days to Substantive Interaction	89	99	86		
Maximum FDA days to Substantive Interaction	90	136	86		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	5	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	2	0		
MDUFA III Decisions Goal Met	1	2	0		
PMAs pending MDUFA III Decision	0	3	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	N/A		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	3	0	1		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	3	0	0		
MDUFA III Decisions Goal Met	3	0	0		
PMAs pending MDUFA III Decision	0	0	1		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	N/A	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	2	0		
Average FDA days to MDUFA III decision	180.0	164.0	0		
20th Percentile FDA days to MDUFA III decision	180	154	0		
40th Percentile FDA days to MDUFA III decision	180	161	0		
60th Percentile FDA days to MDUFA III decision	180	167	0		
80th Percentile FDA days to MDUFA III decision	180	174	0		
Maximum FDA days to MDUFA III decision	180	180	0		
Average Industry days to MDUFA III decision	260.0	104.0	0		
20th Percentile Industry days to MDUFA III decision	260	82	0		
40th Percentile Industry days to MDUFA III decision	260	97	0		
60th Percentile Industry days to MDUFA III decision	260	111	0		
80th Percentile Industry days to MDUFA III decision	260	126	0		
Maximum Industry days to MDUFA III decision	260	140	0		
Average Total days to MDUFA III decision	440.0	268.0	0		
20th Percentile Total days to MDUFA III decision	440	256	0		
40th Percentile Total days to MDUFA III decision	440	264	0		
60th Percentile Total days to MDUFA III decision	440	272	0		
80th Percentile Total days to MDUFA III decision	440	280	0		
Maximum Total days to MDUFA III decision	440	288	0		

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	0	5	3		
SI Goal Met	0	5	3		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	N/A	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	3		
Average number of FDA days to Substantive Interaction	0	88.8	85.7		
20th Percentile FDA days to Substantive Interaction	0	88	83		
40th Percentile FDA days to Substantive Interaction	0	90	86		
60th Percentile FDA days to Substantive Interaction	0	90	88		
80th Percentile FDA days to Substantive Interaction	0	90	89		
Maximum FDA days to Substantive Interaction	0	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	3		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	3	0		
MDUFA III Decisions Goal Met	0	3	0		
PMAs pending MDUFA III Decision	0	0	3		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	100%	N/A		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	2	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	2	0		
MDUFA III Decisions Goal Met	0	2	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	100%	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	0		
Average FDA days to MDUFA III decision	0	177.3	0		
20th Percentile FDA days to MDUFA III decision	0	175	0		
40th Percentile FDA days to MDUFA III decision	0	178	0		
60th Percentile FDA days to MDUFA III decision	0	179	0		
80th Percentile FDA days to MDUFA III decision	0	180	0		
Maximum FDA days to MDUFA III decision	0	180	0		
Average Industry days to MDUFA III decision	0	49.0	0		
20th Percentile Industry days to MDUFA III decision	0	46	0		
40th Percentile Industry days to MDUFA III decision	0	47	0		
60th Percentile Industry days to MDUFA III decision	0	49	0		
80th Percentile Industry days to MDUFA III decision	0	52	0		
Maximum Industry days to MDUFA III decision	0	55	0		
Average Total days to MDUFA III decision	0	226.3	0		
20th Percentile Total days to MDUFA III decision	0	222	0		
40th Percentile Total days to MDUFA III decision	0	223	0		
60th Percentile Total days to MDUFA III decision	0	226	0		
80th Percentile Total days to MDUFA III decision	0	230	0		
Maximum Total days to MDUFA III decision	0	234	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	0	2	0		
Average FDA days to MDUFA III decision	0	350	0		
20th Percentile FDA days to MDUFA III decision	0	332	0		
40th Percentile FDA days to MDUFA III decision	0	344	0		
60th Percentile FDA days to MDUFA III decision	0	355	0		
80th Percentile FDA days to MDUFA III decision	0	367	0		
Maximum FDA days to MDUFA III decision	0	379	0		
Average Industry days to MDUFA III decision	0	99.0	0		
20th Percentile Industry days to MDUFA III decision	0	52	0		
40th Percentile Industry days to MDUFA III decision	0	83	0		
60th Percentile Industry days to MDUFA III decision	0	115	0		
80th Percentile Industry days to MDUFA III decision	0	146	0		
Maximum Industry days to MDUFA III decision	0	178	0		
Average Total days to MDUFA III decision	0	448.5	0		
20th Percentile Total days to MDUFA III decision	0	419	0		
40th Percentile Total days to MDUFA III decision	0	439	0		
60th Percentile Total days to MDUFA III decision	0	458	0		
80th Percentile Total days to MDUFA III decision	0	478	0		
Maximum Total days to MDUFA III decision	0	498	0		

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

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

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

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	2	6		
Number Accepted	2	2	5		
Completed RTF	2	2	4		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	2	2	4		
SI Goal Met	2	2	3		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2	2	3		
Average number of FDA days to Substantive Interaction	90.0	88.0	77.3		
20th Percentile FDA days to Substantive Interaction	90	87	68		
40th Percentile FDA days to Substantive Interaction	90	88	80		
60th Percentile FDA days to Substantive Interaction	90	88	87		
80th Percentile FDA days to Substantive Interaction	90	89	88		
Maximum FDA days to Substantive Interaction	90	89	90		

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

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	2	2	4		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	2	1	1		
MDUFA III Decisions Goal Met	2	1	1		
PMAs pending MDUFA III Decision	0	1	3		
PMAs pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

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

Table 1.7.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	1	1		
Average FDA days to MDUFA III decision	176.5	179.0	177.0		
20th Percentile FDA days to MDUFA III decision	175	179	177		
40th Percentile FDA days to MDUFA III decision	176	179	177		
60th Percentile FDA days to MDUFA III decision	177	179	177		
80th Percentile FDA days to MDUFA III decision	178	179	177		
Maximum FDA days to MDUFA III decision	179	179	177		
Average Industry days to MDUFA III decision	266.5	0	0		
20th Percentile Industry days to MDUFA III decision	186	0	0		
40th Percentile Industry days to MDUFA III decision	240	0	0		
60th Percentile Industry days to MDUFA III decision	293	0	0		
80th Percentile Industry days to MDUFA III decision	347	0	0		
Maximum Industry days to MDUFA III decision	400	0	0		
Average Total days to MDUFA III decision	443.0	179.0	177.0		
20th Percentile Total days to MDUFA III decision	361	179	177		
40th Percentile Total days to MDUFA III decision	416	179	177		
60th Percentile Total days to MDUFA III decision	470	179	177		
80th Percentile Total days to MDUFA III decision	525	179	177		
Maximum Total days to MDUFA III decision	579	179	177		

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 1.2.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		
Number Accepted	2	1	3		
Completed RTF	2	1	3		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0%	0%	0%		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	2	1	3		
SI Goal Met	2	1	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100.0%		

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	1		
Average number of FDA days to Substantive Interaction	86	83	87		
20th Percentile FDA days to Substantive Interaction	86	83	87		
40th Percentile FDA days to Substantive Interaction	86	83	87		
60th Percentile FDA days to Substantive Interaction	86	83	87		
80th Percentile FDA days to Substantive Interaction	86	83	87		
Maximum FDA days to Substantive Interaction	86	83	87		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	1	1		
Average FDA days to MDUFA III decision	177.0	179.0	159.0		
20th Percentile FDA days to MDUFA III decision	177	179	159		
40th Percentile FDA days to MDUFA III decision	177	179	159		
60th Percentile FDA days to MDUFA III decision	177	179	159		
80th Percentile FDA days to MDUFA III decision	177	179	159		
Maximum FDA days to MDUFA III decision	177	179	159		
Average Industry days to MDUFA III decision	107.0	0	78.0		
20th Percentile Industry days to MDUFA III decision	107	0	78		
40th Percentile Industry days to MDUFA III decision	107	0	78		
60th Percentile Industry days to MDUFA III decision	107	0	78		
80th Percentile Industry days to MDUFA III decision	107	0	78		
Maximum Industry days to MDUFA III decision	107	0	78		
Average Total days to MDUFA III decision	284.0	179.0	237.0		
20th Percentile Total days to MDUFA III decision	284	179	237		
40th Percentile Total days to MDUFA III decision	284	179	237		
60th Percentile Total days to MDUFA III decision	284	179	237		
80th Percentile Total days to MDUFA III decision	284	179	237		
Maximum Total days to MDUFA III decision	284	179	237		

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		
Average FDA days to MDUFA III decision	297.0	0	0		
20th Percentile FDA days to MDUFA III decision	297	0	0		
40th Percentile FDA days to MDUFA III decision	297	0	0		
60th Percentile FDA days to MDUFA III decision	297	0	0		
80th Percentile FDA days to MDUFA III decision	297	0	0		
Maximum FDA days to MDUFA III decision	297	0	0		
Average Industry days to MDUFA III decision	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
Average Total days to MDUFA III decision	297.0	0	0		
20th Percentile Total days to MDUFA III decision	297	0	0		
40th Percentile Total days to MDUFA III decision	297	0	0		
60th Percentile Total days to MDUFA III decision	297	0	0		
80th Percentile Total days to MDUFA III decision	297	0	0		
Maximum Total days to MDUFA III decision	297	0	0		

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

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

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

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

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

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

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

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

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

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

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

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	4	1	4		
SI Goal Met	4	1	3		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

Table 1.4.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	3		
Average number of FDA days to Substantive Interaction	95.3	86.0	83.7		
20th Percentile FDA days to Substantive Interaction	90	86	79		
40th Percentile FDA days to Substantive Interaction	90	86	86		
60th Percentile FDA days to Substantive Interaction	90	86	90		
80th Percentile FDA days to Substantive Interaction	99	86	90		
Maximum FDA days to Substantive Interaction	112	86	90		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	2	1	2		
Average FDA days to MDUFA III decision	107.5	86.0	151.5		
20th Percentile FDA days to MDUFA III decision	102	86	140		
40th Percentile FDA days to MDUFA III decision	106	86	148		
60th Percentile FDA days to MDUFA III decision	109	86	155		
80th Percentile FDA days to MDUFA III decision	113	86	163		
Maximum FDA days to MDUFA III decision	116	86	170		
Average Industry days to MDUFA III decision	94.5	0	51.5		
20th Percentile Industry days to MDUFA III decision	80	0	45		
40th Percentile Industry days to MDUFA III decision	90	0	49		
60th Percentile Industry days to MDUFA III decision	99	0	54		
80th Percentile Industry days to MDUFA III decision	109	0	58		
Maximum Industry days to MDUFA III decision	118	0	63		
Average Total days to MDUFA III decision	202.0	86.0	203.0		
20th Percentile Total days to MDUFA III decision	193	86	199		
40th Percentile Total days to MDUFA III decision	199	86	202		
60th Percentile Total days to MDUFA III decision	205	86	204		
80th Percentile Total days to MDUFA III decision	211	86	207		
Maximum Total days to MDUFA III decision	217	86	210		

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		
Average FDA days to MDUFA III decision	320.0	0	0		
20th Percentile FDA days to MDUFA III decision	317	0	0		
40th Percentile FDA days to MDUFA III decision	319	0	0		
60th Percentile FDA days to MDUFA III decision	321	0	0		
80th Percentile FDA days to MDUFA III decision	323	0	0		
Maximum FDA days to MDUFA III decision	325	0	0		
Average Industry days to MDUFA III decision	147.0	0	0		
20th Percentile Industry days to MDUFA III decision	122	0	0		
40th Percentile Industry days to MDUFA III decision	139	0	0		
60th Percentile Industry days to MDUFA III decision	155	0	0		
80th Percentile Industry days to MDUFA III decision	172	0	0		
Maximum Industry days to MDUFA III decision	189	0	0		
Average Total days to MDUFA III decision	467.0	0	0		
20th Percentile Total days to MDUFA III decision	445	0	0		
40th Percentile Total days to MDUFA III decision	460	0	0		
60th Percentile Total days to MDUFA III decision	474	0	0		
80th Percentile Total days to MDUFA III decision	489	0	0		
Maximum Total days to MDUFA III decision	504	0	0		

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	1	2	0		
Average FDA days to MDUFA III decision	167.0	178.0	0		
20th Percentile FDA days to MDUFA III decision	167	177	0		
40th Percentile FDA days to MDUFA III decision	167	178	0		
60th Percentile FDA days to MDUFA III decision	167	178	0		
80th Percentile FDA days to MDUFA III decision	167	179	0		
Maximum FDA days to MDUFA III decision	167	179	0		
Average Industry days to MDUFA III decision	81.0	113.0	0		
20th Percentile Industry days to MDUFA III decision	81	109	0		
40th Percentile Industry days to MDUFA III decision	81	112	0		
60th Percentile Industry days to MDUFA III decision	81	114	0		
80th Percentile Industry days to MDUFA III decision	81	117	0		
Maximum Industry days to MDUFA III decision	81	120	0		
Average Total days to MDUFA III decision	248.0	291.0	0		
20th Percentile Total days to MDUFA III decision	248	286	0		
40th Percentile Total days to MDUFA III decision	248	289	0		
60th Percentile Total days to MDUFA III decision	248	293	0		
80th Percentile Total days to MDUFA III decision	248	296	0		
Maximum Total days to MDUFA III decision	248	299	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		
Average FDA days to MDUFA III decision	206.0	0	0		
20th Percentile FDA days to MDUFA III decision	206	0	0		
40th Percentile FDA days to MDUFA III decision	206	0	0		
60th Percentile FDA days to MDUFA III decision	206	0	0		
80th Percentile FDA days to MDUFA III decision	206	0	0		
Maximum FDA days to MDUFA III decision	206	0	0		
Average Industry days to MDUFA III decision	0	0	0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	0	0		
80th Percentile Industry days to MDUFA III decision	0	0	0		
Maximum Industry days to MDUFA III decision	0	0	0		
Average Total days to MDUFA III decision	206.0	0	0		
20th Percentile Total days to MDUFA III decision	206	0	0		
40th Percentile Total days to MDUFA III decision	206	0	0		
60th Percentile Total days to MDUFA III decision	206	0	0		
80th Percentile Total days to MDUFA III decision	206	0	0		
Maximum Total days to MDUFA III decision	206	0	0		

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

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

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

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

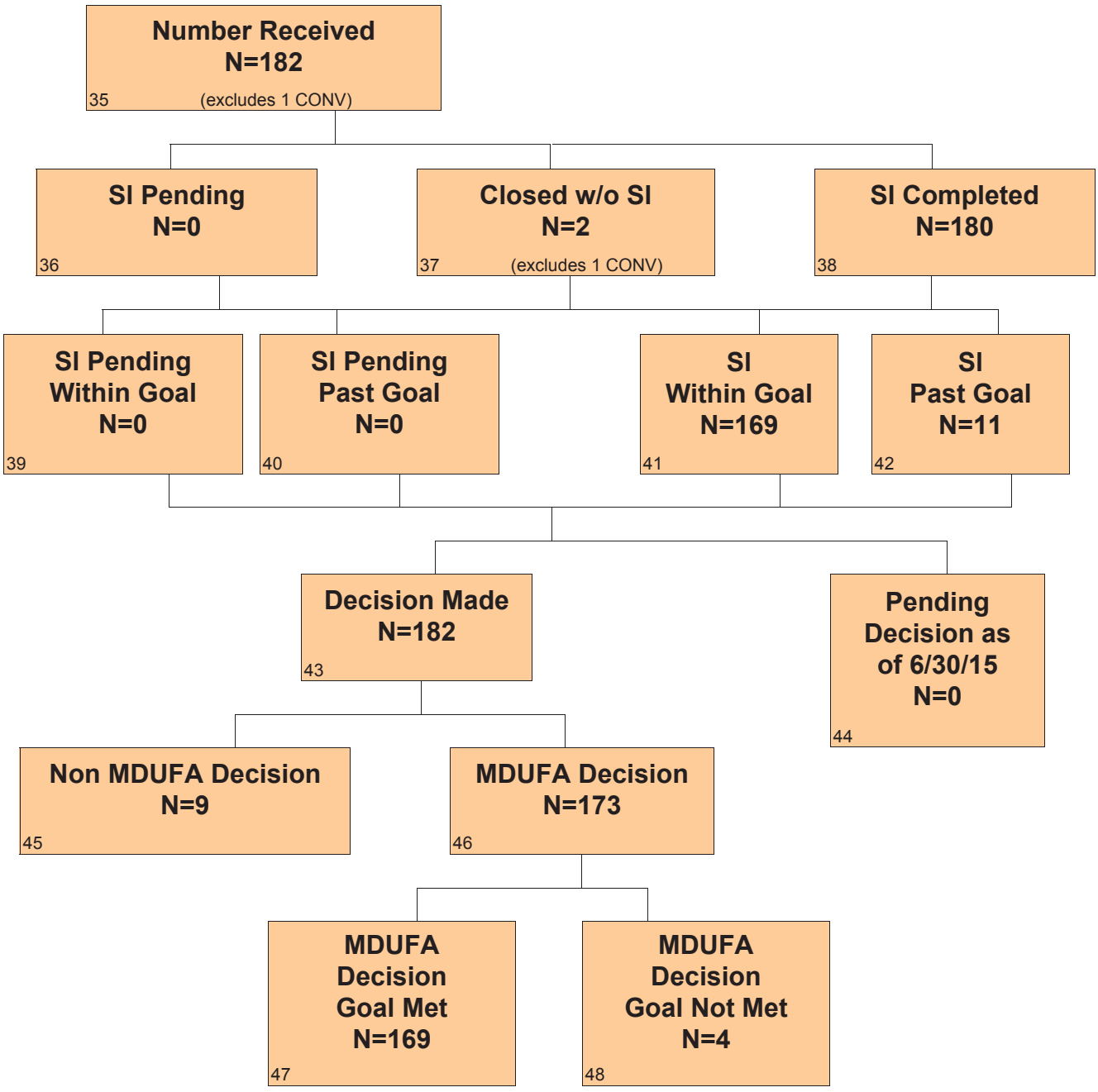
Table 1.11.DRH - OIR – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

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

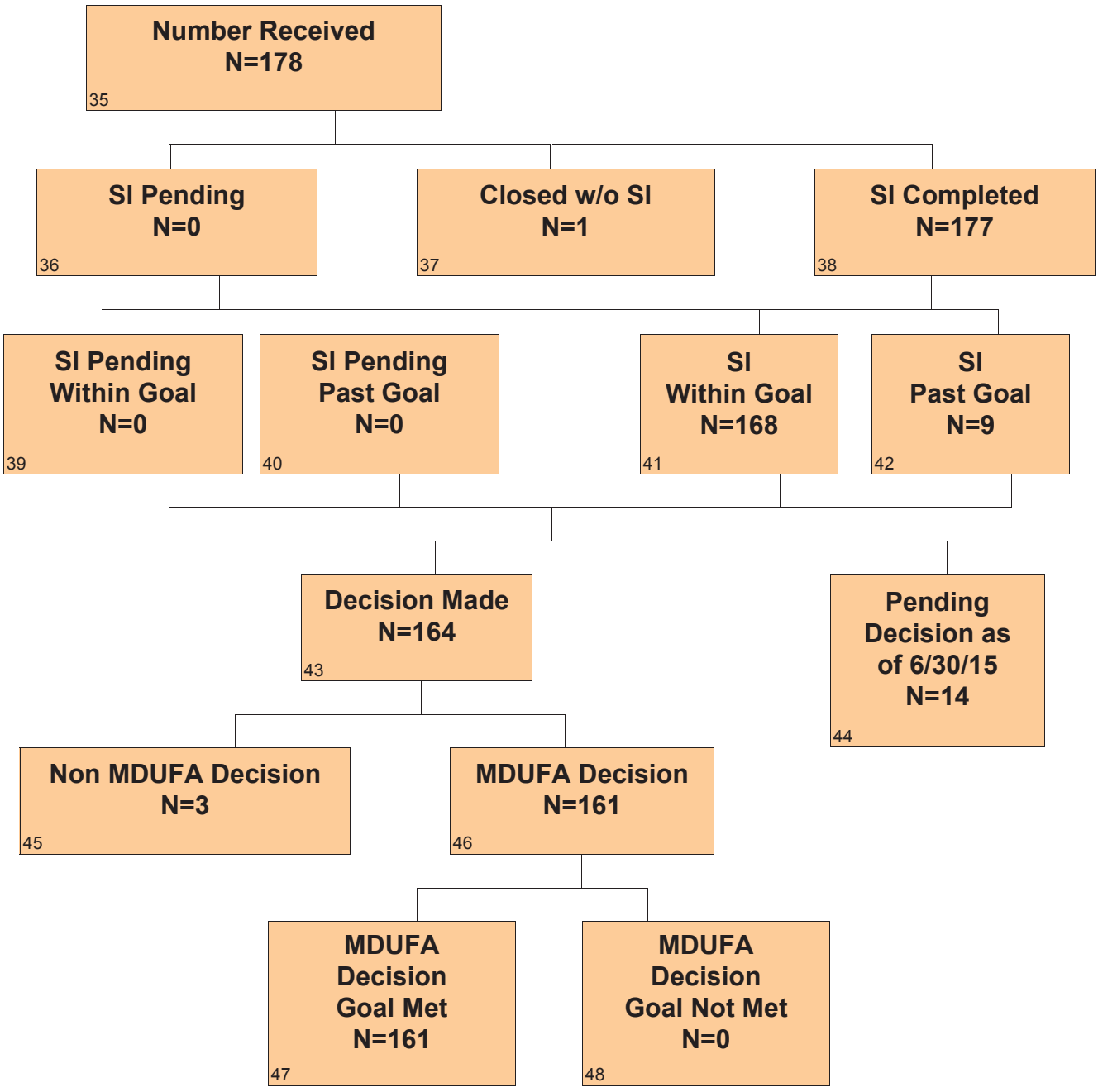
Table 1.12.DRH - OIR – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

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

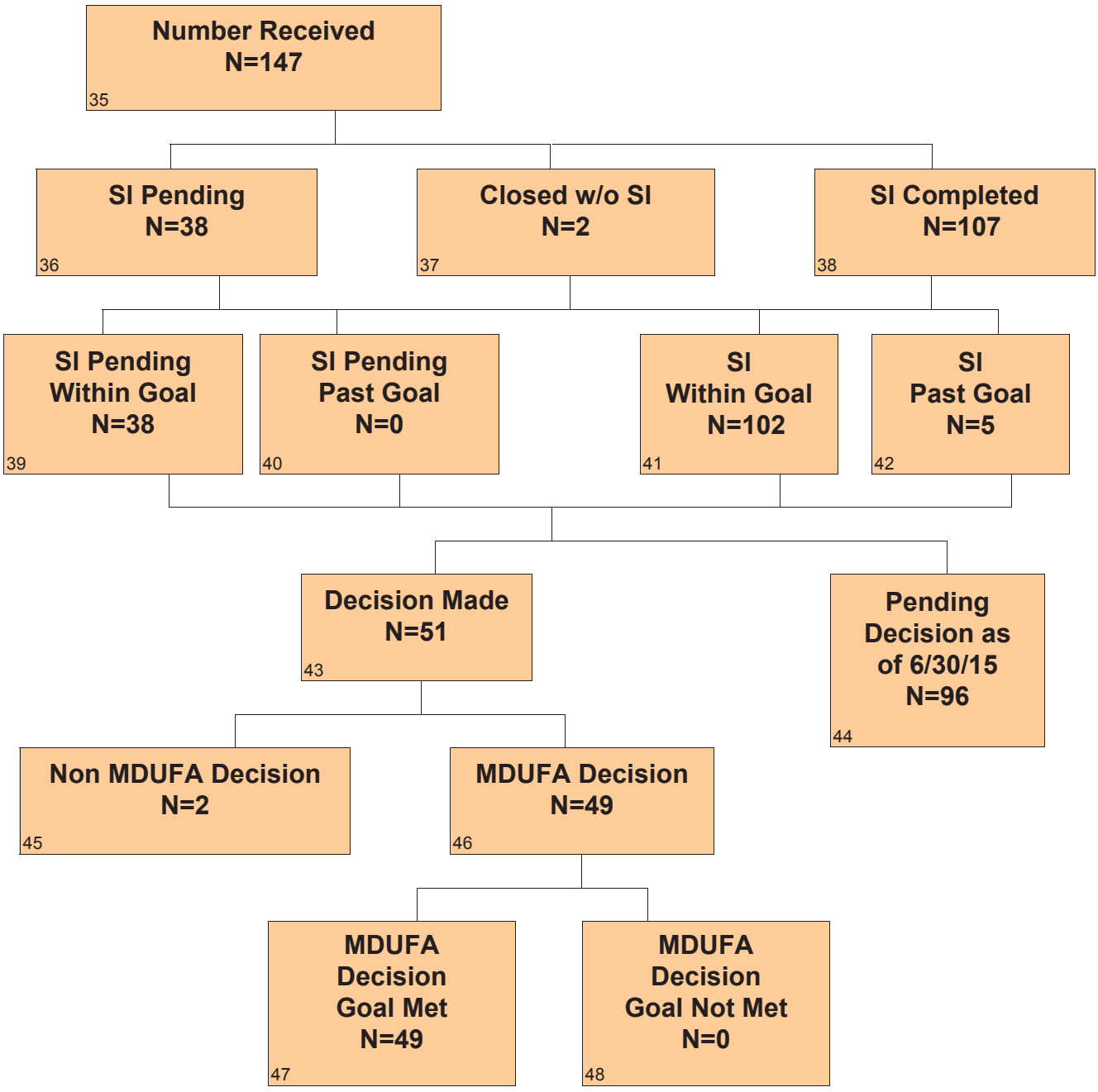
CDRH PMA 180 Day Supplements - FY 2013 As of 6/30/15



