

Agenda for Quarterly Meeting on MDUFA II (2008-2012) Performance

January 29, 2014

1:00 P.M.

Welcome. *Barbara Zimmerman, CDRH-ODE.*

FDA MDUFMA / MDUFA Performance — Actions through December 31, 2013

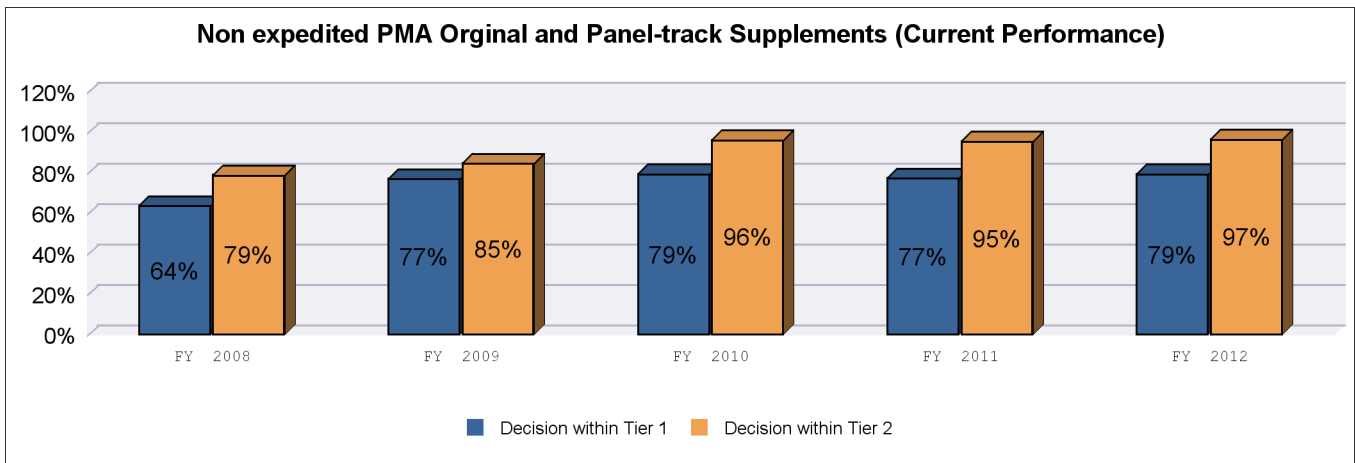
- Reports on all decision goals for the FY 2008 - FY 2012 cohorts.
 - CDRH: *Barbara Zimmerman, CDRH.*

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**Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----
Action through