CDRH PMA 180 Day Supplements - FY 2014 As of 6/30/15



CDRH PMA 180 Day Supplements - FY 2015 As of 6/30/15



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Section 2 PMA 180 Day Supplements - Center Level

Table 2.1 CDRH – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	183	178	147		
SI Goal Met	169	168	102		
SI Goal Not Met	11	9	5		
SI Pending Within Goal	0	0	38		
SI Pending Past Goal	0	0	0		
Closed without SI	3	1	2		
Current SI Performance Percent Goal Met	93.9%	94.9%	95.3%		

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	183	178	147		
Non-MDUFA III Decisions	10	3	2		
MDUFA III Decisions	173	161	49		
MDUFA III Decisions Goal Met	169	161	49		
Supplements pending MDUFA III Decision	0	14	96		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	97.7%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	183	178	147		
Number with MDUFA decision	173	161	49		
Number of Not Approvable	11	5	0		
Rate of Not Approvable	6.4%	3.1%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4	0	0		
Mean FDA days for submissions that missed goal	209	0	0		
Mean Industry days for submissions that missed goal	247	0	0		

Section 2 PMA 180 Day Supplements - Office Level

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	162	165	122		
SI Goal Met	148	155	87		
SI Goal Not Met	11	9	5		
SI Pending Within Goal	0	0	30		
SI Pending Past Goal	0	0	0		
Closed without SI	3	1	0		
Current SI Performance Percent Goal Met	93.1%	94.5%	94.6%		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	162	165	122		
Non-MDUFA III Decisions	9	3	0		
MDUFA III Decisions	153	152	45		
MDUFA III Decisions Goal Met	149	152	45		
Supplements pending MDUFA III Decision	0	10	77		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	97.4%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	162	165	122		
Number with MDUFA decision	153	152	45		
Number of Not Approvable	11	5	0		
Rate of Not Approvable	7.2%	3.3%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4	0	0		
Mean FDA days for submissions that missed goal	209	0	0		
Mean Industry days for submissions that missed goal	247	0	0		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	21	13	25		
SI Goal Met	21	13	15		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	8		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	2		
Current SI Performance Percent Goal Met	100%	100%	100%		

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	21	13	25		
Non-MDUFA III Decisions	1	0	2		
MDUFA III Decisions	20	9	4		
MDUFA III Decisions Goal Met	20	9	4		
Supplements pending MDUFA III Decision	0	4	19		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	21	13	25		
Number with MDUFA decision	20	9	4		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

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

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

Section 2 PMA 180 Day Supplements - Division Level

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

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

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		
Non-MDUFA III Decisions	2	1	0		
MDUFA III Decisions	8	6	0		
MDUFA III Decisions Goal Met	6	6	0		
Supplements pending MDUFA III Decision	0	2	7		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	75.0%	100%	N/A		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	9	7		
Number with MDUFA decision	8	6	0		
Number of Not Approvable	1	2	0		
Rate of Not Approvable	12.5%	33.3%	N/A		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0	0		
Mean FDA days for submissions that missed goal	197	0	0		
Mean Industry days for submissions that missed goal	313	0	0		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	116	94	73		
SI Goal Met	108	93	57		
SI Goal Not Met	5	1	0		
SI Pending Within Goal	0	0	16		
SI Pending Past Goal	0	0	0		
Closed without SI	3	0	0		
Current SI Performance Percent Goal Met	95.6%	98.9%	100%		

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	116	94	73		
Non-MDUFA III Decisions	4	1	0		
MDUFA III Decisions	112	93	24		
MDUFA III Decisions Goal Met	111	93	24		
Supplements pending MDUFA III Decision	0	0	49		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	99.1%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	116	94	73		
Number with MDUFA decision	112	93	24		
Number of Not Approvable	6	0	0		
Rate of Not Approvable	5.4%	0%	0%		

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

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

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	8	14	9		
SI Goal Met	7	13	5		
SI Goal Not Met	1	0	1		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed without SI	0	1	0		
Current SI Performance Percent Goal Met	87.5%	100%	83.3%		

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	8	14	9		
Non-MDUFA III Decisions	2	1	0		
MDUFA III Decisions	6	13	2		
MDUFA III Decisions Goal Met	6	13	2		
Supplements pending MDUFA III Decision	0	0	7		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	14	9		
Number with MDUFA decision	6	13	2		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	16.7%	0%	0%		

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

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

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	2	4	5		
SI Goal Met	2	2	1		
SI Goal Not Met	0	2	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	50.0%	100%		

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

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

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

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

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

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

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	12	24	15		
SI Goal Met	11	24	12		
SI Goal Not Met	1	0	1		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	91.7%	100%	92.3%		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	12	24	15		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	12	19	11		
MDUFA III Decisions Goal Met	12	19	11		
Supplements pending MDUFA III Decision	0	5	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	12	24	15		
Number with MDUFA decision	12	19	11		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	8.3%	5.3%	0%		

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

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

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	10	7	7		
SI Goal Met	9	7	5		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	90.0%	100%	100.0%		

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	7		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	10	7	4		
MDUFA III Decisions Goal Met	10	7	4		
Supplements pending MDUFA III Decision	0	0	3		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	7	7		
Number with MDUFA decision	10	7	4		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	10.0%	14.3%	0%		

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

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

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

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	4	13	6		
SI Goal Met	3	9	3		
SI Goal Not Met	1	4	2		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	75.0%	69.2%	60.0%		

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	4	13	6		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	3	12	3		
MDUFA III Decisions Goal Met	2	12	3		
Supplements pending MDUFA III Decision	0	1	3		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	66.7%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	13	6		
Number with MDUFA decision	3	12	3		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	33.3%	8.3%	0%		

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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	5		
SI Goal Met	7	4	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	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	5		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	6	4	1		
MDUFA III Decisions Goal Met	6	4	1		
Supplements pending MDUFA III Decision	0	0	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

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

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

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

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

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	10		
SI Goal Met	5	4	8		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	2		
Current SI Performance Percent Goal Met	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	10		
Non-MDUFA III Decisions	0	0	2		
MDUFA III Decisions	5	3	2		
MDUFA III Decisions Goal Met	5	3	2		
Supplements pending MDUFA III Decision	0	1	6		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	10		
Number with MDUFA decision	5	3	2		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	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		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

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

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		
SI Goal Met	5	1	3		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

Table 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		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	5	1	1		
MDUFA III Decisions Goal Met	5	1	1		
Supplements pending MDUFA III Decision	0	0	3		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

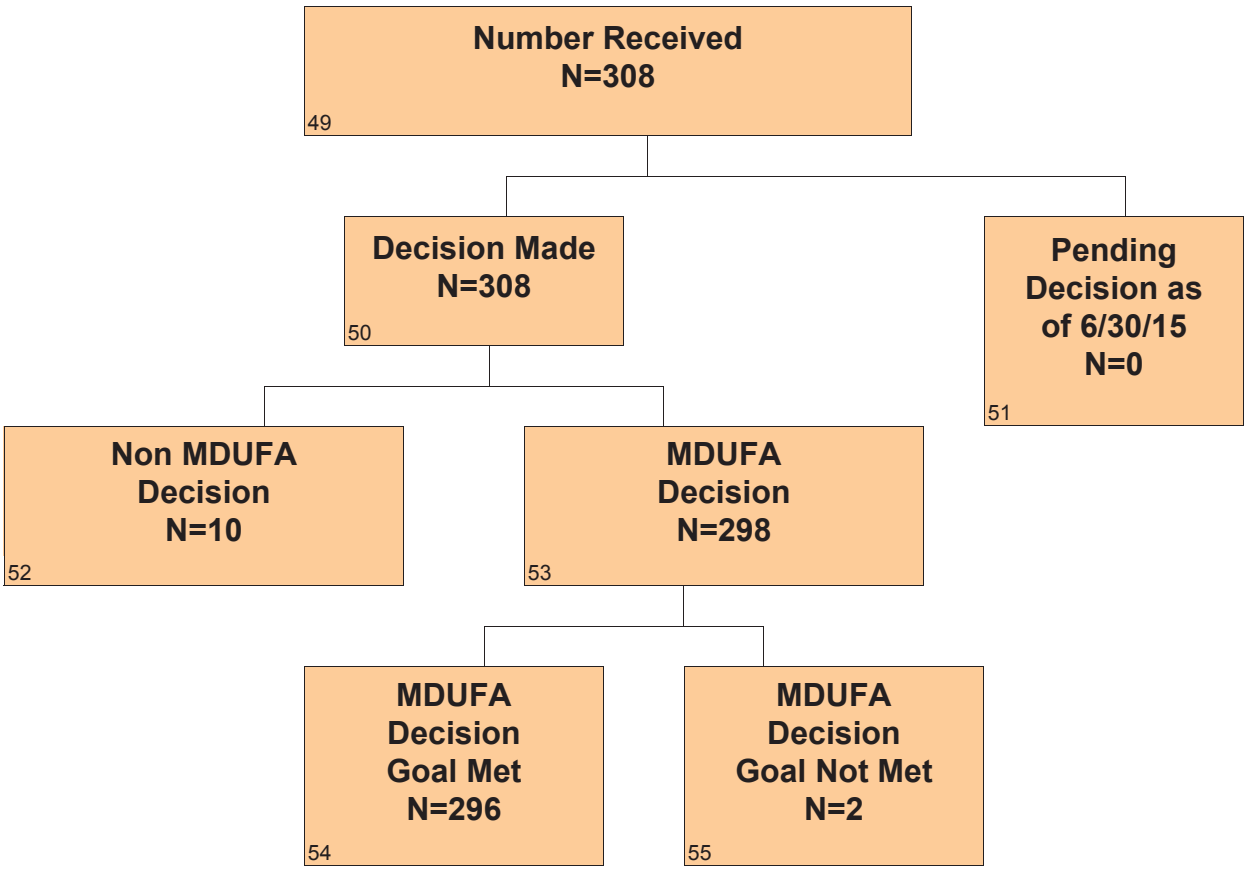
Table 2.3.DRH DRH - PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

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

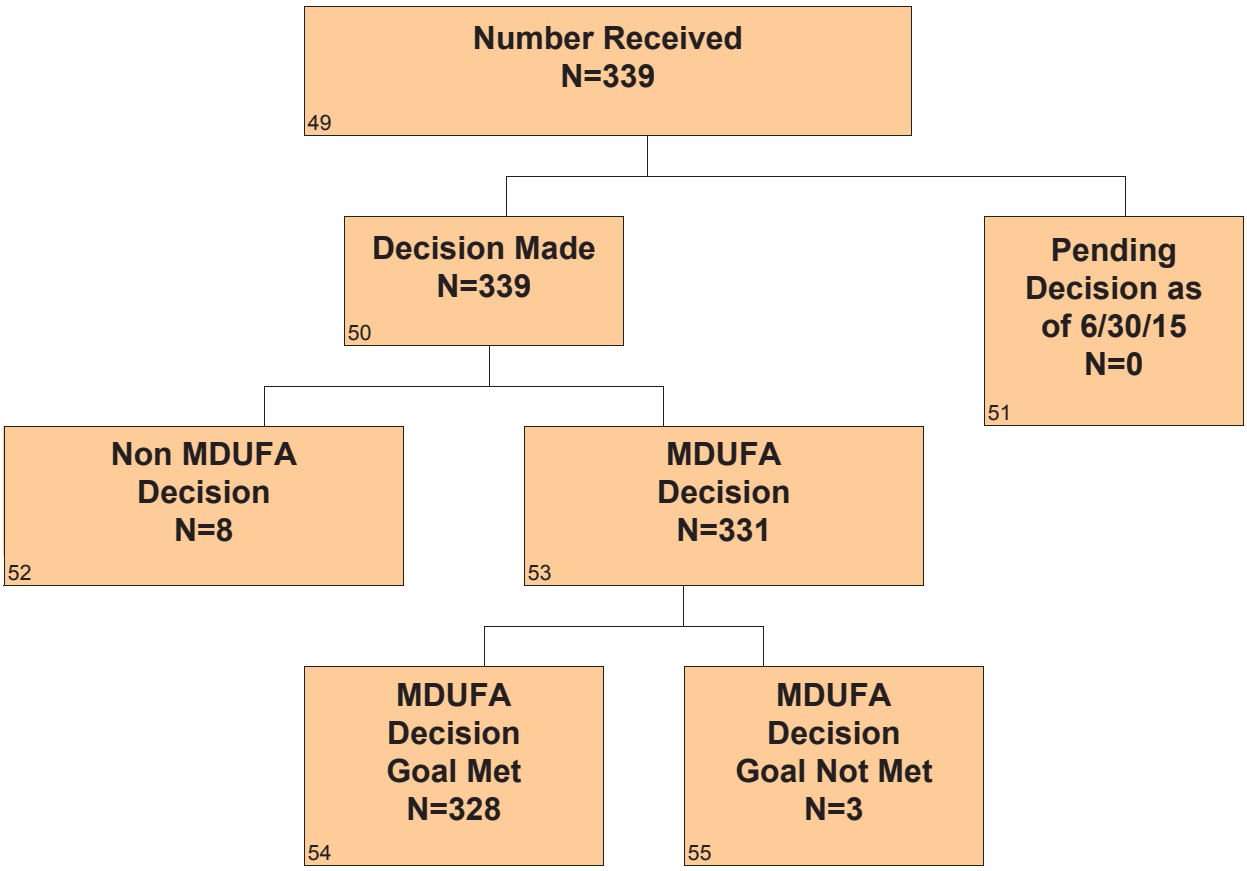
Table 2.4.DRH - OIR - PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

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

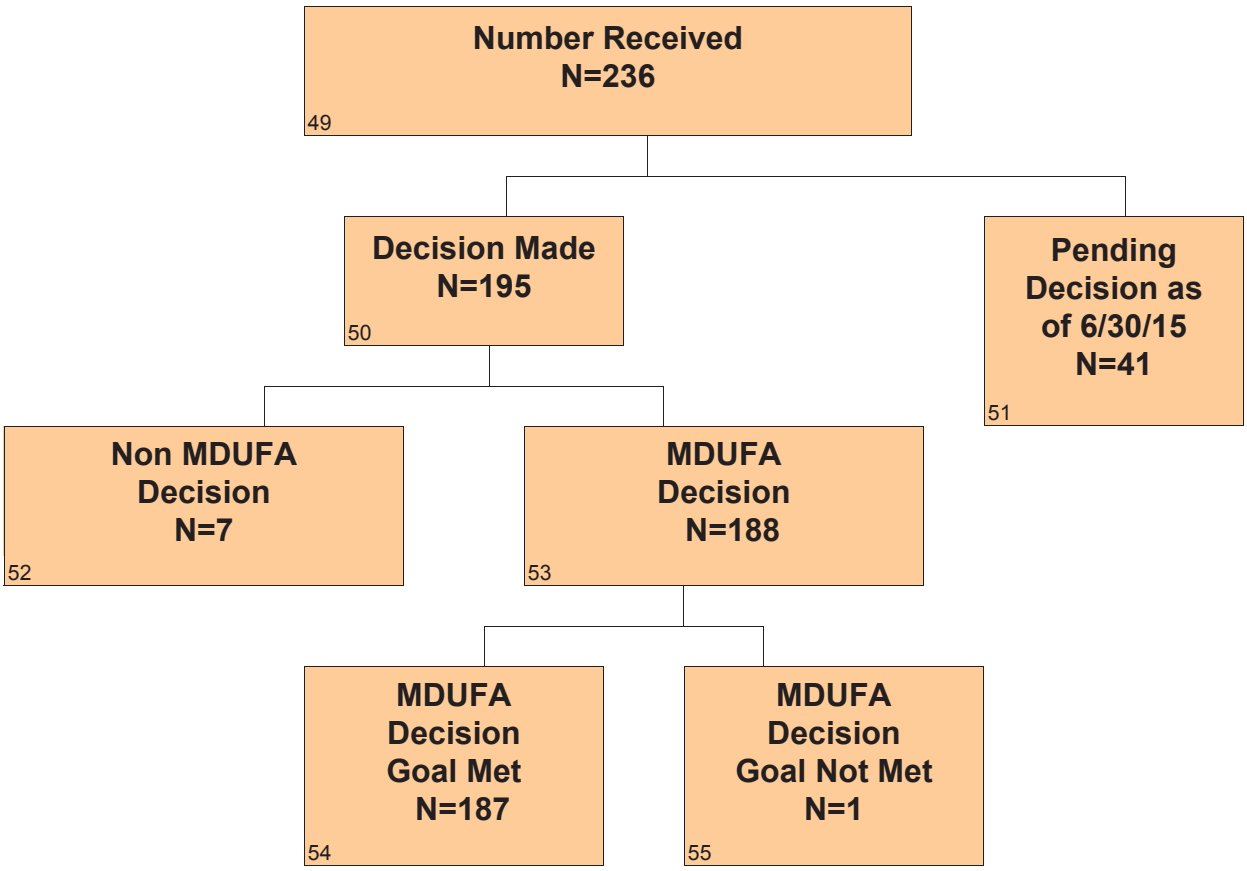
CDRH PMA Real Time Supplements - FY 2013 As of 6/30/15



CDRH PMA Real Time Supplements - FY 2014 As of 6/30/15



CDRH PMA Real Time Supplements - FY 2015 As of 6/30/15



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Section 3 PMA Real Time Supplements - Center Level Metrics

Table 3.1 CDRH – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	308	339	236		
Non-MDUFA III Decisions	10	8	7		
MDUFA III Decisions	298	331	188		
MDUFA III Decisions Goal Met	296	328	187		
Supplements pending MDUFA III Decision	0	0	41		
Supplements pending MDUFA III Decision Past Goal	0	0	2		
Current Performance Percent Goal Met	99.3%	99.1%	98.4%		

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	236		
Number with MDUFA decision	298	331	188		
Number of Not Approvable	20	3	12		
Rate of Not Approvable	6.7%	0.9%	6.4%		

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	3	1		
Mean FDA days for submissions that missed goal	143	99	97		
Mean Industry days for submissions that missed goal	0	0	0		

Section 3 PMA Real Time Supplements - Office Level Metrics

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	269	283	193		
Non-MDUFA III Decisions	9	6	6		
MDUFA III Decisions	260	277	153		
MDUFA III Decisions Goal Met	258	274	152		
Supplements pending MDUFA III Decision	0	0	34		
Supplements pending MDUFA III Decision Past Goal	0	0	2		
Current Performance Percent Goal Met	99.2%	98.9%	98.1%		

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	193		
Number with MDUFA decision	260	277	153		
Number of Not Approvable	15	3	9		
Rate of Not Approvable	5.8%	1.1%	5.9%		

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	3	1		
Mean FDA days for submissions that missed goal	143	99	97		
Mean Industry days for submissions that missed goal	0	0	0		

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

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	43		
Non-MDUFA III Decisions	1	2	1		
MDUFA III Decisions	38	54	35		
MDUFA III Decisions Goal Met	38	54	35		
Supplements pending MDUFA III Decision	0	0	7		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

Table 3.2.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	43		
Number with MDUFA decision	38	54	35		
Number of Not Approvable	5	0	3		
Rate of Not Approvable	13.2%	0%	8.6%		

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

Section 3 PMA Real Time Supplements - Division Level Metrics

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	13	8	4		
Non-MDUFA III Decisions	0	1	0		
MDUFA III Decisions	13	7	1		
MDUFA III Decisions Goal Met	13	5	1		
Supplements pending MDUFA III Decision	0	0	3		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.0%	71.4%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	13	8	4		
Number with MDUFA decision	13	7	1		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	7.7%	14.3%	0%		

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

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

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	176	218	136		
Non-MDUFA III Decisions	6	3	4		
MDUFA III Decisions	170	215	110		
MDUFA III Decisions Goal Met	170	215	109		
Supplements pending MDUFA III Decision	0	0	22		
Supplements pending MDUFA III Decision Past Goal	0	0	2		
Current Performance Percent Goal Met	100%	100%	97.3%		

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	136		
Number with MDUFA decision	170	215	110		
Number of Not Approvable	7	1	8		
Rate of Not Approvable	4.1%	0.5%	7.3%		

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

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

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	23	17	15		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	23	17	11		
MDUFA III Decisions Goal Met	23	16	11		
Supplements pending MDUFA III Decision	0	0	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	94.1%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	23	17	15		
Number with MDUFA decision	23	17	11		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	4.3%	5.9%	0%		

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

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

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	8	10	8		
Non-MDUFA III Decisions	0	2	1		
MDUFA III Decisions	8	8	6		
MDUFA III Decisions Goal Met	8	8	6		
Supplements pending MDUFA III Decision	0	0	1		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	10	8		
Number with MDUFA decision	8	8	6		
Number of Not Approvable	2	0	0		
Rate of Not Approvable	25.0%	0%	0%		

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

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

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	16	17	18		
Non-MDUFA III Decisions	0	0	1		
MDUFA III Decisions	16	17	16		
MDUFA III Decisions Goal Met	16	17	16		
Supplements pending MDUFA III Decision	0	0	1		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

Table 3.2.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	18		
Number with MDUFA decision	16	17	16		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

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

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

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	19	2	8		
Non-MDUFA III Decisions	2	0	0		
MDUFA III Decisions	17	2	7		
MDUFA III Decisions Goal Met	17	2	7		
Supplements pending MDUFA III Decision	0	0	1		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

Table 3.2.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	8		
Number with MDUFA decision	17	2	7		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	5.9%	0%	0%		

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

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

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	14	11	4		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	13	11	2		
MDUFA III Decisions Goal Met	11	11	2		
Supplements pending MDUFA III Decision	0	0	2		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	84.6%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	14	11	4		
Number with MDUFA decision	13	11	2		
Number of Not Approvable	3	0	1		
Rate of Not Approvable	23.1%	0%	50%		

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

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

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

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	6	19	16		
Non-MDUFA III Decisions	0	2	0		
MDUFA III Decisions	6	17	13		
MDUFA III Decisions Goal Met	6	17	13		
Supplements pending MDUFA III Decision	0	0	3		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	19	16		
Number with MDUFA decision	6	17	13		
Number of Not Approvable	0	0	3		
Rate of Not Approvable	0%	0%	23.1%		

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

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

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

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

Table 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		
Number with MDUFA decision	12	10	4		
Number of Not Approvable	2	0	0		
Rate of Not Approvable	16.7%	0%	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		
Mean FDA days for submissions that missed goal	0	0	0		
Mean Industry days for submissions that missed goal	0	0	0		

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

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	10		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	13	12	10		
MDUFA III Decisions Goal Met	13	12	10		
Supplements pending MDUFA III Decision	0	0	0		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

Table 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	10		
Number with MDUFA decision	13	12	10		
Number of Not Approvable	3	0	0		
Rate of Not Approvable	23.1%	0%	0%		

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

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

Table 3.1.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	10		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	7	13	6		
MDUFA III Decisions Goal Met	7	13	6		
Supplements pending MDUFA III Decision	0	0	4		
Supplements pending MDUFA III Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

Table 3.2.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	10		
Number with MDUFA decision	7	13	6		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

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

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

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

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

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

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

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

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

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Section 4 Pre-Market Report Submissions

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

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Section 5 PMA Annual Metrics and Goals

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

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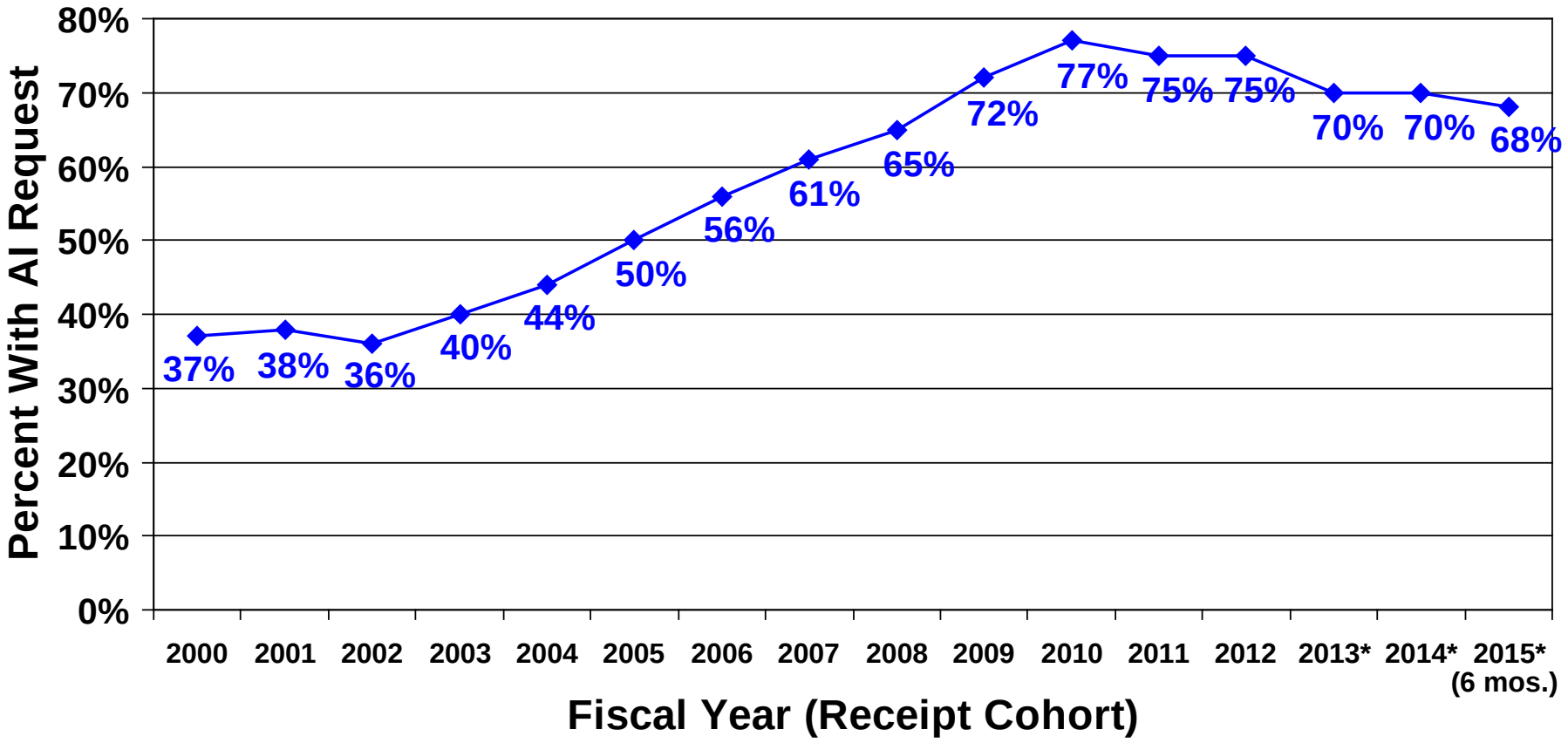
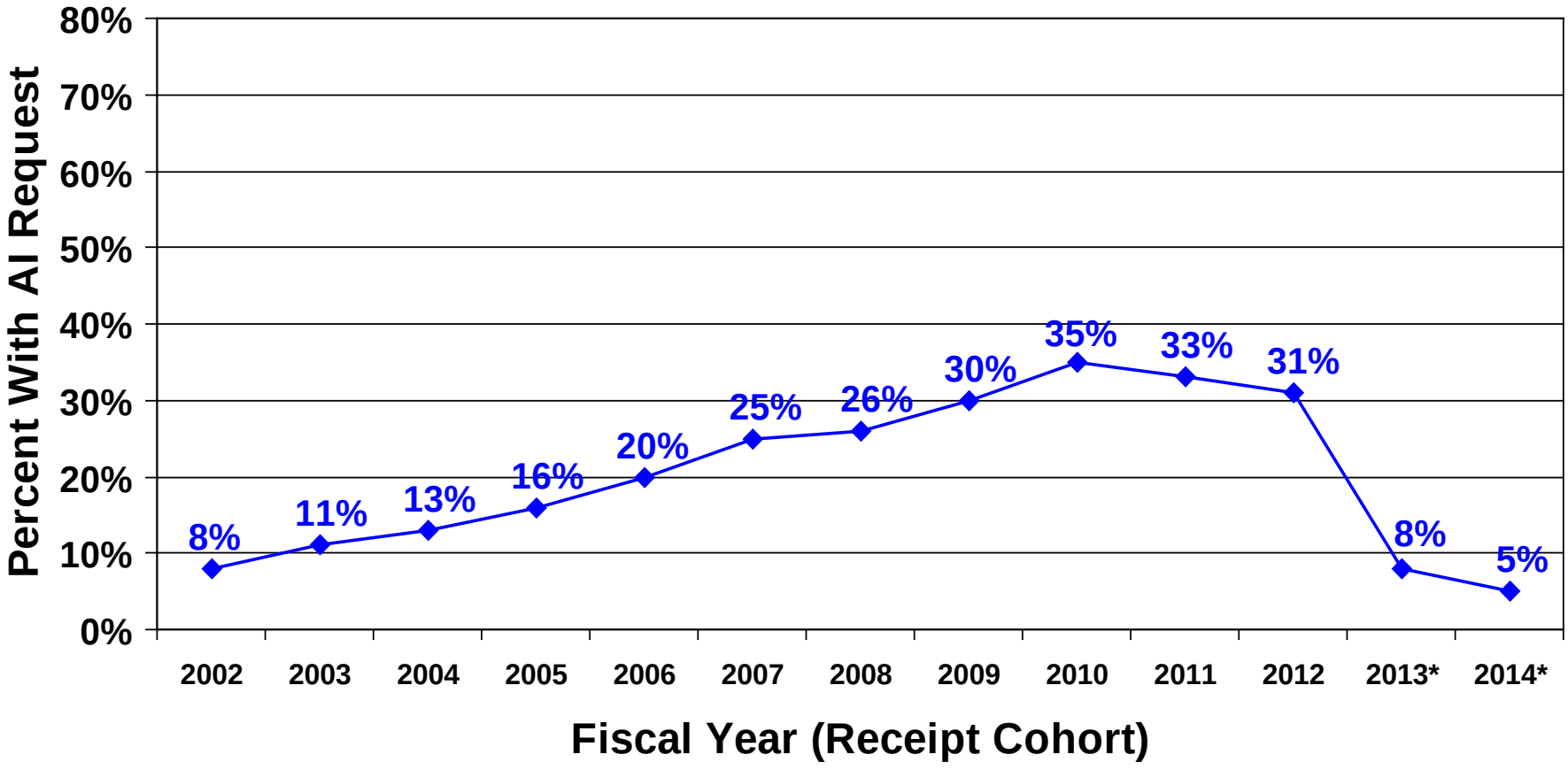
510(k)s

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



*FY 2013 - FY 2015 data are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for submissions accepted as of 03/31/2015; FY 2015 1st cycle cohort is still open as of 06/30/2015 and data may change

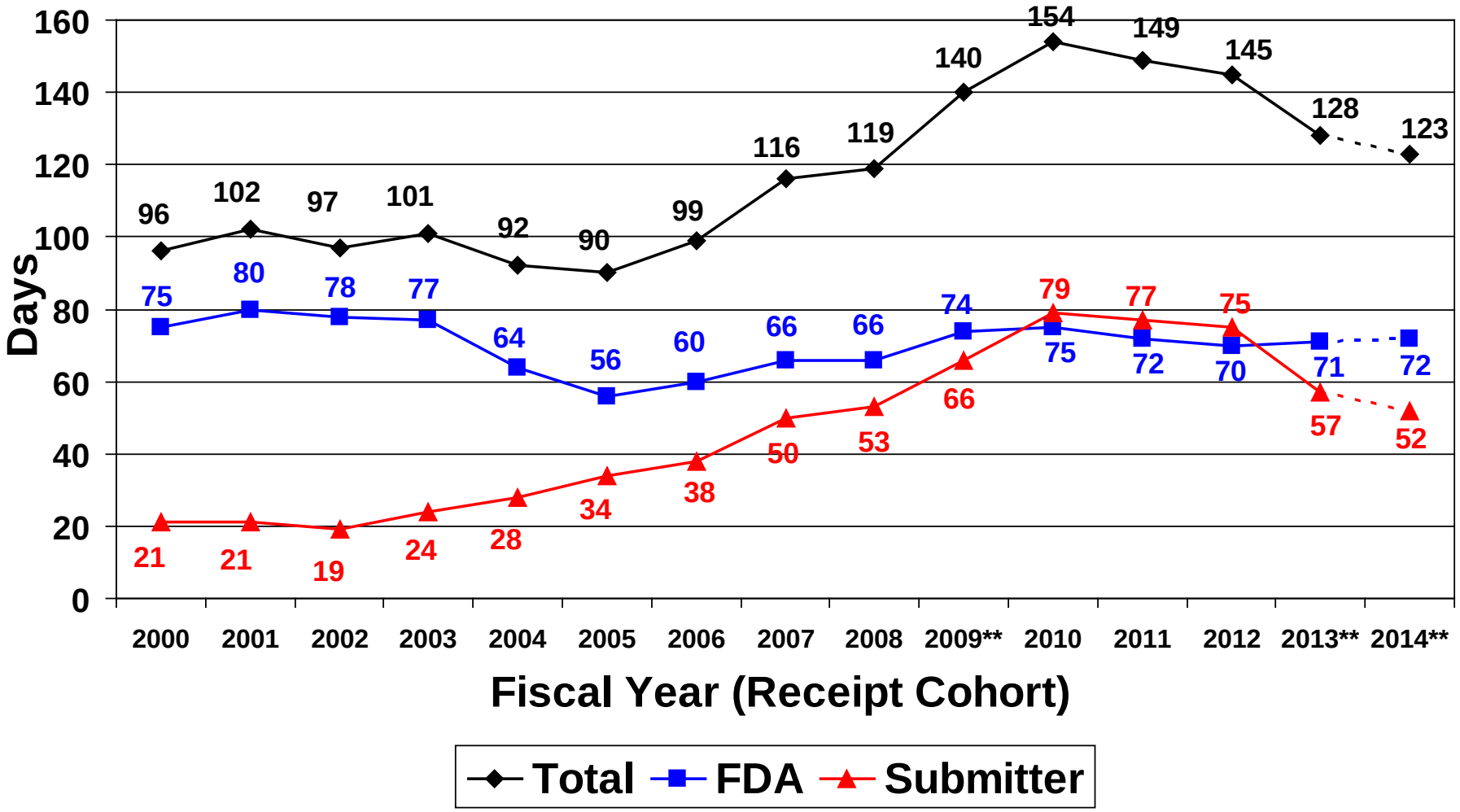
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



*FY 2013 and FY 2014 data are for 510(k)s accepted as of 11/30/2014; FY 2014 2nd cycle cohort is still open as of 06/30/2015 and data may change

Average Time to Decision: 510(k)s*

(Receipt Cohorts as of June 30, 2015)

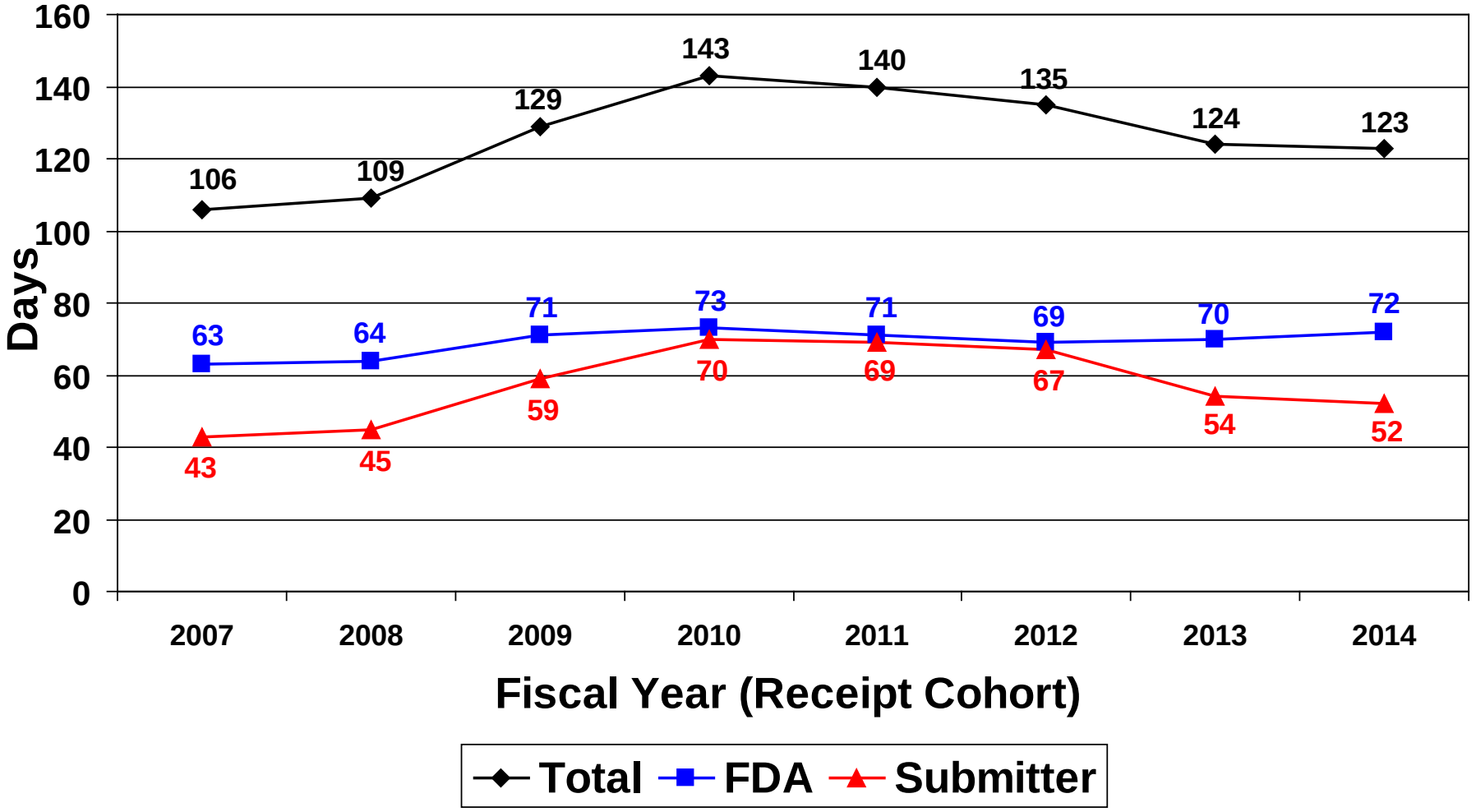


*SE and NSE decisions only; times may not add to total due to rounding

**Cohorts still open; percentage of cohort closed: FY 2009 = 99.9%, FY 2013 = 99.9%, and FY 2014 = 95.9%—average times for FY 2014 will increase

Average Time to Decision: 510(k)s*

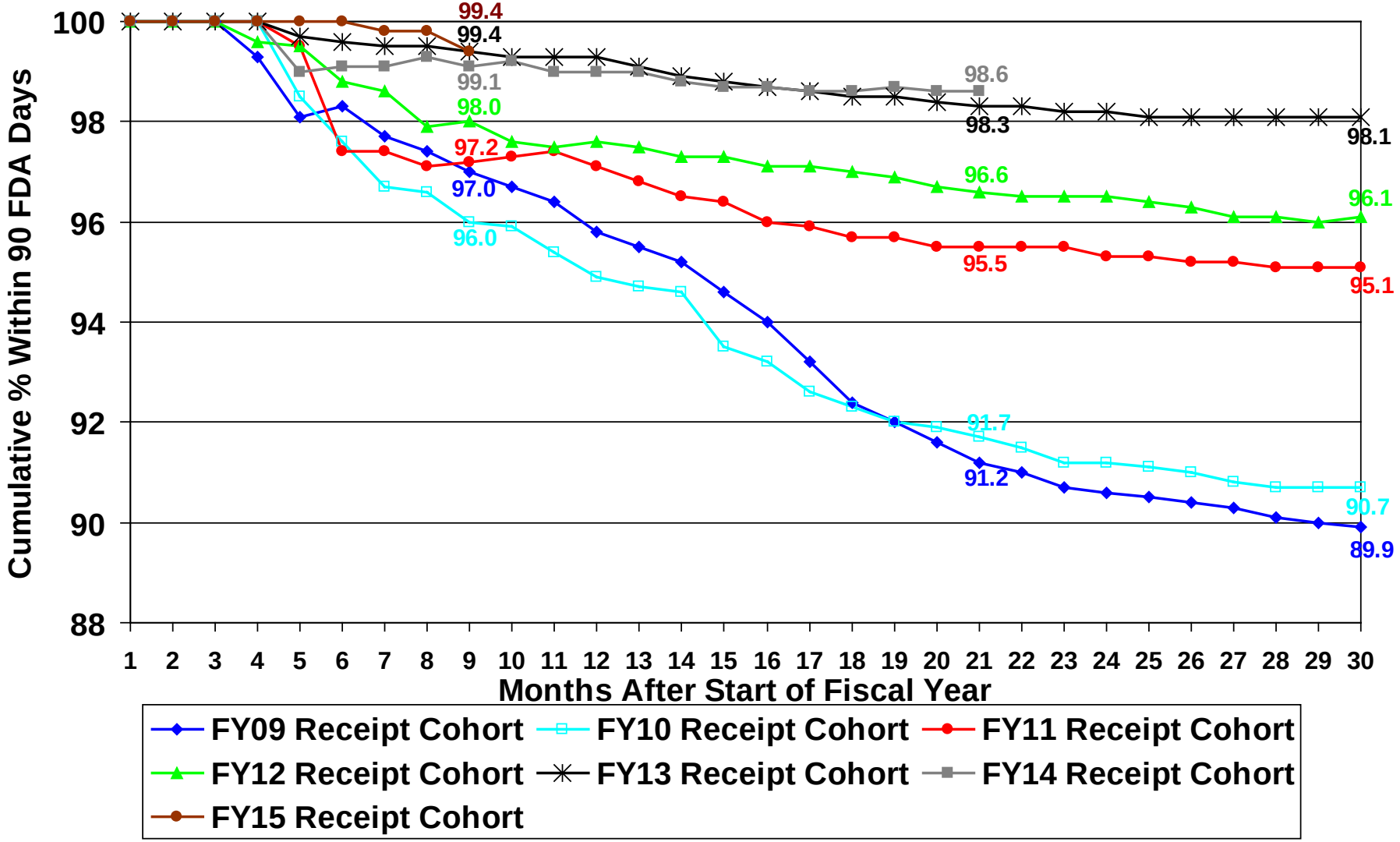
- Comparison of Receipt Cohorts When 95.9% Closed -



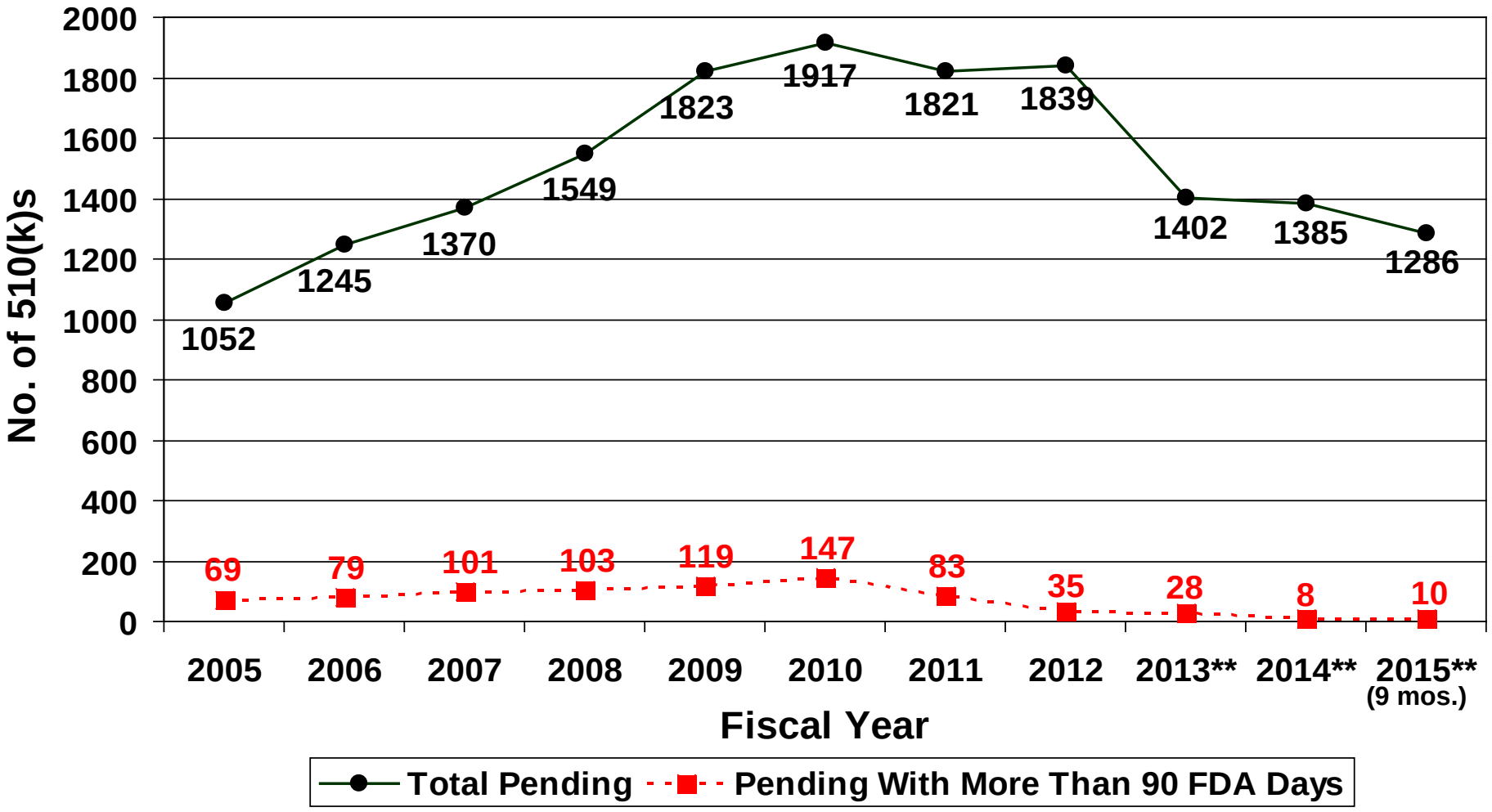
*SE and NSE decisions only; times may not add to total due to rounding

Trend in 510(k) MDUFA Decision Goal Performance

- Comparison of FY09 - FY15 Receipt Cohorts -



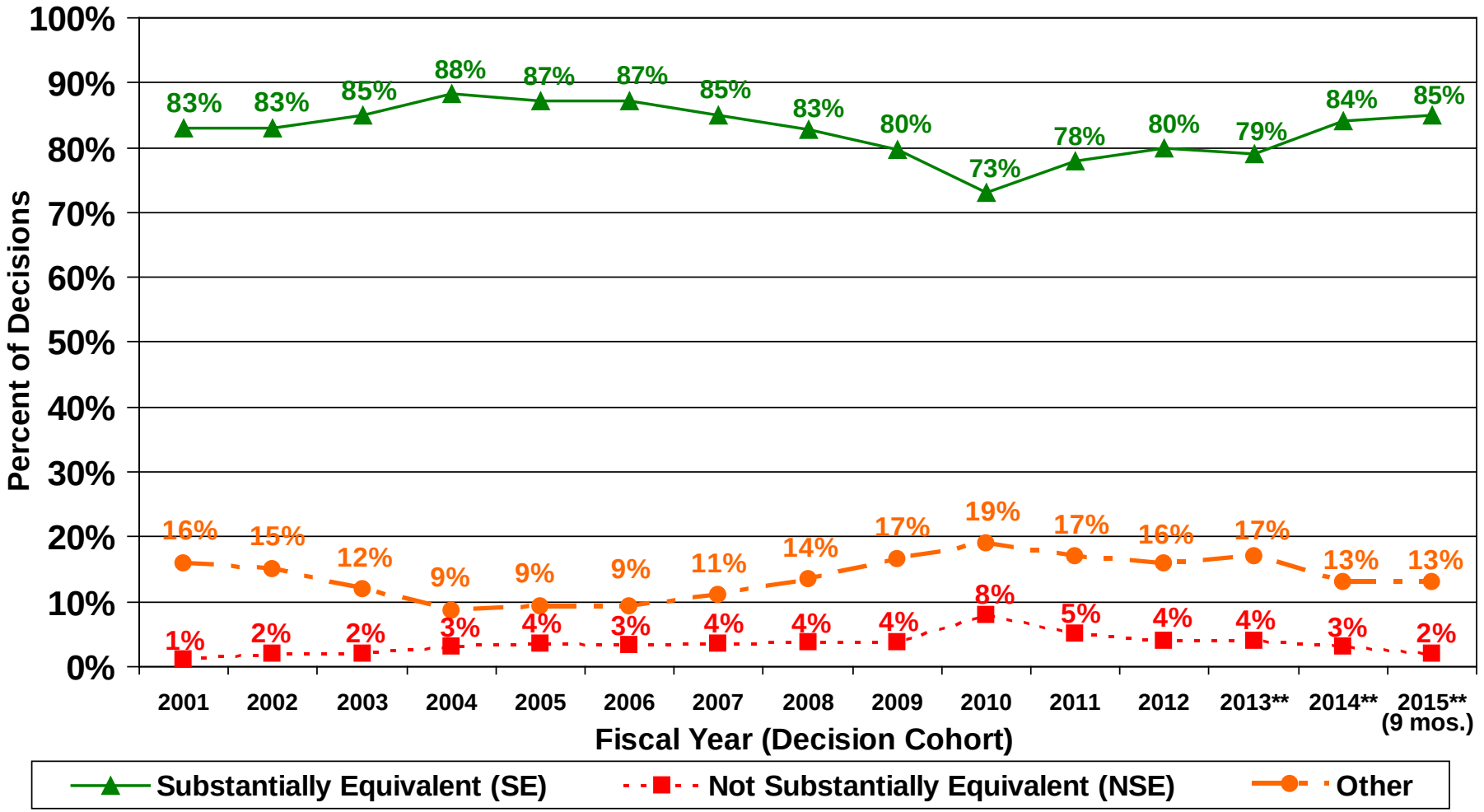
510(k)s Pending* at End of Year



*Under review or on hold; FY 2015 is as of 06/30/2015

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

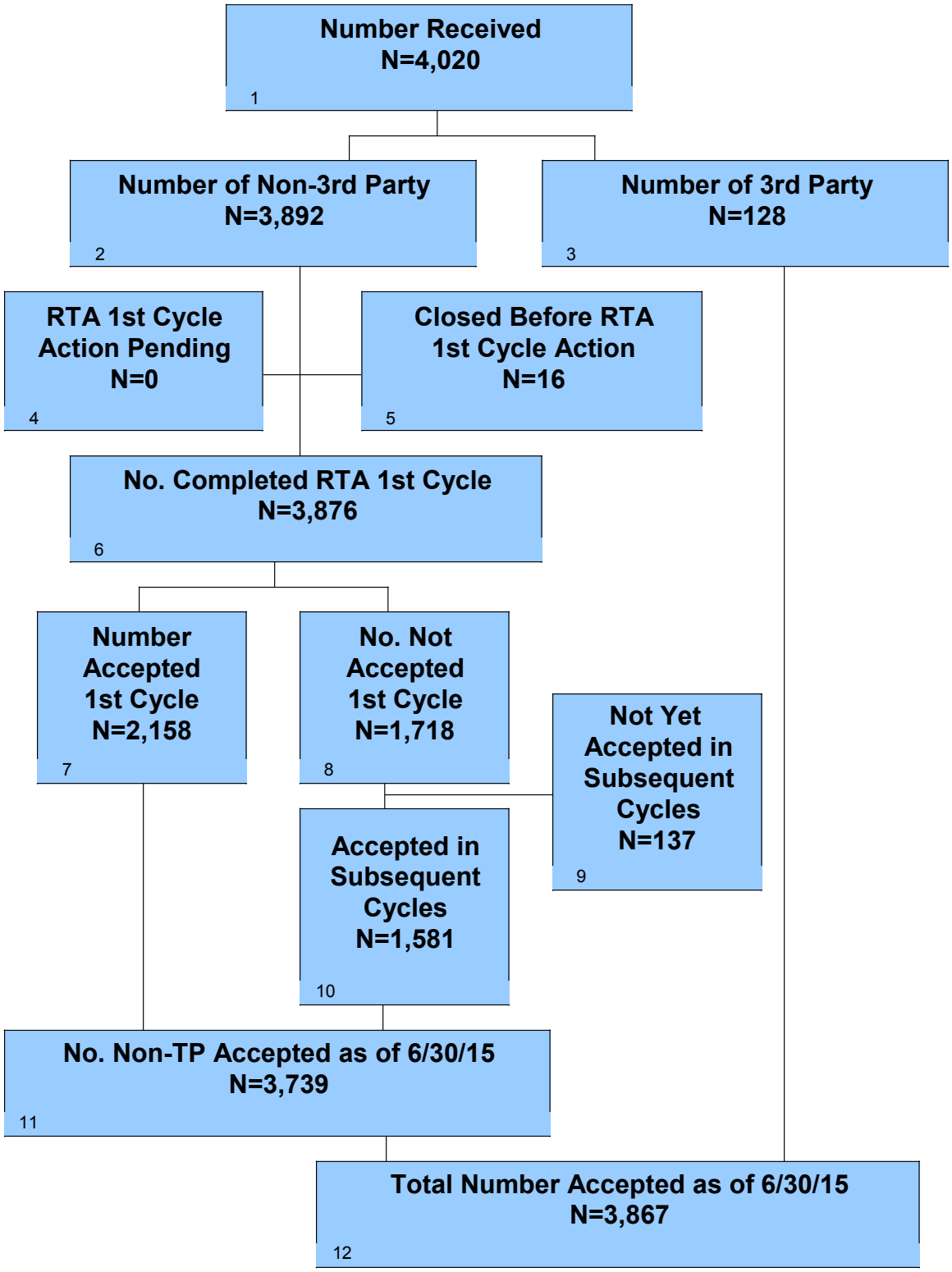
Percent of 510(k)s Determined to be Substantially Equivalent (SE)*



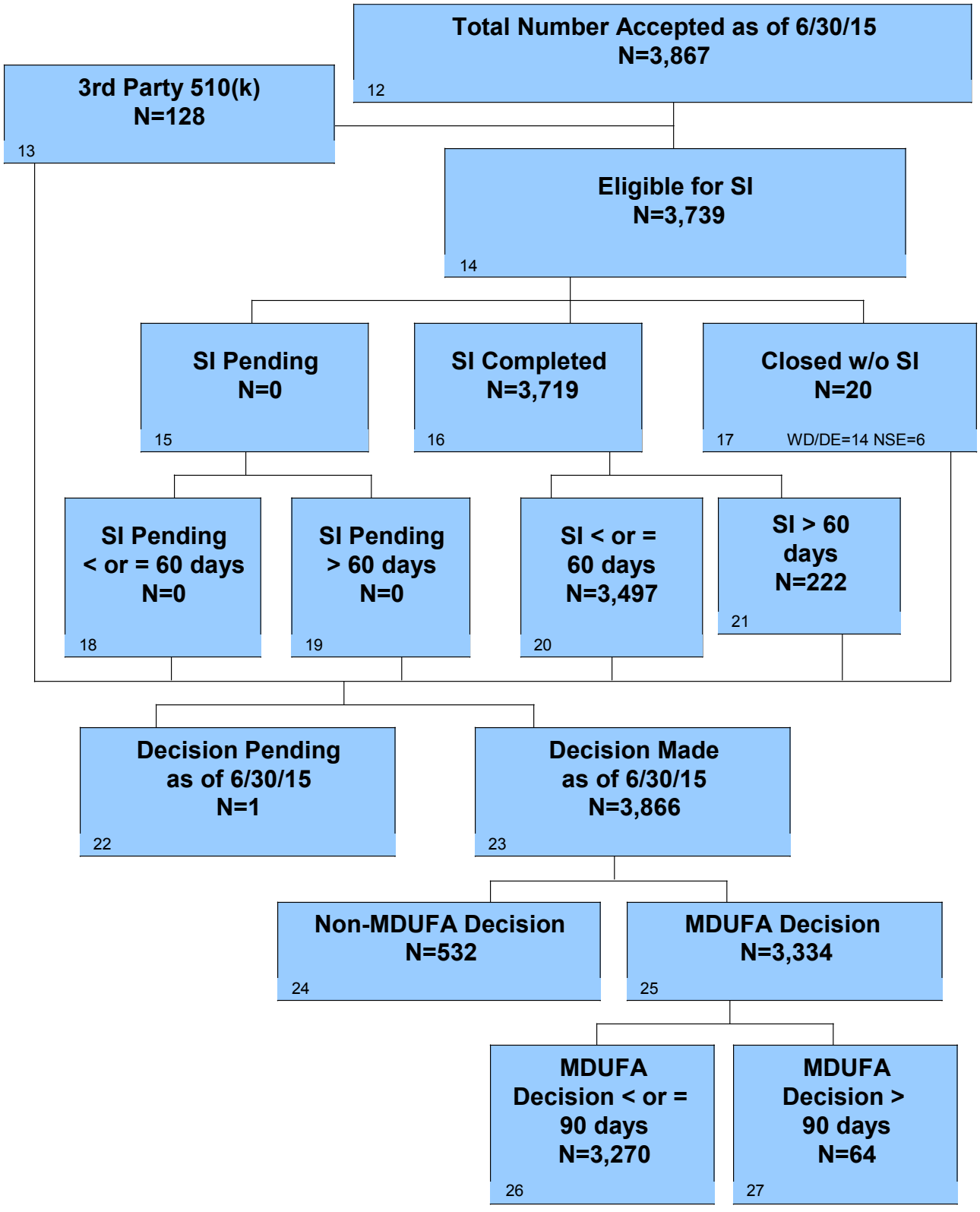
*Percentages may not add to 100% due to rounding

**Excludes final decisions made on FY 2013 - FY 2015 receipts that were not accepted for review as of 06/30/2015

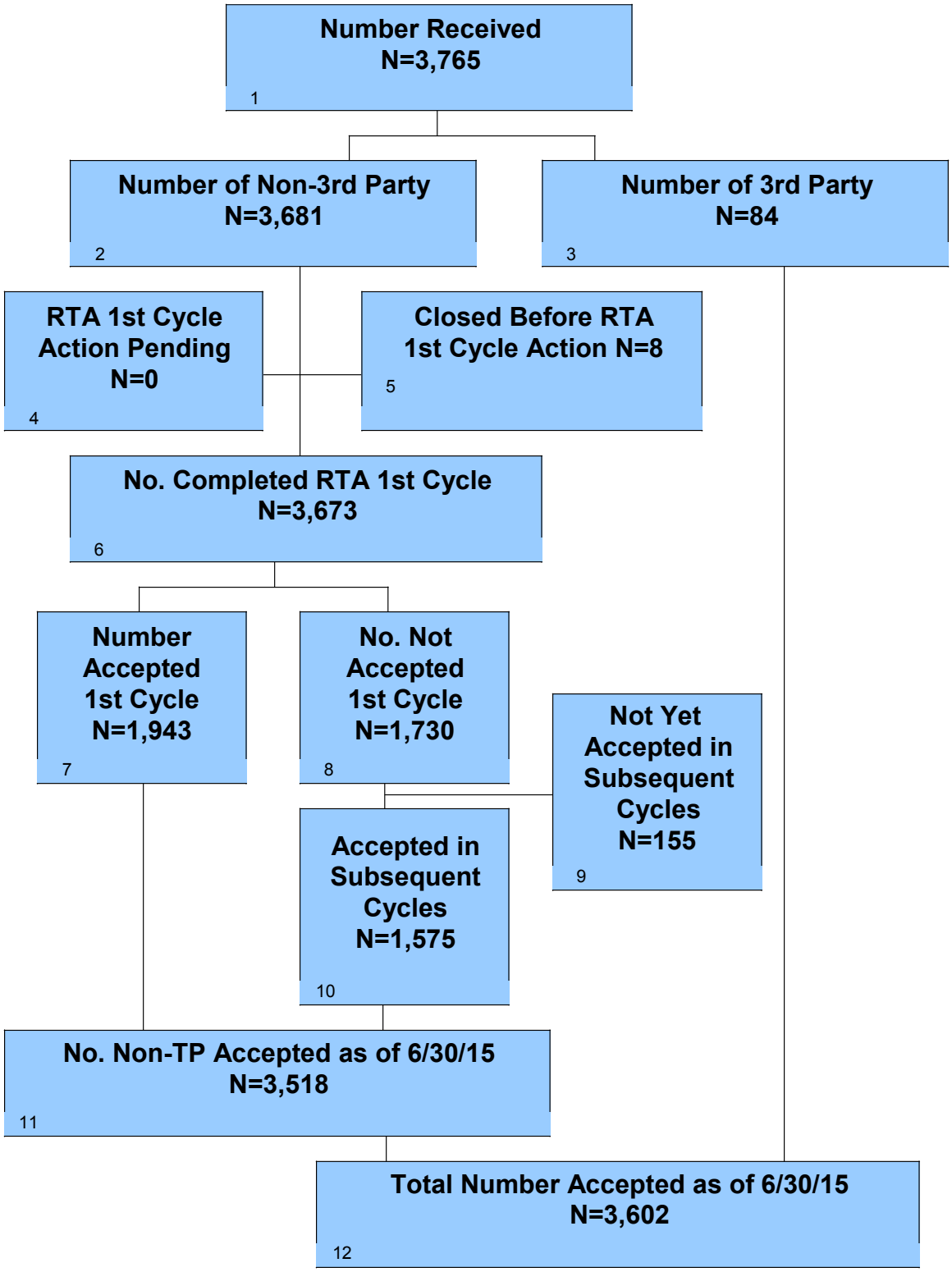
CDRH 510(k)s - FY 2013
As of 6/30/15



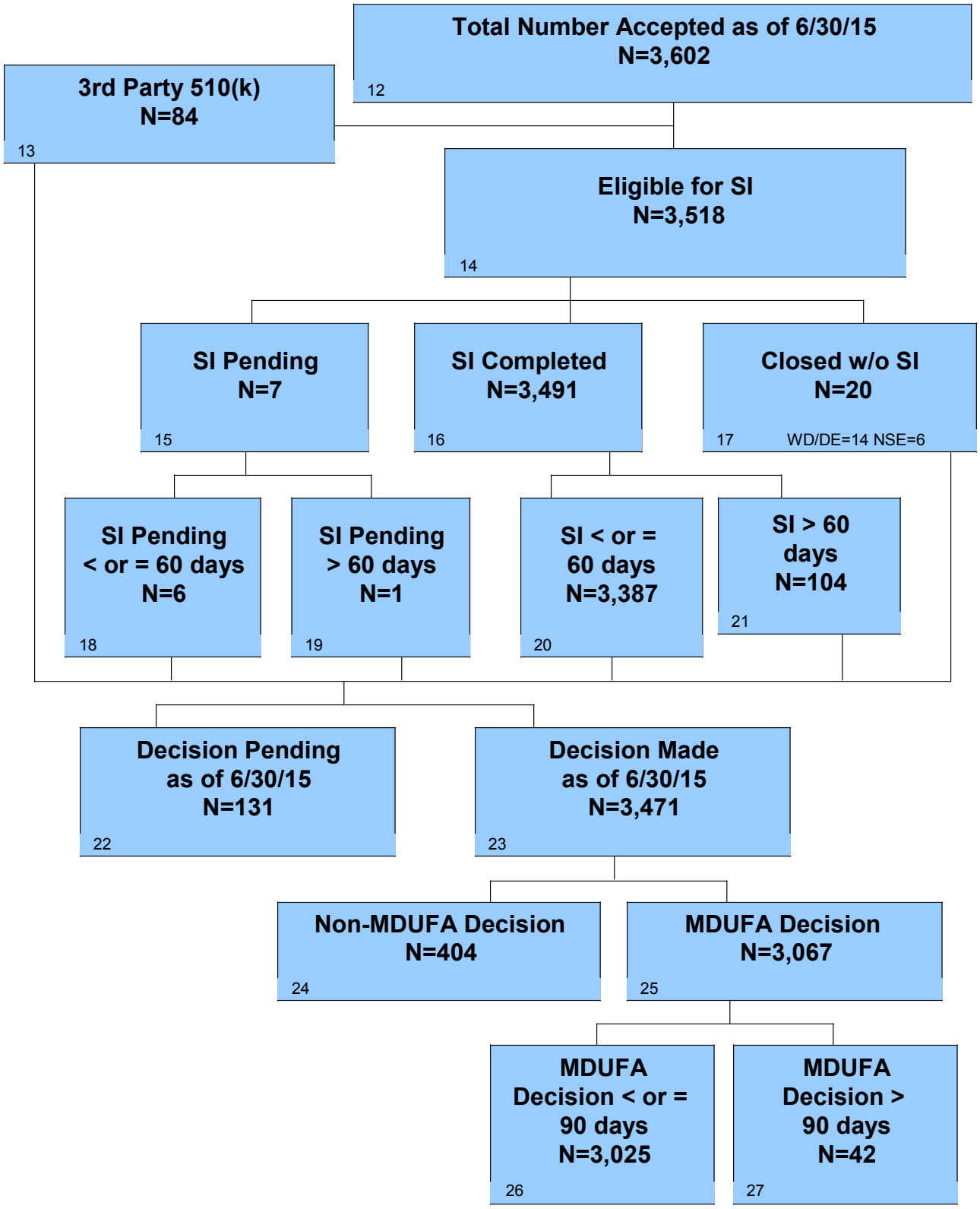
CDRH 510(k)s - FY 2013
As of 6/30/15 Continued



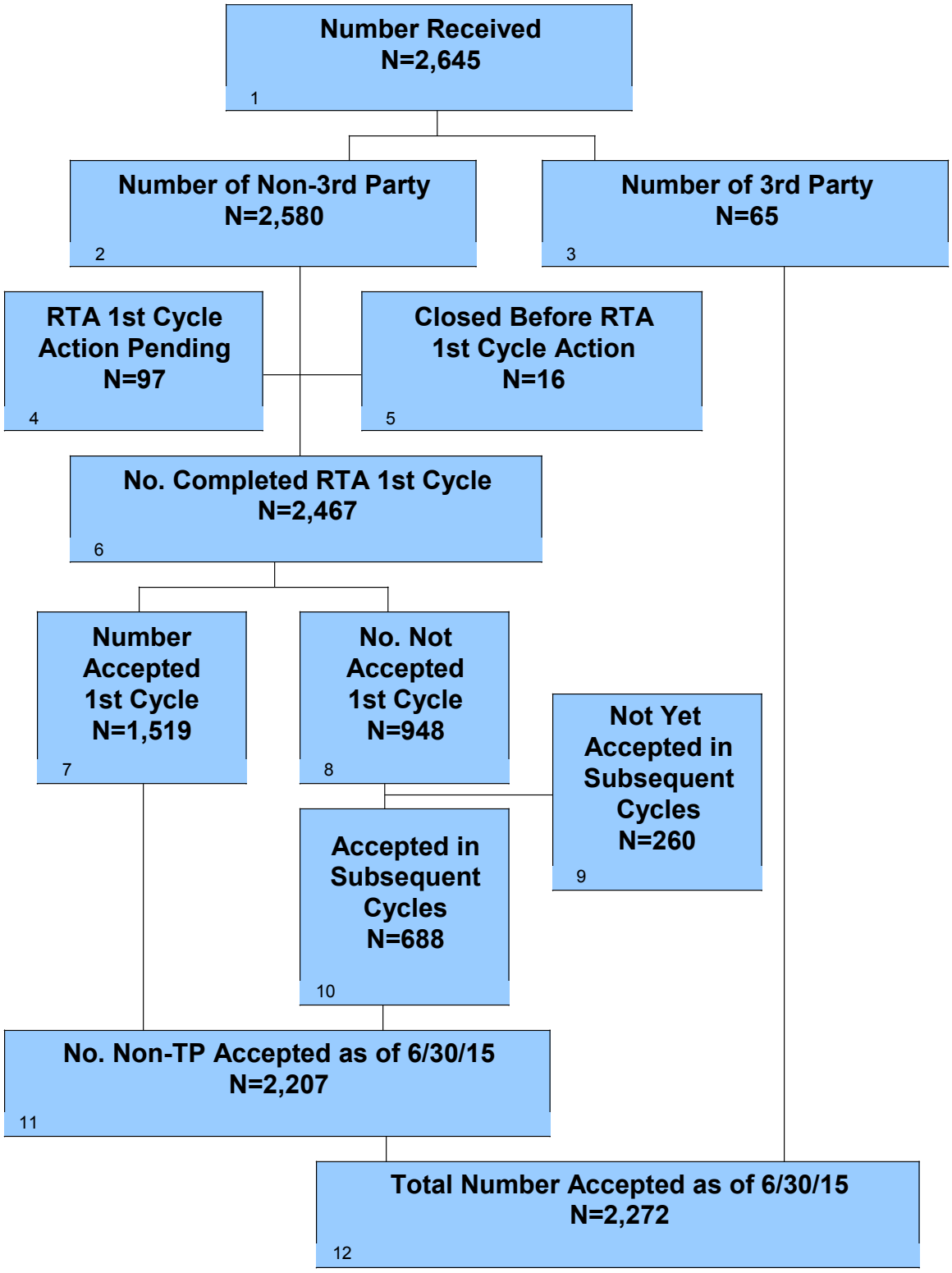
CDRH 510(k)s - FY 2014
As of 6/30/15



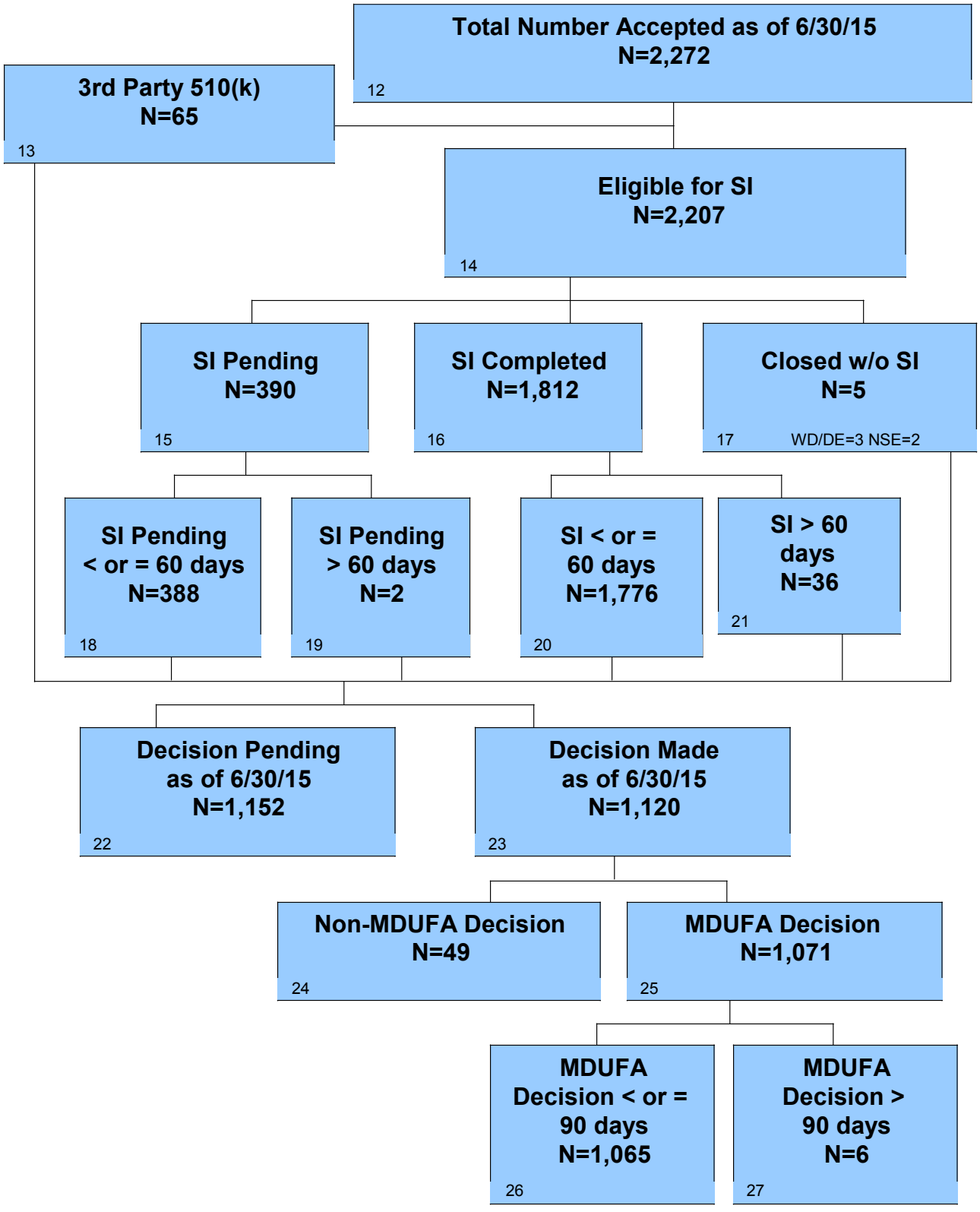
CDRH 510(k)s - FY 2014
As of 6/30/15 Continued



CDRH 510(k)s - FY 2015
As of 6/30/15



CDRH 510(k)s - FY 2015
As of 6/30/15 Continued



Section 6 510(k) Center Level Metrics

Table 6.1 CDRH – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,965	3,681	2,580		
Closed before RTA action	11	8	16		
Number Accepted	1,197	1,886	1,497		
Number without a RTA Review and > 15 Days since Date Received	42	57	22		
Number without a RTA Review and <= 15 Days since Date Received	0	0	97		
Number Not Accepted	1,715	1,730	948		
Rate of submissions not accepted for filing review	58.1%	47.1%	38.4%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	3,739	3,518	2,207		
Deleted or withdrawn prior to SI	14	14	3		
SI within 60 FDA days	3,497	3,387	1,776		
SI over 60 FDA days	222	104	36		
SI pending within 60 FDA days	0	6	388		
SI pending over 60 FDA days	0	1	2		
510(k)s NSE without SI	6	6	2		
Current SI Performance Percent within 60 FDA days	93.9%	96.8%	97.8%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	3,719	3,491	1,812		
Average number of FDA days to Substantive Interaction	47.6	49.4	48.7		
20th Percentile FDA days to Substantive Interaction	30	33	30		
40th Percentile FDA days to Substantive Interaction	48	52	50		
60th Percentile FDA days to Substantive Interaction	56	57	57		
80th Percentile FDA days to Substantive Interaction	59	59	59		
Maximum FDA days to Substantive Interaction	98	188	93		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,867	3,602	2,272		
Non-MDUFA III Decisions	532	404	49		
MDUFA III Decisions (SE/NSE)	3,334	3,067	1,071		
MDUFA III Decisions within 90 FDA Days	3,270	3,025	1,065		
510(k)s pending MDUFA III Decision	1	131	1,152		
510(k) pending MDUFA III Decision over 90 FDA days	0	5	3		
Current Performance Percent within 90 FDA Days	98.1%	98.5%	99.2%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.7	1.5		
Number with MDUFA III decision	3,334	3,067	1,071		
Average FDA days to MDUFA III decision	70.8	71.6	63.3		
20th Percentile FDA days to MDUFA III decision	48	51	30		
40th Percentile FDA days to MDUFA III decision	76	79	57		
60th Percentile FDA days to MDUFA III decision	86	87	83		
80th Percentile FDA days to MDUFA III decision	89	89	88		
Maximum FDA days to MDUFA III decision	342	245	99		
Average Industry days to MDUFA III decision	57.1	51.7	20.3		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	14	12	0		
60th Percentile Industry days to MDUFA III decision	44	42	13		
80th Percentile Industry days to MDUFA III decision	116	106	39		
Maximum Industry days to MDUFA III decision	467	469	185		
Average Total days to MDUFA III decision	127.8	123.3	83.6		
20th Percentile Total days to MDUFA III decision	56	57	30		
40th Percentile Total days to MDUFA III decision	90	90	66		
60th Percentile Total days to MDUFA III decision	127	123	90		
80th Percentile Total days to MDUFA III decision	199	191	121		
Maximum Total days to MDUFA III decision	691	556	262		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,867	3,602	2,272		
Number with MDUFA decision	3,334	3,067	1,071		
Number of SE decisions	3,201	2,991	1,060		
Number of NSE decisions	133	76	11		
Number of Withdrawals	231	190	30		
Number deleted	279	181	11		
Rate of SE decisions	96.0%	97.5%	99.0%		
Rate of NSE decisions	4.0%	2.5%	1.0%		
Rate of Withdrawals	6.0%	5.3%	1.3%		
Rate of Deleted	7.2%	5.0%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	64	42	6		
Mean FDA days for submissions that missed goal	119	106	94		
Mean industry days for submissions that missed goal	138	105	11		

Section 6 510(k) Office Level Metrics

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,389	2,955	2,123		
Closed before RTA action	9	6	15		
Number Accepted	821	1,339	1,137		
Number without a RTA Review and > 15 Days since Date Received	24	50	20		
Number without a RTA Review and <= 15 Days since Date Received	0	0	81		
Number Not Accepted	1,535	1,560	870		
Rate of submissions not accepted for filing review	64.5%	52.9%	42.9%		

*** 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
Eligible for SI	2,976	2,822	1,797		
Deleted or withdrawn prior to SI	13	14	2		
SI within 60 FDA days	2,778	2,707	1,438		
SI over 60 FDA days	179	89	32		
SI pending within 60 FDA days	0	5	321		
SI pending over 60 FDA days	0	1	2		
510(k)s NSE without SI	6	6	2		
Current SI Performance Percent within 60 FDA days	93.8%	96.6%	97.6%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2,957	2,796	1,470		
Average number of FDA days to Substantive Interaction	48.3	50.4	49.6		
20th Percentile FDA days to Substantive Interaction	30	37	35		
40th Percentile FDA days to Substantive Interaction	49	54	52		
60th Percentile FDA days to Substantive Interaction	57	58	57		
80th Percentile FDA days to Substantive Interaction	59	60	59		
Maximum FDA days to Substantive Interaction	98	188	93		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,050	2,869	1,839		
Non-MDUFA III Decisions	446	338	43		
MDUFA III Decisions (SE/NSE)	2,604	2,426	843		
MDUFA III Decisions within 90 FDA Days	2,547	2,399	837		
510(k)s pending MDUFA III Decision	0	105	953		
510(k) pending MDUFA III Decision over 90 FDA days	0	5	3		
Current Performance Percent within 90 FDA Days	97.8%	98.7%	98.9%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.7	1.5		
Number with MDUFA III decision	2,604	2,426	843		
Average FDA days to MDUFA III decision	72.8	73.4	66.0		
20th Percentile FDA days to MDUFA III decision	53	55	30		
40th Percentile FDA days to MDUFA III decision	80	82	59		
60th Percentile FDA days to MDUFA III decision	87	87	86		
80th Percentile FDA days to MDUFA III decision	89	89	89		
Maximum FDA days to MDUFA III decision	342	245	99		
Average Industry days to MDUFA III decision	57.3	52.7	21.0		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	17	14	0		
60th Percentile Industry days to MDUFA III decision	46	44	15		
80th Percentile Industry days to MDUFA III decision	116	109	40		
Maximum Industry days to MDUFA III decision	438	359	178		
Average Total days to MDUFA III decision	130.1	126.0	87.0		
20th Percentile Total days to MDUFA III decision	59	60	39		
40th Percentile Total days to MDUFA III decision	94	92	74		
60th Percentile Total days to MDUFA III decision	129	128	93		
80th Percentile Total days to MDUFA III decision	200	196	125		
Maximum Total days to MDUFA III decision	691	448	262		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	3,050	2,869	1,839		
Number with MDUFA decision	2,604	2,426	843		
Number of SE decisions	2,493	2,368	836		
Number of NSE decisions	111	58	7		
Number of Withdrawals	189	155	26		
Number deleted	237	151	9		
Rate of SE decisions	95.7%	97.6%	99.2%		
Rate of NSE decisions	4.3%	2.4%	0.8%		
Rate of Withdrawals	6.2%	5.4%	1.4%		
Rate of Deleted	7.8%	5.3%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	57	27	6		
Mean FDA days for submissions that missed goal	121	110	94		
Mean industry days for submissions that missed goal	137	126	11		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	576	726	457		
Closed before RTA action	2	2	1		
Number Accepted	376	547	360		
Number without a RTA Review and > 15 Days since Date Received	18	7	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	16		
Number Not Accepted	180	170	78		
Rate of submissions not accepted for filing review	31.4%	23.5%	17.7%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	763	696	410		
Deleted or withdrawn prior to SI	1	0	1		
SI within 60 FDA days	719	680	338		
SI over 60 FDA days	43	15	4		
SI pending within 60 FDA days	0	1	67		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	94.4%	97.8%	98.8%		

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	695	342		
Average number of FDA days to Substantive Interaction	45.0	45.6	44.7		
20th Percentile FDA days to Substantive Interaction	29	30	30		
40th Percentile FDA days to Substantive Interaction	43	45	43		
60th Percentile FDA days to Substantive Interaction	51	53	51		
80th Percentile FDA days to Substantive Interaction	58	58	58		
Maximum FDA days to Substantive Interaction	91	93	70		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	817	733	433		
Non-MDUFA III Decisions	86	66	6		
MDUFA III Decisions (SE/NSE)	730	641	228		
MDUFA III Decisions within 90 FDA Days	723	626	228		
510(k)s pending MDUFA III Decision	1	26	199		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	99.0%	97.7%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.7	1.4		
Number with MDUFA III decision	730	641	228		
Average FDA days to MDUFA III decision	63.5	65.1	53.4		
20th Percentile FDA days to MDUFA III decision	34	32	29		
40th Percentile FDA days to MDUFA III decision	58	60	42		
60th Percentile FDA days to MDUFA III decision	80	83	61		
80th Percentile FDA days to MDUFA III decision	88	88	82		
Maximum FDA days to MDUFA III decision	121	137	90		
Average Industry days to MDUFA III decision	56.2	48.1	17.7		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	35	33	0		
80th Percentile Industry days to MDUFA III decision	111	95	35		
Maximum Industry days to MDUFA III decision	467	469	185		
Average Total days to MDUFA III decision	119.6	113.1	71.0		
20th Percentile Total days to MDUFA III decision	36	34	29		
40th Percentile Total days to MDUFA III decision	77	84	48		
60th Percentile Total days to MDUFA III decision	111	111	74		
80th Percentile Total days to MDUFA III decision	192	173	106		
Maximum Total days to MDUFA III decision	557	556	246		

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	733	433		
Number with MDUFA decision	730	641	228		
Number of SE decisions	708	623	224		
Number of NSE decisions	22	18	4		
Number of Withdrawals	42	35	4		
Number deleted	42	30	2		
Rate of SE decisions	97.0%	97.2%	98%		
Rate of NSE decisions	3.0%	2.8%	1.8%		
Rate of Withdrawals	5.1%	4.8%	0.9%		
Rate of Deleted	5.1%	4.1%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	7	15	0		
Mean FDA days for submissions that missed goal	103	100	0		
Mean industry days for submissions that missed goal	143	67	0		

Section 6 510(k) Division Level Metrics

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	637	775	530		
Closed before RTA action	6	1	2		
Number Accepted	189	317	245		
Number without a RTA Review and > 15 Days since Date Received	5	14	5		
Number without a RTA Review and <= 15 Days since Date Received	0	0	23		
Number Not Accepted	437	443	255		
Rate of submissions not accepted for filing review	69.3%	57.2%	50.5%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	782	720	418		
Deleted or withdrawn prior to SI	3	7	0		
SI within 60 FDA days	749	706	323		
SI over 60 FDA days	26	3	4		
SI pending within 60 FDA days	0	1	88		
SI pending over 60 FDA days	0	0	1		
510(k)s NSE without SI	4	3	2		
Current SI Performance Percent within 60 FDA days	96.1%	99.2%	97.9%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	775	709	327		
Average number of FDA days to Substantive Interaction	50.9	53.4	53.4		
20th Percentile FDA days to Substantive Interaction	43	50	50		
40th Percentile FDA days to Substantive Interaction	55	57	56		
60th Percentile FDA days to Substantive Interaction	58	59	58		
80th Percentile FDA days to Substantive Interaction	60	60	60		
Maximum FDA days to Substantive Interaction	90	188	69		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	797	734	431		
Non-MDUFA III Decisions	165	97	12		
MDUFA III Decisions (SE/NSE)	632	594	159		
MDUFA III Decisions within 90 FDA Days	613	584	155		
510(k)s pending MDUFA III Decision	0	43	260		
510(k) pending MDUFA III Decision over 90 FDA days	0	2	0		
Current Performance Percent within 90 FDA Days	97.0%	98.0%	97.5%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.8	1.7		
Number with MDUFA III decision	632	594	159		
Average FDA days to MDUFA III decision	78.0	79.6	76.7		
20th Percentile FDA days to MDUFA III decision	63	77	59		
40th Percentile FDA days to MDUFA III decision	84	86	87		
60th Percentile FDA days to MDUFA III decision	88	88	88		
80th Percentile FDA days to MDUFA III decision	90	90	90		
Maximum FDA days to MDUFA III decision	280	107	99		
Average Industry days to MDUFA III decision	64.2	63.7	27.1		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	21	27	10		
60th Percentile Industry days to MDUFA III decision	54	64	22		
80th Percentile Industry days to MDUFA III decision	141	129	51		
Maximum Industry days to MDUFA III decision	420	272	147		
Average Total days to MDUFA III decision	142.2	143.3	103.8		
20th Percentile Total days to MDUFA III decision	78	86	78		
40th Percentile Total days to MDUFA III decision	102	111	90		
60th Percentile Total days to MDUFA III decision	140	149	106		
80th Percentile Total days to MDUFA III decision	220	217	138		
Maximum Total days to MDUFA III decision	610	361	237		

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	734	431		
Number with MDUFA decision	632	594	159		
Number of SE decisions	603	572	156		
Number of NSE decisions	29	22	3		
Number of Withdrawals	56	46	8		
Number deleted	104	40	1		
Rate of SE decisions	95.4%	96.3%	98%		
Rate of NSE decisions	4.6%	3.7%	2%		
Rate of Withdrawals	7.0%	6.3%	1.9%		
Rate of Deleted	13.0%	5.4%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	19	10	4		
Mean FDA days for submissions that missed goal	125	99	93		
Mean industry days for submissions that missed goal	157	160	2		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	336	407	274		
Closed before RTA action	0	1	2		
Number Accepted	151	196	162		
Number without a RTA Review and > 15 Days since Date Received	10	9	5		
Number without a RTA Review and <= 15 Days since Date Received	0	0	12		
Number Not Accepted	175	201	93		
Rate of submissions not accepted for filing review	52.1%	49.5%	35.8%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	432	400	237		
Deleted or withdrawn prior to SI	2	2	1		
SI within 60 FDA days	392	379	188		
SI over 60 FDA days	38	19	5		
SI pending within 60 FDA days	0	0	42		
SI pending over 60 FDA days	0	0	1		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	91.2%	95.2%	96.9%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	430	398	193		
Average number of FDA days to Substantive Interaction	45.5	46.5	46.3		
20th Percentile FDA days to Substantive Interaction	29	29	29		
40th Percentile FDA days to Substantive Interaction	43	46	48		
60th Percentile FDA days to Substantive Interaction	50	55	53		
80th Percentile FDA days to Substantive Interaction	58	59	59		
Maximum FDA days to Substantive Interaction	98	90	83		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	456	414	245		
Non-MDUFA III Decisions	29	40	4		
MDUFA III Decisions (SE/NSE)	427	366	137		
MDUFA III Decisions within 90 FDA Days	412	361	136		
510(k)s pending MDUFA III Decision	0	8	104		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1		
Current Performance Percent within 90 FDA Days	96.5%	98.6%	98.6%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.7	1.6	1.5		
Number with MDUFA III decision	427	366	137		
Average FDA days to MDUFA III decision	67.2	67.8	60.7		
20th Percentile FDA days to MDUFA III decision	36	37	30		
40th Percentile FDA days to MDUFA III decision	59	60	57		
60th Percentile FDA days to MDUFA III decision	86	87	76		
80th Percentile FDA days to MDUFA III decision	89	89	89		
Maximum FDA days to MDUFA III decision	237	140	94		
Average Industry days to MDUFA III decision	47.5	46.0	23.9		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	11	8	0		
60th Percentile Industry days to MDUFA III decision	38	34	15		
80th Percentile Industry days to MDUFA III decision	84	101	41		
Maximum Industry days to MDUFA III decision	358	226	176		
Average Total days to MDUFA III decision	114.8	113.8	84.5		
20th Percentile Total days to MDUFA III decision	41	42	30		
40th Percentile Total days to MDUFA III decision	85	86	59		
60th Percentile Total days to MDUFA III decision	119	118	93		
80th Percentile Total days to MDUFA III decision	171	186	128		
Maximum Total days to MDUFA III decision	451	315	230		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	456	414	245		
Number with MDUFA decision	427	366	137		
Number of SE decisions	418	363	136		
Number of NSE decisions	9	3	1		
Number of Withdrawals	14	21	4		
Number deleted	14	19	0		
Rate of SE decisions	97.9%	99.2%	99.3%		
Rate of NSE decisions	2.1%	1%	1%		
Rate of Withdrawals	3.1%	5.1%	2%		
Rate of Deleted	3.1%	4.6%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	15	5	1		
Mean FDA days for submissions that missed goal	123	110	94		
Mean industry days for submissions that missed goal	114	104	34		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	190	206	155		
Closed before RTA action	0	1	0		
Number Accepted	39	81	62		
Number without a RTA Review and > 15 Days since Date Received	1	4	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	8		
Number Not Accepted	150	120	83		
Rate of submissions not accepted for filing review	78.9%	58.5%	56.5%		

*** 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
Eligible for SI	230	188	122		
Deleted or withdrawn prior to SI	1	1	0		
SI within 60 FDA days	203	180	103		
SI over 60 FDA days	26	7	1		
SI pending within 60 FDA days	0	0	18		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	88.6%	96.3%	99.0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	229	187	104		
Average number of FDA days to Substantive Interaction	51.9	53.8	54.5		
20th Percentile FDA days to Substantive Interaction	43	53	53		
40th Percentile FDA days to Substantive Interaction	55	58	58		
60th Percentile FDA days to Substantive Interaction	58	59	60		
80th Percentile FDA days to Substantive Interaction	60	60	60		
Maximum FDA days to Substantive Interaction	80	64	61		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	236	191	128		
Non-MDUFA III Decisions	31	35	2		
MDUFA III Decisions (SE/NSE)	205	152	49		
MDUFA III Decisions within 90 FDA Days	199	148	49		
510(k)s pending MDUFA III Decision	0	4	77		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	1		
Current Performance Percent within 90 FDA Days	97.1%	97.4%	98.0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.9	1.9	1.8		
Number with MDUFA III decision	205	152	49		
Average FDA days to MDUFA III decision	83.7	83.8	77.0		
20th Percentile FDA days to MDUFA III decision	86	86	58		
40th Percentile FDA days to MDUFA III decision	88	88	88		
60th Percentile FDA days to MDUFA III decision	89	89	90		
80th Percentile FDA days to MDUFA III decision	90	90	90		
Maximum FDA days to MDUFA III decision	148	245	90		
Average Industry days to MDUFA III decision	77.5	74.1	29.3		
20th Percentile Industry days to MDUFA III decision	8	7	0		
40th Percentile Industry days to MDUFA III decision	41	43	14		
60th Percentile Industry days to MDUFA III decision	84	81	23		
80th Percentile Industry days to MDUFA III decision	152	151	48		
Maximum Industry days to MDUFA III decision	345	191	125		
Average Total days to MDUFA III decision	161.2	157.9	106.4		
20th Percentile Total days to MDUFA III decision	90	90	73		
40th Percentile Total days to MDUFA III decision	128	130	98		
60th Percentile Total days to MDUFA III decision	174	166	112		
80th Percentile Total days to MDUFA III decision	240	246	137		
Maximum Total days to MDUFA III decision	435	291	214		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	236	191	128		
Number with MDUFA decision	205	152	49		
Number of SE decisions	187	144	49		
Number of NSE decisions	18	8	0		
Number of Withdrawals	13	17	1		
Number deleted	13	15	0		
Rate of SE decisions	91.2%	94.7%	100%		
Rate of NSE decisions	8.8%	5.3%	0%		
Rate of Withdrawals	5.5%	8.9%	0.8%		
Rate of Deleted	5.5%	7.9%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	6	4	0		
Mean FDA days for submissions that missed goal	105	150	0		
Mean industry days for submissions that missed goal	122	95	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	508		
Closed before RTA action	0	1	2		
Number Accepted	181	313	272		
Number without a RTA Review and > 15 Days since Date Received	0	3	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	21		
Number Not Accepted	342	348	213		
Rate of submissions not accepted for filing review	65.4%	52.4%	43.9%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	655	654	453		
Deleted or withdrawn prior to SI	3	1	0		
SI within 60 FDA days	623	634	371		
SI over 60 FDA days	29	15	9		
SI pending within 60 FDA days	0	2	73		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	2	0		
Current SI Performance Percent within 60 FDA days	95.6%	97.4%	97.6%		

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	649	380		
Average number of FDA days to Substantive Interaction	47.9	48.7	47.5		
20th Percentile FDA days to Substantive Interaction	30	29	30		
40th Percentile FDA days to Substantive Interaction	48	52	49		
60th Percentile FDA days to Substantive Interaction	56	57	56		
80th Percentile FDA days to Substantive Interaction	59	59	58		
Maximum FDA days to Substantive Interaction	88	90	92		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	656	654	453		
Non-MDUFA III Decisions	73	44	3		
MDUFA III Decisions (SE/NSE)	583	599	252		
MDUFA III Decisions within 90 FDA Days	579	597	252		
510(k)s pending MDUFA III Decision	0	11	198		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	99.3%	99.7%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.6	1.6	1.4		
Number with MDUFA III decision	583	599	252		
Average FDA days to MDUFA III decision	69.9	68.8	62.5		
20th Percentile FDA days to MDUFA III decision	49	47	30		
40th Percentile FDA days to MDUFA III decision	74	73	56		
60th Percentile FDA days to MDUFA III decision	85	85	79		
80th Percentile FDA days to MDUFA III decision	88	88	87		
Maximum FDA days to MDUFA III decision	100	94	90		
Average Industry days to MDUFA III decision	40.5	37.2	15.3		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	2	0	0		
60th Percentile Industry days to MDUFA III decision	30	22	0		
80th Percentile Industry days to MDUFA III decision	75	77	24		
Maximum Industry days to MDUFA III decision	430	264	178		
Average Total days to MDUFA III decision	110.4	106.1	77.8		
20th Percentile Total days to MDUFA III decision	52	50	34		
40th Percentile Total days to MDUFA III decision	85	83	59		
60th Percentile Total days to MDUFA III decision	110	104	87		
80th Percentile Total days to MDUFA III decision	163	159	105		
Maximum Total days to MDUFA III decision	520	352	262		

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	453		
Number with MDUFA decision	583	599	252		
Number of SE decisions	564	592	252		
Number of NSE decisions	19	7	0		
Number of Withdrawals	37	25	2		
Number deleted	35	19	1		
Rate of SE decisions	96.7%	98.8%	100%		
Rate of NSE decisions	3.3%	1.2%	0%		
Rate of Withdrawals	5.6%	3.8%	0%		
Rate of Deleted	5.3%	2.9%	0%		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	118	142	99		
Closed before RTA action	0	0	1		
Number Accepted	59	75	52		
Number without a RTA Review and > 15 Days since Date Received	5	2	2		
Number without a RTA Review and <= 15 Days since Date Received	0	0	2		
Number Not Accepted	54	65	42		
Rate of submissions not accepted for filing review	45.8%	45.8%	43.8%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	139	136	88		
Deleted or withdrawn prior to SI	0	0	0		
SI within 60 FDA days	134	134	75		
SI over 60 FDA days	5	1	1		
SI pending within 60 FDA days	0	0	12		
SI pending over 60 FDA days	0	1	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	96.4%	99%	98.7%		

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	135	76		
Average number of FDA days to Substantive Interaction	48.7	51.5	51.3		
20th Percentile FDA days to Substantive Interaction	43	46	48		
40th Percentile FDA days to Substantive Interaction	49	53	54		
60th Percentile FDA days to Substantive Interaction	54	57	57		
80th Percentile FDA days to Substantive Interaction	57	59	59		
Maximum FDA days to Substantive Interaction	88	62	63		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	146	138	91		
Non-MDUFA III Decisions	20	21	6		
MDUFA III Decisions (SE/NSE)	126	109	43		
MDUFA III Decisions within 90 FDA Days	123	109	43		
510(k)s pending MDUFA III Decision	0	8	42		
510(k) pending MDUFA III Decision over 90 FDA days	0	1	0		
Current Performance Percent within 90 FDA Days	97.6%	99.1%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.8	1.6		
Number with MDUFA III decision	126	109	43		
Average FDA days to MDUFA III decision	75.5	78.1	65.8		
20th Percentile FDA days to MDUFA III decision	56	60	46		
40th Percentile FDA days to MDUFA III decision	84	87	58		
60th Percentile FDA days to MDUFA III decision	88	89	85		
80th Percentile FDA days to MDUFA III decision	90	90	90		
Maximum FDA days to MDUFA III decision	91	90	90		
Average Industry days to MDUFA III decision	62.8	54.4	22.5		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	21	20	0		
60th Percentile Industry days to MDUFA III decision	60	41	15		
80th Percentile Industry days to MDUFA III decision	160	110	45		
Maximum Industry days to MDUFA III decision	250	333	161		
Average Total days to MDUFA III decision	138.3	132.5	88.3		
20th Percentile Total days to MDUFA III decision	70	76	52		
40th Percentile Total days to MDUFA III decision	105	104	69		
60th Percentile Total days to MDUFA III decision	135	131	89		
80th Percentile Total days to MDUFA III decision	230	194	125		
Maximum Total days to MDUFA III decision	332	423	249		

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	138	91		
Number with MDUFA decision	126	109	43		
Number of SE decisions	121	103	41		
Number of NSE decisions	5	6	2		
Number of Withdrawals	8	4	3		
Number deleted	11	14	2		
Rate of SE decisions	96.0%	94.5%	95.3%		
Rate of NSE decisions	4.0%	5.5%	4.7%		
Rate of Withdrawals	5.5%	2.9%	3.3%		
Rate of Deleted	7.5%	10.1%	2.2%		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	210	277	201		
Closed before RTA action	0	2	7		
Number Accepted	66	145	129		
Number without a RTA Review and > 15 Days since Date Received	0	7	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	6		
Number Not Accepted	144	123	58		
Rate of submissions not accepted for filing review	68.6%	44.7%	30.9%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	265	267	169		
Deleted or withdrawn prior to SI	1	3	1		
SI within 60 FDA days	253	255	137		
SI over 60 FDA days	9	7	2		
SI pending within 60 FDA days	0	1	29		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	2	1	0		
Current SI Performance Percent within 60 FDA days	95.8%	97.0%	98.6%		

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	262	139		
Average number of FDA days to Substantive Interaction	48.2	48.9	47.8		
20th Percentile FDA days to Substantive Interaction	36	38	36		
40th Percentile FDA days to Substantive Interaction	50	50	48		
60th Percentile FDA days to Substantive Interaction	56	56	56		
80th Percentile FDA days to Substantive Interaction	58	59	59		
Maximum FDA days to Substantive Interaction	73	100	87		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	278	274	173		
Non-MDUFA III Decisions	42	35	4		
MDUFA III Decisions (SE/NSE)	236	233	62		
MDUFA III Decisions within 90 FDA Days	236	233	62		
510(k)s pending MDUFA III Decision	0	6	107		
510(k) pending MDUFA III Decision over 90 FDA days	0	1	0		
Current Performance Percent within 90 FDA Days	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.9	1.8	1.4		
Number with MDUFA III decision	236	233	62		
Average FDA days to MDUFA III decision	71.4	70.8	60.7		
20th Percentile FDA days to MDUFA III decision	54	51	29		
40th Percentile FDA days to MDUFA III decision	80	76	55		
60th Percentile FDA days to MDUFA III decision	86	86	78		
80th Percentile FDA days to MDUFA III decision	88	88	88		
Maximum FDA days to MDUFA III decision	90	90	90		
Average Industry days to MDUFA III decision	73.1	55.8	15.9		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	32	22	0		
60th Percentile Industry days to MDUFA III decision	74	53	0		
80th Percentile Industry days to MDUFA III decision	152	106	31		
Maximum Industry days to MDUFA III decision	416	236	121		
Average Total days to MDUFA III decision	144.6	126.6	76.5		
20th Percentile Total days to MDUFA III decision	59	59	30		
40th Percentile Total days to MDUFA III decision	112	102	64		
60th Percentile Total days to MDUFA III decision	154	130	90		
80th Percentile Total days to MDUFA III decision	239	193	103		
Maximum Total days to MDUFA III decision	506	316	209		

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	173		
Number with MDUFA decision	236	233	62		
Number of SE decisions	221	229	62		
Number of NSE decisions	15	4	0		
Number of Withdrawals	18	11	3		
Number deleted	22	20	1		
Rate of SE decisions	93.6%	98.3%	100%		
Rate of NSE decisions	6.4%	1.7%	0%		
Rate of Withdrawals	6.5%	4.0%	1.7%		
Rate of Deleted	7.9%	7.3%	0.6%		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	375	483	356		
Closed before RTA action	3	0	1		
Number Accepted	136	212	215		
Number without a RTA Review and > 15 Days since Date Received	3	11	5		
Number without a RTA Review and <= 15 Days since Date Received	0	0	9		
Number Not Accepted	233	260	126		
Rate of submissions not accepted for filing review	62.6%	53.8%	36.4%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	473	457	310		
Deleted or withdrawn prior to SI	3	0	0		
SI within 60 FDA days	424	419	241		
SI over 60 FDA days	46	37	10		
SI pending within 60 FDA days	0	1	59		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	90.2%	91.9%	96.0%		

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	456	251		
Average number of FDA days to Substantive Interaction	45.4	50.5	48.9		
20th Percentile FDA days to Substantive Interaction	28	37	29		
40th Percentile FDA days to Substantive Interaction	44	53	53		
60th Percentile FDA days to Substantive Interaction	56	57	57		
80th Percentile FDA days to Substantive Interaction	59	60	59		
Maximum FDA days to Substantive Interaction	90	90	93		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	481	464	318		
Non-MDUFA III Decisions	86	66	12		
MDUFA III Decisions (SE/NSE)	395	373	141		
MDUFA III Decisions within 90 FDA Days	385	367	140		
510(k)s pending MDUFA III Decision	0	25	165		
510(k) pending MDUFA III Decision over 90 FDA days	0	1	1		
Current Performance Percent within 90 FDA Days	97.5%	98.1%	98.6%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8	1.7	1.5		
Number with MDUFA III decision	395	373	141		
Average FDA days to MDUFA III decision	69.0	72.3	64.0		
20th Percentile FDA days to MDUFA III decision	43	54	29		
40th Percentile FDA days to MDUFA III decision	70	79	58		
60th Percentile FDA days to MDUFA III decision	85	87	84		
80th Percentile FDA days to MDUFA III decision	89	89	89		
Maximum FDA days to MDUFA III decision	342	147	94		
Average Industry days to MDUFA III decision	60.0	55.1	20.6		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	20	14	0		
60th Percentile Industry days to MDUFA III decision	44	47	17		
80th Percentile Industry days to MDUFA III decision	125	110	35		
Maximum Industry days to MDUFA III decision	438	359	113		
Average Total days to MDUFA III decision	129.1	127.4	84.6		
20th Percentile Total days to MDUFA III decision	51	60	29		
40th Percentile Total days to MDUFA III decision	93	90	76		
60th Percentile Total days to MDUFA III decision	128	132	94		
80th Percentile Total days to MDUFA III decision	204	199	119		
Maximum Total days to MDUFA III decision	691	448	203		

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	464	318		
Number with MDUFA decision	395	373	141		
Number of SE decisions	379	365	140		
Number of NSE decisions	16	8	1		
Number of Withdrawals	43	31	5		
Number deleted	38	24	4		
Rate of SE decisions	95.9%	97.9%	99.3%		
Rate of NSE decisions	4.1%	2.1%	0.7%		
Rate of Withdrawals	8.9%	6.7%	1.6%		
Rate of Deleted	7.9%	5.2%	1.3%		

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	6	1		
Mean FDA days for submissions that missed goal	137	106	94		
Mean industry days for submissions that missed goal	160	131	27		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	188	195	141		
Closed before RTA action	1	1	1		
Number Accepted	118	127	109		
Number without a RTA Review and > 15 Days since Date Received	0	1	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	4		
Number Not Accepted	69	66	27		
Rate of submissions not accepted for filing review	36.9%	34.0%	19.9%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	247	184	125		
Deleted or withdrawn prior to SI	0	0	0		
SI within 60 FDA days	247	183	102		
SI over 60 FDA days	0	0	2		
SI pending within 60 FDA days	0	1	21		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	100%	100%	98.1%		

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	183	104		
Average number of FDA days to Substantive Interaction	41.0	42.6	41.4		
20th Percentile FDA days to Substantive Interaction	29	30	29		
40th Percentile FDA days to Substantive Interaction	38	43	35		
60th Percentile FDA days to Substantive Interaction	45	47	46		
80th Percentile FDA days to Substantive Interaction	52	54	55		
Maximum FDA days to Substantive Interaction	60	60	65		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	247	184	125		
Non-MDUFA III Decisions	34	31	2		
MDUFA III Decisions (SE/NSE)	212	137	54		
MDUFA III Decisions within 90 FDA Days	211	135	54		
510(k)s pending MDUFA III Decision	1	16	69		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	99.5%	98.5%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.9	1.8	1.3		
Number with MDUFA III decision	212	137	54		
Average FDA days to MDUFA III decision	64.8	65.4	53.0		
20th Percentile FDA days to MDUFA III decision	34	34	29		
40th Percentile FDA days to MDUFA III decision	58	58	34		
60th Percentile FDA days to MDUFA III decision	84	85	58		
80th Percentile FDA days to MDUFA III decision	88	88	82		
Maximum FDA days to MDUFA III decision	99	131	90		
Average Industry days to MDUFA III decision	81.8	70.3	16		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	11	2	0		
60th Percentile Industry days to MDUFA III decision	68	54	0		
80th Percentile Industry days to MDUFA III decision	163	155	29		
Maximum Industry days to MDUFA III decision	467	469	118		
Average Total days to MDUFA III decision	146.7	135.7	68.8		
20th Percentile Total days to MDUFA III decision	35	34	29		
40th Percentile Total days to MDUFA III decision	86	76	34		
60th Percentile Total days to MDUFA III decision	148	139	73		
80th Percentile Total days to MDUFA III decision	244	241	103		
Maximum Total days to MDUFA III decision	557	556	208		

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	125		
Number with MDUFA decision	212	137	54		
Number of SE decisions	206	136	54		
Number of NSE decisions	6	1	0		
Number of Withdrawals	17	19	1		
Number deleted	17	12	1		
Rate of SE decisions	97.2%	99.3%	100%		
Rate of NSE decisions	2.8%	0.7%	0%		
Rate of Withdrawals	6.9%	10.3%	0.8%		
Rate of Deleted	6.9%	6.5%	0.8%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	2	0		
Mean FDA days for submissions that missed goal	99	121	0		
Mean industry days for submissions that missed goal	193	254	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	56	73	47		
Closed before RTA action	1	1	0		
Number Accepted	38	57	37		
Number without a RTA Review and > 15 Days since Date Received	3	0	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	1		
Number Not Accepted	14	15	8		
Rate of submissions not accepted for filing review	25.5%	20.8%	17.4%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	69	64	42		
Deleted or withdrawn prior to SI	0	0	1		
SI within 60 FDA days	68	64	31		
SI over 60 FDA days	1	0	0		
SI pending within 60 FDA days	0	0	10		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	98.6%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	69	64	31		
Average number of FDA days to Substantive Interaction	47.6	50.8	51.9		
20th Percentile FDA days to Substantive Interaction	41	46	42		
40th Percentile FDA days to Substantive Interaction	50	51	57		
60th Percentile FDA days to Substantive Interaction	54	57	59		
80th Percentile FDA days to Substantive Interaction	58	58	60		
Maximum FDA days to Substantive Interaction	63	60	60		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	69	64	42		
Non-MDUFA III Decisions	22	20	4		
MDUFA III Decisions (SE/NSE)	47	43	10		
MDUFA III Decisions within 90 FDA Days	47	42	10		
510(k)s pending MDUFA III Decision	0	1	28		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	100%	97.7%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	2.0	1.8	1.3		
Number with MDUFA III decision	47	43	10		
Average FDA days to MDUFA III decision	71.6	79.2	51.0		
20th Percentile FDA days to MDUFA III decision	50	67	30		
40th Percentile FDA days to MDUFA III decision	77	88	30		
60th Percentile FDA days to MDUFA III decision	86	89	49		
80th Percentile FDA days to MDUFA III decision	88	90	85		
Maximum FDA days to MDUFA III decision	90	91	90		
Average Industry days to MDUFA III decision	115.4	101.3	22.4		
20th Percentile Industry days to MDUFA III decision	29	43	0		
40th Percentile Industry days to MDUFA III decision	89	61	0		
60th Percentile Industry days to MDUFA III decision	157	152	0		
80th Percentile Industry days to MDUFA III decision	177	176	17		
Maximum Industry days to MDUFA III decision	329	180	140		
Average Total days to MDUFA III decision	187.0	180.5	73.4		
20th Percentile Total days to MDUFA III decision	91	116	30		
40th Percentile Total days to MDUFA III decision	151	140	30		
60th Percentile Total days to MDUFA III decision	236	233	49		
80th Percentile Total days to MDUFA III decision	264	264	105		
Maximum Total days to MDUFA III decision	417	270	230		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	69	64	42		
Number with MDUFA decision	47	43	10		
Number of SE decisions	43	36	10		
Number of NSE decisions	4	7	0		
Number of Withdrawals	6	7	3		
Number deleted	14	13	1		
Rate of SE decisions	91.5%	83.7%	100%		
Rate of NSE decisions	8.5%	16.3%	0%		
Rate of Withdrawals	8.7%	10.9%	7.1%		
Rate of Deleted	20.3%	20.3%	2.4%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	1	0		
Mean FDA days for submissions that missed goal	0	91	0		
Mean industry days for submissions that missed goal	0	47	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	38		
Closed before RTA action	0	0	0		
Number Accepted	55	80	35		
Number without a RTA Review and > 15 Days since Date Received	0	1	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	2		
Number Not Accepted	4	3	1		
Rate of submissions not accepted for filing review	6.8%	3.6%	2.8%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	80	83	35		
Deleted or withdrawn prior to SI	0	0	0		
SI within 60 FDA days	79	82	30		
SI over 60 FDA days	1	1	0		
SI pending within 60 FDA days	0	0	5		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	98.8%	98.8%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	80	83	30		
Average number of FDA days to Substantive Interaction	43.1	47.6	49.3		
20th Percentile FDA days to Substantive Interaction	28	29	35		
40th Percentile FDA days to Substantive Interaction	39	51	55		
60th Percentile FDA days to Substantive Interaction	53	56	56		
80th Percentile FDA days to Substantive Interaction	57	59	58		
Maximum FDA days to Substantive Interaction	61	61	59		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	80	83	35		
Non-MDUFA III Decisions	9	7	0		
MDUFA III Decisions (SE/NSE)	71	74	19		
MDUFA III Decisions within 90 FDA Days	71	74	19		
510(k)s pending MDUFA III Decision	0	2	16		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.3	1.4	1.3		
Number with MDUFA III decision	71	74	19		
Average FDA days to MDUFA III decision	58.5	65.4	67.3		
20th Percentile FDA days to MDUFA III decision	29	33	37		
40th Percentile FDA days to MDUFA III decision	55	71	83		
60th Percentile FDA days to MDUFA III decision	78	81	84		
80th Percentile FDA days to MDUFA III decision	81	86	86		
Maximum FDA days to MDUFA III decision	89	90	88		
Average Industry days to MDUFA III decision	31.5	46.2	17		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	21	0		
80th Percentile Industry days to MDUFA III decision	65	115	33		
Maximum Industry days to MDUFA III decision	180	182	84		
Average Total days to MDUFA III decision	90.0	111.6	84.0		
20th Percentile Total days to MDUFA III decision	29	33	47		
40th Percentile Total days to MDUFA III decision	58	85	83		
60th Percentile Total days to MDUFA III decision	81	92	87		
80th Percentile Total days to MDUFA III decision	133	191	117		
Maximum Total days to MDUFA III decision	267	265	147		

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	35		
Number with MDUFA decision	71	74	19		
Number of SE decisions	71	71	19		
Number of NSE decisions	0	3	0		
Number of Withdrawals	6	5	0		
Number deleted	3	2	0		
Rate of SE decisions	100%	95.9%	100%		
Rate of NSE decisions	0%	4.1%	0%		
Rate of Withdrawals	7.5%	6.0%	0%		
Rate of Deleted	3.8%	2.4%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	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	3		
Closed before RTA action	0	0	0		
Number Accepted	14	9	3		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted	3	0	0		
Rate of submissions not accepted for filing review	17.6%	0%	0%		

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	18	9	3		
Deleted or withdrawn prior to SI	0	0	0		
SI within 60 FDA days	18	9	2		
SI over 60 FDA days	0	0	0		
SI pending within 60 FDA days	0	0	1		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	100%	100%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	18	9	2		
Average number of FDA days to Substantive Interaction	51.7	45.8	53.0		
20th Percentile FDA days to Substantive Interaction	44	29	51		
40th Percentile FDA days to Substantive Interaction	55	47	52		
60th Percentile FDA days to Substantive Interaction	58	56	54		
80th Percentile FDA days to Substantive Interaction	59	58	55		
Maximum FDA days to Substantive Interaction	60	60	57		

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

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

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	2.4	1.6	0		
Number with MDUFA III decision	14	7	0		
Average FDA days to MDUFA III decision	83.7	78.1	0		
20th Percentile FDA days to MDUFA III decision	81	79	0		
40th Percentile FDA days to MDUFA III decision	88	88	0		
60th Percentile FDA days to MDUFA III decision	88	89	0		
80th Percentile FDA days to MDUFA III decision	89	90	0		
Maximum FDA days to MDUFA III decision	90	90	0		
Average Industry days to MDUFA III decision	151.9	81.7	0		
20th Percentile Industry days to MDUFA III decision	26	0	0		
40th Percentile Industry days to MDUFA III decision	166	16	0		
60th Percentile Industry days to MDUFA III decision	175	122	0		
80th Percentile Industry days to MDUFA III decision	233	177	0		
Maximum Industry days to MDUFA III decision	320	179	0		
Average Total days to MDUFA III decision	235.6	159.9	0		
20th Percentile Total days to MDUFA III decision	103	80	0		
40th Percentile Total days to MDUFA III decision	255	106	0		
60th Percentile Total days to MDUFA III decision	263	211	0		
80th Percentile Total days to MDUFA III decision	317	266	0		
Maximum Total days to MDUFA III decision	408	267	0		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	18	9	3		
Number with MDUFA decision	14	7	0		
Number of SE decisions	11	6	0		
Number of NSE decisions	3	1	0		
Number of Withdrawals	3	2	0		
Number deleted	1	0	0		
Rate of SE decisions	78.6%	85.7%	N/A		
Rate of NSE decisions	21.4%	14.3%	N/A		
Rate of Withdrawals	16.7%	22.2%	0%		
Rate of Deleted	5.6%	0%	0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0	0		
Mean FDA days for submissions that missed goal	0	0	0		
Mean industry days for submissions that missed goal	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	228		
Closed before RTA action	0	0	0		
Number Accepted	151	274	176		
Number without a RTA Review and > 15 Days since Date Received	15	5	1		
Number without a RTA Review and <= 15 Days since Date Received	0	0	9		
Number Not Accepted	90	86	42		
Rate of submissions not accepted for filing review	35.2%	23.6%	19.2%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Eligible for SI	349	356	205		
Deleted or withdrawn prior to SI	1	0	0		
SI within 60 FDA days	307	342	173		
SI over 60 FDA days	41	14	2		
SI pending within 60 FDA days	0	0	30		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	88.2%	96.1%	98.9%		

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	175		
Average number of FDA days to Substantive Interaction	47.4	45.8	44.6		
20th Percentile FDA days to Substantive Interaction	31	30	30		
40th Percentile FDA days to Substantive Interaction	44	44	45		
60th Percentile FDA days to Substantive Interaction	56	54	51		
80th Percentile FDA days to Substantive Interaction	59	59	57		
Maximum FDA days to Substantive Interaction	91	93	70		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
510(k)s accepted	403	393	228		
Non-MDUFA III Decisions	17	6	0		
MDUFA III Decisions (SE/NSE)	386	380	145		
MDUFA III Decisions within 90 FDA Days	380	368	145		
510(k)s pending MDUFA III Decision	0	7	83		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	98.4%	96.8%	100%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.6	1.6	1.4		
Number with MDUFA III decision	386	380	145		
Average FDA days to MDUFA III decision	61.9	63.0	51.9		
20th Percentile FDA days to MDUFA III decision	35	31	28		
40th Percentile FDA days to MDUFA III decision	56	58	46		
60th Percentile FDA days to MDUFA III decision	77	79	58		
80th Percentile FDA days to MDUFA III decision	87	88	74		
Maximum FDA days to MDUFA III decision	121	137	90		
Average Industry days to MDUFA III decision	35.9	33.8	18.2		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	20	26	0		
80th Percentile Industry days to MDUFA III decision	60	62	35		
Maximum Industry days to MDUFA III decision	358	214	185		
Average Total days to MDUFA III decision	97.8	96.8	70.0		
20th Percentile Total days to MDUFA III decision	37	32	28		
40th Percentile Total days to MDUFA III decision	71	77	50		
60th Percentile Total days to MDUFA III decision	90	101	70		
80th Percentile Total days to MDUFA III decision	137	139	105		
Maximum Total days to MDUFA III decision	466	304	246		

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	228		
Number with MDUFA decision	386	380	145		
Number of SE decisions	377	374	141		
Number of NSE decisions	9	6	4		
Number of Withdrawals	10	2	0		
Number deleted	7	3	0		
Rate of SE decisions	97.7%	98.4%	97.2%		
Rate of NSE decisions	2.3%	1.6%	2.8%		
Rate of Withdrawals	2.5%	0.5%	0%		
Rate of Deleted	1.7%	0.8%	0%		

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

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

Section 7 510(k) Annual General Metrics

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

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Section 8 Annual Metrics for De Novo Requests

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

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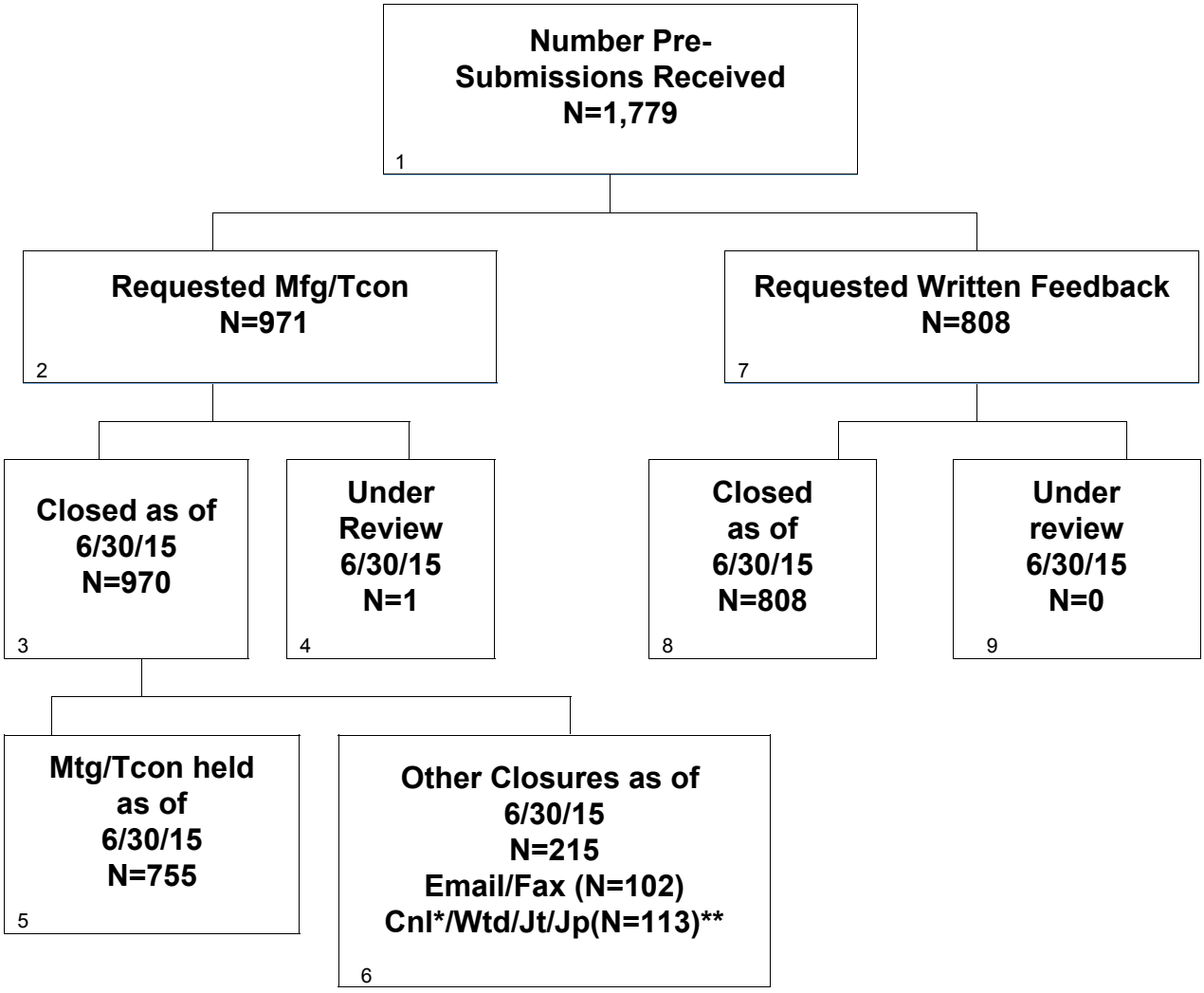
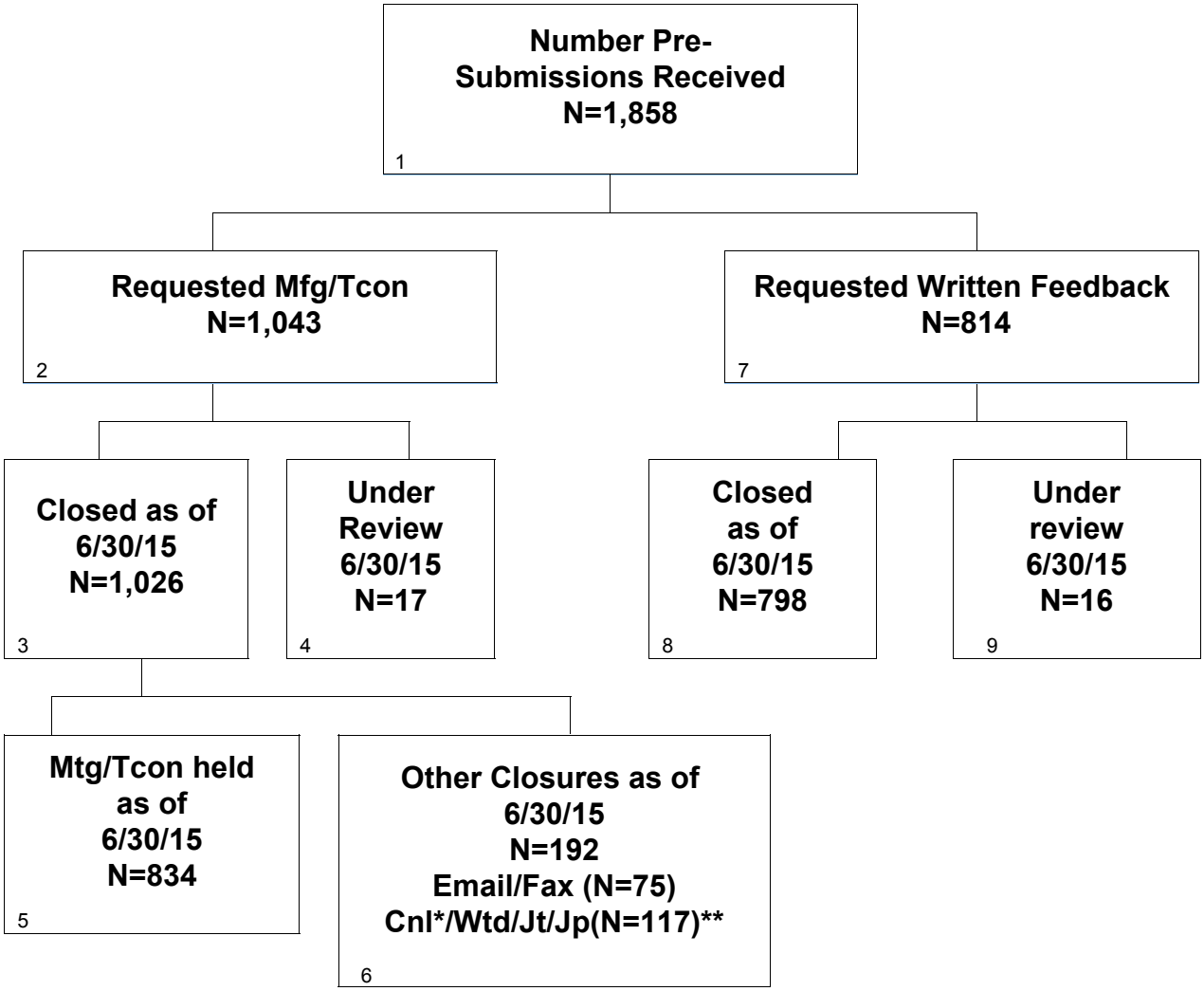
CDRH Pre-Submissions - FY 2013
As of 6/30/15



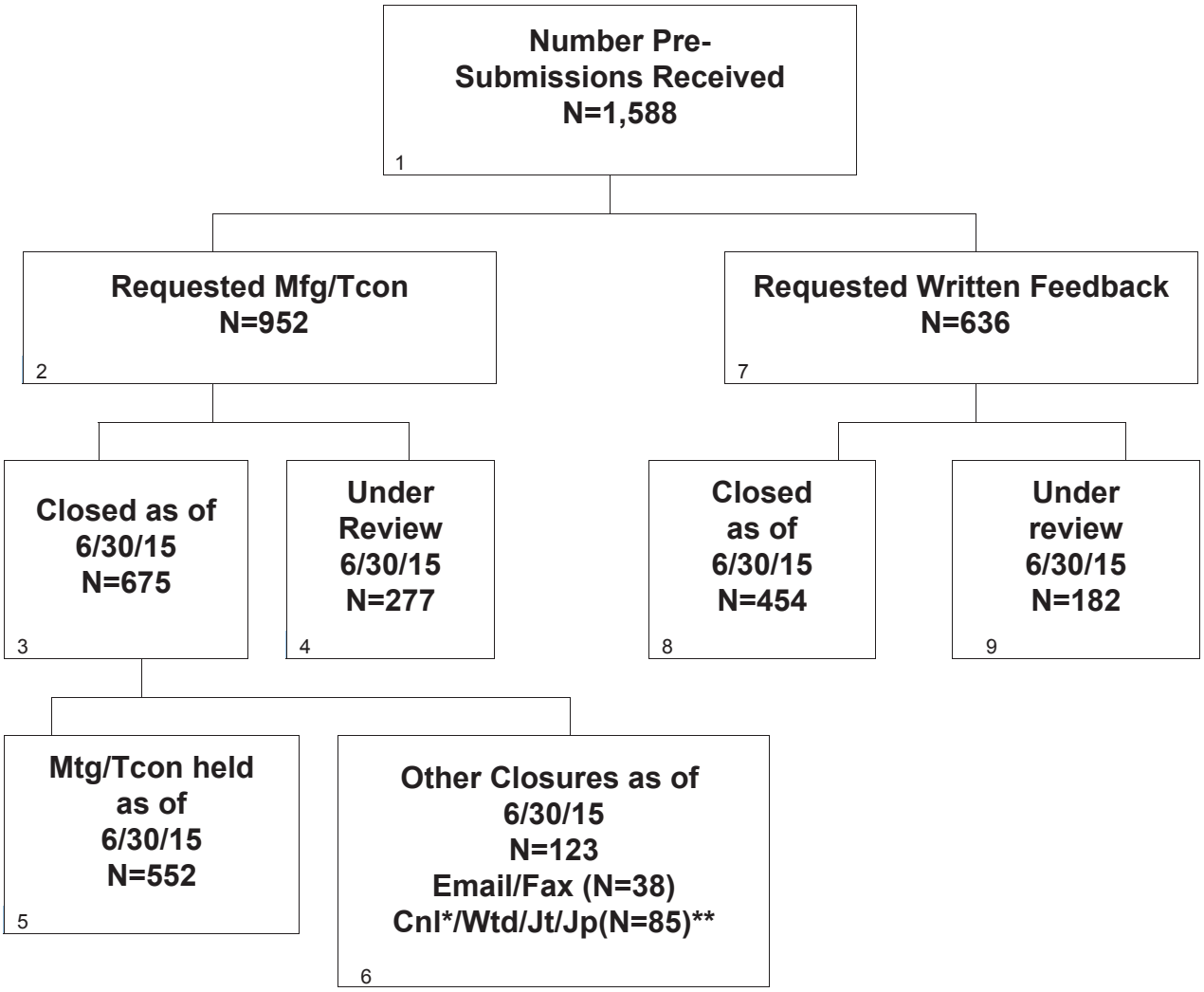
*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient
**Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

CDRH Pre-Submissions - FY 2014
As of 6/30/15



*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient
**Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

CDRH Pre-Submissions - FY 2015
As of 6/30/15



*Including meetings canceled by sponsors when 3-day advance feedback deemed sufficient
**Cnl/Wtd/Jt/Jp= Cancelled / Withdrawn / Jurisdiction Transferred / Jurisdiction Pending

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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	1,588		
Number requesting a meeting or teleconference	971	1,043	952		
Number with meetings or teleconferences held	755	834	552		
Average days to meeting	59.2	64.9	63.6		
20th Percentile days to meeting	38	48	48		
40th Percentile days to meeting	55	62	63		
60th Percentile days to meeting	66	70	70		
80th Percentile days to meeting	77	78	77		
Maximum days to meeting	183	243	178		

Section 9 Pre-Submission Office Level Metrics

Table 9.1.ODE - CDRH – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	981	1,141	998		
Number requesting a meeting or teleconference	611	697	626		
Number with meetings or teleconferences held	455	550	340		
Average days to meeting	62	68	67		
20th Percentile days to meeting	40	49	50		
40th Percentile days to meeting	57	63	64		
60th Percentile days to meeting	67	72	72		
80th Percentile days to meeting	79	83	81		
Maximum days to meeting	183	243	178		

Table 9.1.OIR - CDRH – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	798	717	590		
Number requesting a meeting or teleconference	360	346	326		
Number with meetings or teleconferences held	300	284	212		
Average days to meeting	55	59	58		
20th Percentile days to meeting	37	46	45		
40th Percentile days to meeting	53	60	59		
60th Percentile days to meeting	63	68	67		
80th Percentile days to meeting	71	72	71		
Maximum days to meeting	138	115	112		

Section 9 Pre-Submission Division Level Metrics

Table 9.1.DAGRID - ODE - Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	156	204	175		
Number requesting a meeting or teleconference	82	110	103		
Number with meetings or teleconferences held	58	82	52		
Average days to meeting	68	71	72		
20th Percentile days to meeting	52	55	59		
40th Percentile days to meeting	65	65	67		
60th Percentile days to meeting	75	75	77		
80th Percentile days to meeting	83	85	85		
Maximum days to meeting	121	149	142		

Table 9.1.DCD - ODE - Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	307	372	270		
Number requesting a meeting or teleconference	214	234	183		
Number with meetings or teleconferences held	173	196	108		
Average days to meeting	56	59	56		
20th Percentile days to meeting	35	44	43		
40th Percentile days to meeting	49	53	51		
60th Percentile days to meeting	62	65	63		
80th Percentile days to meeting	74	73	71		
Maximum days to meeting	134	140	99		

Table 9.1.DNPMD - ODE - Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	78	115	114		
Number requesting a meeting or teleconference	50	72	74		
Number with meetings or teleconferences held	32	48	36		
Average days to meeting	70	88	84		
20th Percentile days to meeting	48	67	72		
40th Percentile days to meeting	63	78	78		
60th Percentile days to meeting	77	90	88		
80th Percentile days to meeting	91	108	100		
Maximum days to meeting	163	243	178		

Table 9.1.DOD - ODE - Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	98	106	95		
Number requesting a meeting or teleconference	61	72	66		
Number with meetings or teleconferences held	39	62	40		
Average days to meeting	61	75	72		
20th Percentile days to meeting	45	62	59		
40th Percentile days to meeting	57	71	70		
60th Percentile days to meeting	69	77	76		
80th Percentile days to meeting	77	89	84		
Maximum days to meeting	129	158	126		

Table 9.1.DOED - ODE - Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	87	73	83		
Number requesting a meeting or teleconference	49	46	56		
Number with meetings or teleconferences held	35	34	30		
Average days to meeting	66	75	73		
20th Percentile days to meeting	53	66	65		
40th Percentile days to meeting	64	69	71		
60th Percentile days to meeting	70	73	76		
80th Percentile days to meeting	83	86	82		
Maximum days to meeting	118	146	91		

Table 9.1.DRGUD - ODE - Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	131	136	121		
Number requesting a meeting or teleconference	76	83	65		
Number with meetings or teleconferences held	60	66	34		
Average days to meeting	60	60	64		
20th Percentile days to meeting	47	44	49		
40th Percentile days to meeting	60	57	63		
60th Percentile days to meeting	67	67	69		
80th Percentile days to meeting	71	75	74		
Maximum days to meeting	132	119	106		

Table 9.1.DSD - ODE - Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	124	135	140		
Number requesting a meeting or teleconference	79	80	79		
Number with meetings or teleconferences held	58	62	40		
Average days to meeting	68	72	69		
20th Percentile days to meeting	41	63	57		
40th Percentile days to meeting	64	69	68		
60th Percentile days to meeting	73	77	72		
80th Percentile days to meeting	85	89	78		
Maximum days to meeting	183	111	125		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	219	178	174		
Number requesting a meeting or teleconference	107	99	109		
Number with meetings or teleconferences held	91	88	76		
Average days to meeting	51	57	51		
20th Percentile days to meeting	36	42	26		
40th Percentile days to meeting	49	55	54		
60th Percentile days to meeting	59	65	63		
80th Percentile days to meeting	68	70	70		
Maximum days to meeting	90	112	97		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	130	127	90		
Number requesting a meeting or teleconference	66	72	48		
Number with meetings or teleconferences held	54	67	36		
Average days to meeting	61	65	69		
20th Percentile days to meeting	41	56	63		
40th Percentile days to meeting	64	67	67		
60th Percentile days to meeting	70	71	70		
80th Percentile days to meeting	81	73	73		
Maximum days to meeting	99	113	93		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	234	204	152		
Number requesting a meeting or teleconference	59	48	48		
Number with meetings or teleconferences held	49	28	21		
Average days to meeting	53	60	56		
20th Percentile days to meeting	42	43	31		
40th Percentile days to meeting	51	56	57		
60th Percentile days to meeting	61	68	66		
80th Percentile days to meeting	67	77	73		
Maximum days to meeting	81	91	112		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	145	154	127		
Number requesting a meeting or teleconference	83	90	86		
Number with meetings or teleconferences held	70	69	58		
Average days to meeting	63	58	61		
20th Percentile days to meeting	44	40	51		
40th Percentile days to meeting	56	60	62		
60th Percentile days to meeting	66	68	69		
80th Percentile days to meeting	83	71	73		
Maximum days to meeting	138	115	94		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	70	54	47		
Number requesting a meeting or teleconference	45	37	35		
Number with meetings or teleconferences held	36	32	21		
Average days to meeting	47	58	60		
20th Percentile days to meeting	31	47	49		
40th Percentile days to meeting	43	59	57		
60th Percentile days to meeting	57	68	65		
80th Percentile days to meeting	63	72	70		
Maximum days to meeting	98	107	91		

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Section 10 CLIA Waiver Annual Metrics

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

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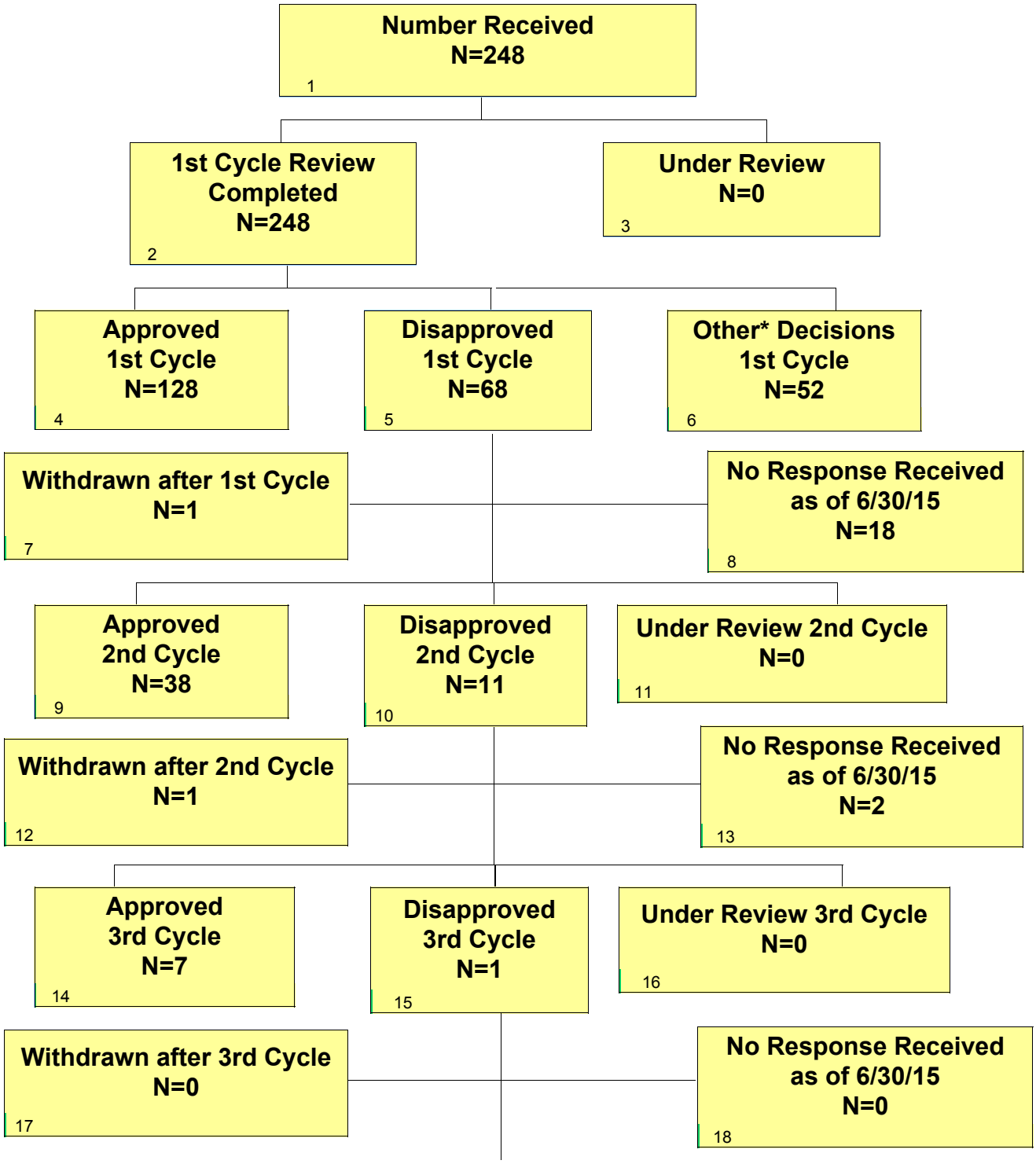
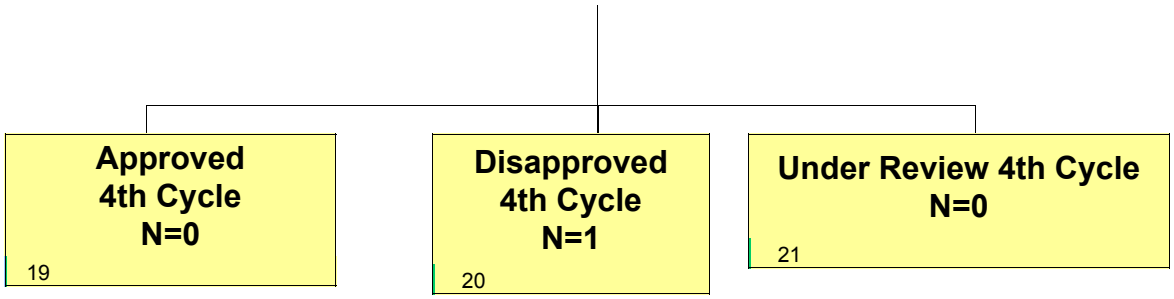
CDRH IDEs - FY 2014
As of 6/30/15

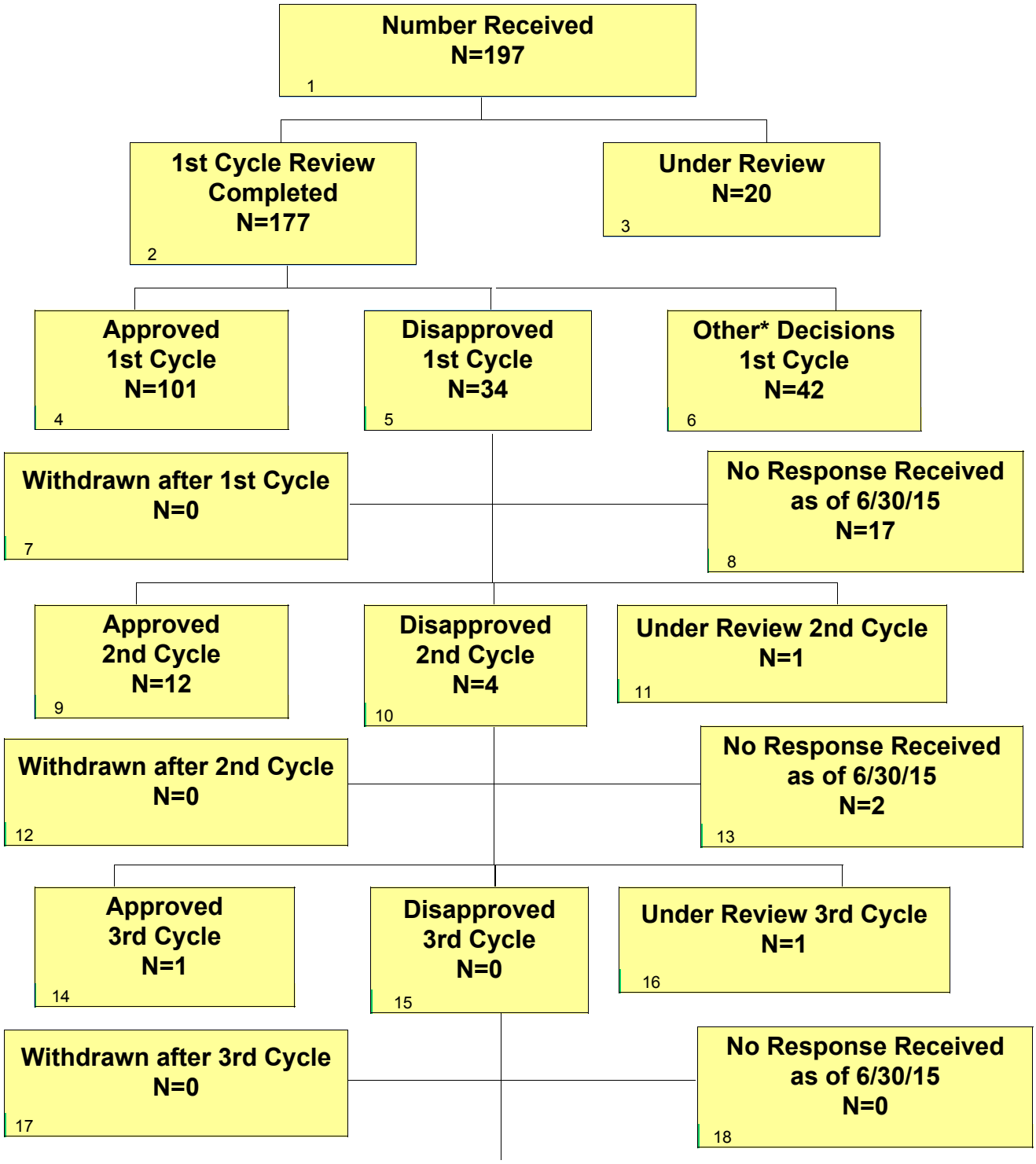


*** Other decisions include withdrawn (N=34), RTA (N=2), nonsignificant risk device (N=10), exempt (N=3), product jurisdition pending (N=0), or product jurisdiction transferred (N=3).**

CDRH IDEs - FY 2014
As of 6/30/15

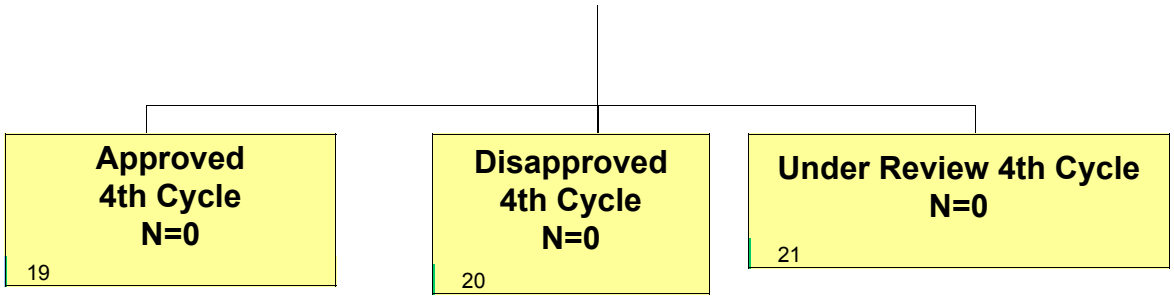


CDRH IDEs - FY 2015
As of 6/30/15



*** Other decisions include withdrawn (N=28), RTA (N=0), nonsignificant risk device (N=10), exempt (N=4), product jurisdition pending (N=0), or product jurisdiction transferred (N=0).**

CDRH IDEs - FY 2015
As of 6/30/15



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	197		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.1		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0.1		

Section 11 IDEs - Office Level Metrics

Table 11.1.ODE - CDRH – IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	188	168		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.4	1.1		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.4	0.1		

Table 11.1.OIR - CDRH – IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	60	29		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.1	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.1	0		

Section 11 IDEs - Division Level Metrics

Table 11.1.DAGRID - ODE - IDE Performance Metrics

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

Table 11.1.DCD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	58	42		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.5	1.2		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.5	0.2		

Table 11.1.DNPMD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	35	30		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.3	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3	0		

Table 11.1.DOD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	13	10		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.00		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.00		

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	21		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.1		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0.1		

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	33		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.5	1.2		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.5	0		

Table 11.1.DSD - ODE - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	25	19		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.2	1.1		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2	0		

Table 11.1.DCTD - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	29	11		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.0	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0		

Table 11.1.DIHD - OIR - IDE Performance Metrics

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

Table 11.1.DMD - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	1	1		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.0	1.00		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	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	13		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.0	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0	0		

Table 11.1.DRH - OIR - IDE Performance Metrics

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	2017
Number of IDEs received	N/A	9	2		
Average number of cycles to approval or conditional approval of the IDE	N/A	1.6	1.0		
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.6	0		

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

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

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Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

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

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

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

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

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

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

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

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

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th 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	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th 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 *De Novo* Requests Received	Total number of *de novo* requests received in this fiscal year as of the report cutoff date.
2	Number of *De Novo* Requests with Decision	Number of *de novo* requests received in this fiscal year (line 1) which have also received a final decision as of the report cutoff date.
3	Number of *De Novo* Requests with Decision Pending	Number *de novo* 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 *De Novo* Date Received and *De Novo* Decision Date) for *de novo* 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	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th 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 (line5) 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 (line5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

Table 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	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

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

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

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

#	Measure	Description
1	Dual 510(k) and CLIA Waiver Applications accepted	Number of Dual 510(k) and CLIA Waiver by Applications that were filed in this fiscal year, and had a panel review.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 210 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 210 FDA days
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

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

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

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

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

Quarterly Update on
Medical Device Performance Goals
----MDUFA III CBER Performance Data ----
Action through 30 June 2015

Section 1 PMA Original and Panel Track Supplements - Center Level

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	6	2		
Closed before RTA action	0	0	0		
Number Accepted	1	6	2		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of submissions not accepted for filing review	0.0%	0.0%	0.0%		
Completed RTF	0	0	0		
Number Not Filed	0	0	0		
Rate of submissions Not Filed	0.0%	0.0%	0.0%		

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	1	6	2		
SI within 90 FDA days	0	6	0		
SI over 90 FDA days	1	0	0		
SI pending within 90 FDA days	0	0	2		
SI pending over 90 FDA days	0	0	0		
Closed without SI	0	0	0		
Current SI Performance Percent within 90 FDA days	0.0%	100.0%	0.0%		

Table 1.3 CBER – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1	6	0		
Average number of FDA days to Substantive Interaction	101	88	0		
20th Percentile FDA days to Substantive Interaction	101	87	0		
40th Percentile FDA days to Substantive Interaction	101	88	0		
60th Percentile FDA days to Substantive Interaction	101	88	0		
80th Percentile FDA days to Substantive Interaction	101	90	0		
Maximum FDA days to Substantive Interaction	101	90	0		

Table 1.4 CBER – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	0	6	2		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	0	5	0		
MDUFA III Decisions within 180 FDA Days	0	5	0		
PMAs pending MDUFA III Decision	0	1	2		
PMAs pending MDUFA III Decision over 180 FDA days	0	0	0		
Current Performance Percent within 180 FDA Days	0.0%	100.0%	0.0%		

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

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	1	0	0		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	1	0	0		
MDUFA III Decisions within 320 FDA Days	1	0	0		
PMAs pending MDUFA III Decision	0	0	0		
PMAs pending MDUFA III Decision over 320 FDA days	0	0	0		
Current Performance Percent within 320 FDA Days	100.0%	0.0%	0.0%		

Table 1.6 CBER – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	0	5	0		
Average FDA days to MDUFA III decision	**0**	**175**	**0**		
20th Percentile FDA days to MDUFA III decision	0	170	0		
40th Percentile FDA days to MDUFA III decision	0	172	0		
60th Percentile FDA days to MDUFA III decision	0	176	0		
80th Percentile FDA days to MDUFA III decision	0	177	0		
Maximum FDA days to MDUFA III decision	0	180	0		
Average Industry days to MDUFA III decision	**0**	**101**	**0**		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	0	0	0		
60th Percentile Industry days to MDUFA III decision	0	41	0		
80th Percentile Industry days to MDUFA III decision	0	178	0		
Maximum Industry days to MDUFA III decision	0	284	0		
Average Total days to MDUFA III decision	**0**	**276**	**0**		
20th Percentile Total days to MDUFA III decision	0	170	0		
40th Percentile Total days to MDUFA III decision	0	172	0		
60th Percentile Total days to MDUFA III decision	0	218	0		
80th Percentile Total days to MDUFA III decision	0	358	0		
Maximum Total days to MDUFA III decision	0	460	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		
Average FDA days to MDUFA III decision	**303**	**0**	**0**		
20th Percentile FDA days to MDUFA III decision	303	0	0		
40th Percentile FDA days to MDUFA III decision	303	0	0		
60th Percentile FDA days to MDUFA III decision	303	0	0		
80th Percentile FDA days to MDUFA III decision	303	0	0		
Maximum FDA days to MDUFA III decision	303	0	0		
Average Industry days to MDUFA III decision	**41**	**0**	**0**		
20th Percentile Industry days to MDUFA III decision	41	0	0		
40th Percentile Industry days to MDUFA III decision	41	0	0		
60th Percentile Industry days to MDUFA III decision	41	0	0		
80th Percentile Industry days to MDUFA III decision	41	0	0		
Maximum Industry days to MDUFA III decision	41	0	0		
Average Total days to MDUFA III decision	**344**	**0**	**0**		
20th Percentile Total days to MDUFA III decision	344	0	0		
40th Percentile Total days to MDUFA III decision	344	0	0		
60th Percentile Total days to MDUFA III decision	344	0	0		
80th Percentile Total days to MDUFA III decision	344	0	0		
Maximum Total days to MDUFA III decision	344	0	0		

Table 1.8 CBER – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	6	2		
Number with MDUFA decision	0	5	0		
Number of Withdrawals	0	0	0		
Number of Not Approvable	0	0	0		
Rate of Withdrawals	0.0%	0.0%	0.0%		
Rate of Not Approvable	0.0%	0.0%	0.0%		

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

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

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

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

Table 1.11 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

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

Section 2 PMA 180 Day Supplements - Center Level

Table 2.1 CBER – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	2	1	1		
SI within 90 FDA days	2	1	0		
SI over 90 FDA days	0	0	0		
SI pending within 90 FDA days	0	0	1		
SI pending over 90 FDA days	0	0	0		
Closed without SI	1	0	0		
Current SI Performance Percent within 90 FDA days	100.0%	100.0%	0.0%		

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	3	1	1		
Non-MDUFA III Decisions	1	0	0		
MDUFA III Decisions	2	1	0		
MDUFA III Decisions within 180 FDA Days	2	1	0		
Supplements pending MDUFA III Decision	0	0	1		
Supplements pending MDUFA III Decision over 180 FDA days	0	0	0		
Current Performance Percent within 180 FDA Days	100.0%	100.0%	0.0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	1	1		
Number with MDUFA decision	2	1	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.0%	0.0%	0.0%		

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

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

Section 3 PMA Real Time Supplements - Center Level Metrics

Table 3.1 CBER – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	3	2	3		
Non-MDUFA III Decisions	0	0	0		
MDUFA III Decisions	3	2	3		
MDUFA III Decisions within 90 FDA Days	3	2	3		
Supplements pending MDUFA III Decision	0	0	0		
Supplements pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	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	3		
Number with MDUFA decision	3	2	3		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.0%	0.0%	0.0%		

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

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

Section 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		
Original PMAs (Panel) – Priority	0	0	0		
Original PMAs (No Panel) – Priority	0	0	0		
Original PMAs (Panel) – Non-Priority	1	0	0		
Original PMAs (No Panel) – Non-Priority	0	5	1		
Panel-Tracked Supplements (Panel) – Priority	0	0	0		
Panel-Tracked Supplements (No Panel) – Priority	0	0	0		
Panel-Tracked Supplements (Panel) – Non-Priority	0	0	0		
Panel-Tracked Supplements (No Panel) – Non-Priority	0	1	1		
PMA Modules	7	1	3		
180-Day Supplements	3	1	1		
Real-Time Supplements	3	2	3		

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	2		
Number with a decision (MDUFA or Non-MDUFA)	1	5	0		
% of FY closed	100.0%	83.0%	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	39		
Closed before RTA action	1	4	2		
Number Accepted	40	50	30		
Number without a RTA Review and > 15 Days since Date Received	0	0	0		
Number without a RTA Review and <= 15 Days since Date Received	0	0	3		
Number Not Accepted	19	7	6		
Rate of submissions not accepted for review	32.2%	12.3%	16.7%		

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

Substantive Interaction (SI) Performance Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA days	FY 2015 85% SI within 60 FDA days	FY 2016 95% SI within 60 FDA days	FY 2017 95% SI within 60 FDA days
Eligible for SI	47	50	29		
SI within 60 FDA days	41	48	26		
SI over 60 FDA days	6	1	1		
SI pending within 60 FDA days	0	1	2		
SI pending over 60 FDA days	0	0	0		
510(k)s NSE without SI	0	0	0		
Current SI Performance Percent within 60 FDA days	87.2%	98.0%	96.3%		

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	49	27		
Average number of FDA days to Substantive Interaction	49	49	50		
20th Percentile FDA days to Substantive Interaction	30	31	34		
40th Percentile FDA days to Substantive Interaction	46	52	56		
60th Percentile FDA days to Substantive Interaction	58	56	59		
80th Percentile FDA days to Substantive Interaction	59	59	60		
Maximum FDA days to Substantive Interaction	90	90	62		

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	47	48	30		
Non-MDUFA III Decisions	8	1	3		
MDUFA III Decisions (SE/NSE)	39	40	14		
MDUFA III Decisions within 90 FDA Days	37	40	14		
510(k)s pending MDUFA III Decision	0	9	13		
510(k) pending MDUFA III Decision over 90 FDA days	0	0	0		
Current Performance Percent within 90 FDA Days	94.9%	100.0%	100.0%		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.69	1.45	1.47		
Number with MDUFA III decision	39	40	14		
Average FDA days to MDUFA III decision	71	65	66		
20th Percentile FDA days to MDUFA III decision	30	29	30		
40th Percentile FDA days to MDUFA III decision	81	63	75		
60th Percentile FDA days to MDUFA III decision	87	79	79		
80th Percentile FDA days to MDUFA III decision	89	83	85		
Maximum FDA days to MDUFA III decision	94	90	90		
Average Industry days to MDUFA III decision	76	51	15		
20th Percentile Industry days to MDUFA III decision	0	0	0		
40th Percentile Industry days to MDUFA III decision	19	0	0		
60th Percentile Industry days to MDUFA III decision	83	10	14		
80th Percentile Industry days to MDUFA III decision	150	111	29		
Maximum Industry days to MDUFA III decision	370	296	74		
Average Total days to MDUFA III decision	147	116	81		
20th Percentile Total days to MDUFA III decision	30	35	37		
40th Percentile Total days to MDUFA III decision	108	70	79		
60th Percentile Total days to MDUFA III decision	171	89	84		
80th Percentile Total days to MDUFA III decision	244	167	110		
Maximum Total days to MDUFA III decision	460	381	136		

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	47	50	30		
Number with MDUFA decision	39	40	14		
Number of SE decisions	36	37	13		
Number of NSE decisions	3	3	1		
Number of Withdrawals	8	1	3		
Number deleted	0	0	0		
Rate of SE decisions	92.3%	92.5%	92.9%		
Rate of NSE decisions	7.7%	7.5%	7.1%		
Rate of Withdrawals	17.0%	2.0%	10.0%		
Rate of Deleted	0.0%	0.0%	0.0%		

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

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

Section 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	49	30		
Number of Traditional submissions	34	40	25		
Number of Special submissions	9	9	5		
Number of Abbreviated submissions	4	0	0		
Average number of days to Accept / Refuse to Accept	13	13	13		
Number of Third Party submissions	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	49	30		
Currently Under Review	0	9	13		
Number with Non-MDUFA Decision	8	1	3		
Number with MDUFA III Decision	39	40	14		
Percent of cohort closed	100.0%	81.6%	51.9%		
Number with MDUFA III decision after trimming the upper and lower 2%	37	38	12		
Average Total Time to MDUFA III decision	147	116	81		

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		
Number of De Novo Petitions with Decision	2	0	0		
Number of De Novo Petitions with Decision Pending	0	0	1		
Average Number of Days to Decision	577	0	0		

Section 9 Pre-Submissions

Section 9 Pre-Submission Center Level Metrics

Table 9.1 CBER – Pre-Submission Center Level Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	44	57	46		
Number requesting a meeting or teleconference	34	46	39		
Number with meetings or teleconferences granted	29	41	36		
Number with meeting granted and industry cancelled	13	7	9		
Number with meeting granted and FDA cancelled	0	1	0		
Number with meeting granted and pending within timeframe	0	0	13		
Number with meeting granted and pending outside timeframe	0	0	0		
Number with meetings or teleconferences held	15	33	14		
Average days to meeting	65	68	70		
20th Percentile days to meeting	55	44	66		
40th Percentile days to meeting	58	62	72		
60th Percentile days to meeting	61	78	79		
80th Percentile days to meeting	70	92	84		
Maximum days to meeting	122	132	87		

CBER – Annual General Metric Report for BLAs

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

BLA Efficacy Supplements

CBER – Annual General Metric Report for BLA Efficacy Supplements

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

BLA Prior Approval Manufacturing Supplements

CBER – Annual General Metric Report for BLA PAS Supplements

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard PAS Supplements Filed	20	6	9		
Number of Standard PAS Supplements First Actions less than or equal to 4months	20	6	9		
Number of Standard PAS Supplements First Actions greater than 4 months	0	0	0		
Number of Standard PAS Supplements Pending	0	0	0		

BLA/BLA Resubmissions

CBER – Annual General Metric Report for BLA/BLA Resubmissions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Class 1 Resubmissions Received	10	6	1		
Number of Class 1 Resubmission Actions less than or equal to 2 months	10	6	1		
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0		
Number of Class 1 Resbumssions Pending	0	0	0		
Number of Class 2 Resubmissions Received	0	2	13		
Number of Class 2 Resubmission Actions less than or equal to 6 months	0	2	0		
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0		
Number of Class 2 Resubmissions Pending	0	0	13		

IDEs
CBER – Annual General Metric Report for IDEs

#	Measure	Description	FY14	FY15 (01Oct14-31Mar15)
1	Number of IDEs received	Number of IDEs received in the fiscal year.	23	15
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.	1.04	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.	0.04	0.17 (2/12)

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MDUFA FY 2015 3rd Quarter Collection Report

FY 2015 Medical Device User Fee Collections as of June 30, 2015 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$89,063,028	$355,955	$88,707,073		
Application Fees	$30,258,606	$536,966	$29,721,640		
Total	**$119,321,634**	**$892,921**	**$118,428,712**	**$131,195,000**	**90%**

Medical Device User Fee Collection History Excludes Unearned Fees, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,281,779	$31,676,833	$34,469,732	$27,798,431
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,709,442	$56,941,496	$63,400,607	$69,543,966	$65,156,699
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$99,957,229	$120,326,860	$118,428,712		

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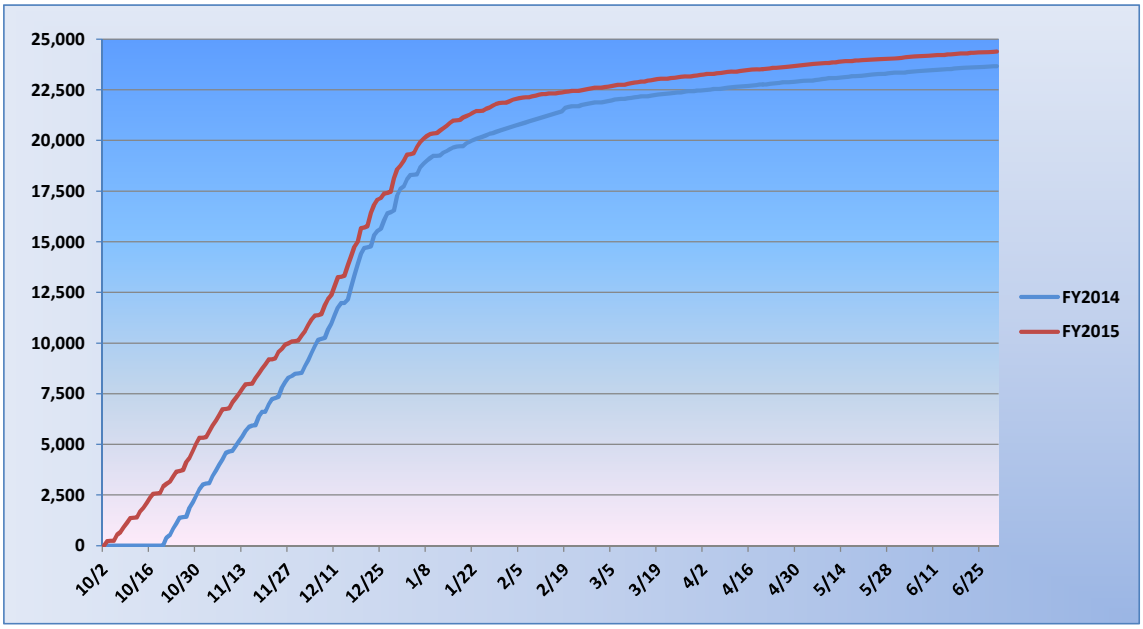
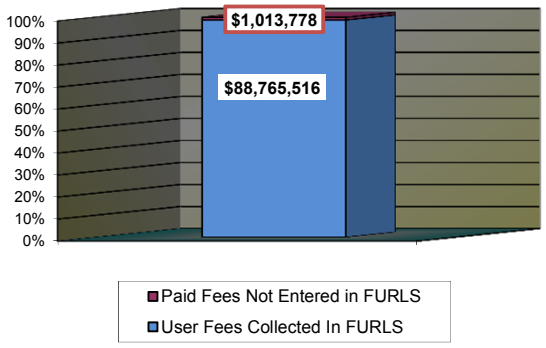
MDUFA III, Registrations, Third Quarter Summary FY2015

Registrations by Type	FY15 End of 3rd Quarter Active			FY14 Year End Active Totals			Progress by Est Type
Est Type	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,842	8,679	14,521	5,751	8,580	14,331	101.33%
Contract Manufacturer	939	1,169	2,108	894	1,113	2,007	105.03%
Contract Sterilizer	74	121	195	76	114	190	102.63%
Specification Developer	1,609	425	2,034	1,659	406	2,065	98.50%
Reprocessor of Single Use Devices	26	0	26	26	1	27	96.30%
U.S. Manufacturer of Export Only Devices	124	0	124	129	0	129	96.12%
Repackager/Relabeler	1,122	173	1,295	1,173	171	1,344	96.35%
Remanufacturer	22	13	35	23	17	40	87.50%
Foreign Exporter/Private Label Distributor	0	613	613	0	619	619	99.03%
Initial Importer	3,185	0	3,185	3,303	0	3,303	96.43%
Unknown	10	10	20	9	8	17	117.65%
Total:	**12,953**	**11,203**	**24,156**	**13,043**	**11,029**	**24,072**	100.35%

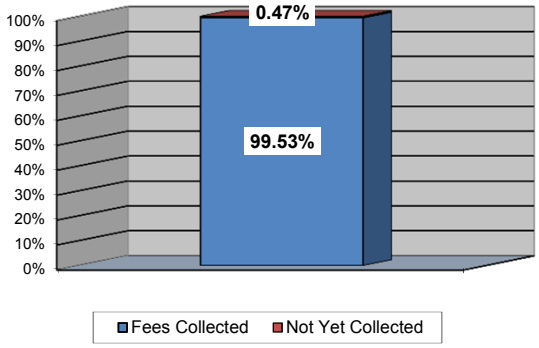
Registration Progress - FY2014 Versus FY2015



User Fees Collected Versus User Fees Paid in Dollars



User Fee Progress - Percent Collected Versus Projections Goals: $89,188,452 fees or 24,462 Registrations



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MDUFA III Quarterly Performance Update
Independent Assessment of Medical Device Review Process

3rd Quarter FY 2015 Status – July 27, 2015

Objectives

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

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

Phase 1:

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

Phase 2:

- Evaluation of the implementation of selected recommendations

Timeline

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

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

Progress to-date:

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

Progress from 3rd Quarter FY 2015:

- BAH Finalized SMART analysis on FDA's Implementation Plan for Priority and Final Recommendations – July 2015
- BAH conducted a stakeholder meeting to demo SMART and discuss the tool's capabilities to improve consistency across the 510(k) premarket review process – June 2015

- Scheduled second quarterly meeting with Industry stakeholders – July 21, 2015
- BAH continues to meet with FDA implementation project teams – Ongoing

Planned Progress in 4th Quarter FY 2015:

- Contractual progress reports and updates from BAH assessment team – Ongoing

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Center for Devices and Radiological Health Internal Training Summary Report

Q3 FY15

October 2014 – June 2015

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

As of: 7/14/2015

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

Table X provides a summary of internal training conducted in CDRH between October 1, 2014 and June 30, 2015. DETD offered 395 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and program activities.

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Table X - FY15 CDRH Internal Training Conducted by DETD:

October 1, 2014 – June 30, 2015

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA III	6	231	558
	ELP	16	252	2948
	Other LAW	74	1064	12097
	LAW Subtotal:	*96*	*2547*	*15603*
Leadership Development Training (LED)	LEAD: Leadership for Managers	42	669	2221
	Leadership for Non-Managers	13	292	1912
	LED Subtotal:	*55*	*961*	*4133*
Professional Development (PRO) Training	New Employee Orientation (NEO)	3	65	455
	Other PRO	79	1507	10678
	PRO Subtotal:	*82*	*1572*	*11133*
Science (SCI) Training	All SCI	142	4065	14548
***Center-Specific Information Technology (CIT) Training**	All CIT	20	95	68
	Grand Total:	**395**	**9240**	**45485**

* CIT is a new category that was added to Table X as of Q2FY15.

Premarket Reviewer Training - RCP

Reviewer Certification Program (RCP):

The development of new employees is vital to CDRH's mission. The Reviewer Certification Program (RCP) is intended for all new review staff in the offices of Device Evaluation (ODE) and In Vitro Diagnostics and Radiological Health (OIR). The RCP is a 10-month program consisting of training which addresses the basic core competencies required for completing the premarket review process. This is taught in cohorts of approximately 40 students.

The program components include:

- 38 courses totaling 140 hours of training,
- Practical activities and Hands-on exercises,
- A Submission Review Audit Process and;
- Knowledge Assessments.

RCP Training Completed Between: *October 2014 – June 2015*

Category	Total Learning Events	Total Participants	Total Completions	Total Training Hours	Examples of Training Conducted
RCP	65	144	2141	11054	• Basic Food and Drug Law • How to Write Effective Pre-market Consulting Reviews • Freedom of Information (FOI) Training

RCP Training by Cohort: *September 2014* – June 2015*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall 2014 Cohort 1	11	26	ODE	37	235	1624
			OIR	22	212	1130
Fall 2014 Cohort 2	11	26	ODE	48	349	1897
			OIR	26	233	1233
Spring 2015 Cohort 1	12	26	ODE	21	313	1859
			OIR	4	96	373
Spring 2015 Cohort 2	12	26	ODE	20	448	1957
			OIR	4	122	453
Summer 2015 Cohort	6	26	ODE	24	243	1056
			OIR	5	57	249
Total:	**52**	**26****	**-**	**211**	**2278**	**11831**

*This chart includes data from September 2014, when both Fall 2014 cohorts began.
** The same online modules were offered to each cohort listed above.

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 pre-market review of the resulting medical devices. The program fosters the premarket reviewers' understanding of how medical devices are developed, clinically tested, manufactured, and utilized.

ELP Training Completed: *October 2014 – June 2015*

Office	# of Site Visits	# of Attendees	Total Training Hours	Focus Area
ODE	15	235	2676	• Endosseous Implants • Refractive lasers • Electrophysiology catheters for diagnostic and therapeutic indications • Hemodialysis used in the home environment
OIR	1	17	272	• Good manufacturing practices under regulation 820
Total	16	252	2948	-

Booz Allen Hamilton (BAH) Independent Assessment Training Recommendation Update

Evaluation of IT Infrastructure and Workload Tools

The Office of Communication and Education (OCE) collaborated with the Office of Device Evaluation (ODE) and Office of InVitro Diagnostics and Radiological Health (OIR) to develop training for CDRH's three primary premarket IT systems: CTS, DocMan and Image2000+. The training is delivered in an online format and will be evaluated using Kirkpatrick's Level 1 and 2 evaluations. Training launched in July and is mandatory for staff involved in premarket review.

Evaluation of Training Programs

OCE continues to implement Kirkpatrick's evaluation Levels 1-4. Specifically, OCE has implemented a revised Level 1 evaluation, and has implemented the Level 2 evaluation data collection process for the Reviewer Certification Program. OCE, ODE and OIR are working together to develop a process for conducting the Level 3 and 4 training evaluation.

Promotion of Informal Training

OCE has a senior ODE reviewer documenting all internal training conducted by the Premarket Offices (which is not currently identified as formal training and is not reflected on a reviewer's official transcript). OCE is currently piloting a standardized process and form used to collect informal training conducted/managed outside of OCE. The pilot will continue through September before the process is required and broadly advertised to the Center.

Leadership Training - LEAD

Leadership Enhancement and Development (LEAD) Program Description:

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

LEAD Training Completed: *October 2014 – June 2015*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	42	669	2221	• Building Strong Customer Relations • Critical Thinking for Better Decision Making • Nonverbal Communication for Managers

LEAD Training for ODE and OIR Completed: *October 2014 – June 2015*

Office	Total # of Managers/Supervisors	# of Training Participants	Training Hours Completed	Training Hours Required	% of Required Training Hours Completed
ODE	64	54	460	1600	29%
OIR	36	27	131	1056	12%
Total:	**100**	**81**	**591**	**2656**	**21%**

Leadership Training - LRP

Leadership Readiness Program (LRP):

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

LRP Participant Data:

LRP Program Year	Office	# of Enrolled Participants	# of Participant Completions
2006 – 2007	OIVD	3	3
	ODE	13	12
2008 – 2009	OIVD	3	3
	ODE	10	10
	Other	17	16
2010 – 2011	OIVD	3	3
	ODE	9	8
	Other	8	8
2012 – 2013	OIR	3	3
	ODE	6	6
	Other	11	11
2014 – 2015	OIR	2	2
	ODE	6	6
	Other	12	12
	Total:	**106**	**103**

CDRH Training Courses by Category:

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

Regulatory and Law (LAW) Training:

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

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

Leadership Development Training for Managers and Non-Managers:

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

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

Professional Development (PRO) Training:

Briefing and Public Speaking Skills	This workshop will review a systematic approach to planning and delivering effective, focused presentations to small or large groups. It will cover techniques for establishing objectives, remaining on target, and responding to difficult questions or challenges.
Critical Thinking and Problem Solving	This one-day workshop develops critical thinking skills for practical everyday use. Participants learn to assist work teams in understanding complex problems, methods for evaluating the possibilities of various decisions and increase their productivity and confidence for the constructive resolution of problems.
Critical TOP Thinking	This training provides an overview and tools for Thought Optimized Processing (TOP) Thinking. Participants will learn how to get more accomplished in a better and pragmatic way while maintaining precision and accuracy. Instruction will also address the ability to think creatively and critically and ensure that reasoning is objective.
Emotional Intelligence	This training provides participants with a proven set of skills in four areas of competency: self-awareness, self-management, social awareness, and social adeptness.

Event-Driven Leadership	This class supports organizational leadership in developing the competencies to deal with ongoing changes and events that impact the professional environment.
Influencing Other for High Impact	This seminar focuses on the skills and strategies necessary to increase the likelihood that others will say "yes". Instruction includes the opportunity to translate theory into practice.
Sparking Creativity and Innovation	This class offers strategies and techniques to help the participant harness innovative thinking, find solutions to problems and enhance their own and others' ability to think more clearly and make better decisions.

Science (SCI) Training:

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

Center-Specific IT (CIT) Training

Center Ad Hoc Reporting Systems (CARS): Overview	This course provides the participants with a functional overview of the system, a survey of the TPLC universe, and examples of office-specific foundational reports.
Learning about SharePoint	This training provides participants with a basic overview of SharePoint, examples of how it is used in CDRH and how to find additional resources. The relationship between

	SharePoint and Knowledge Management is also discussed.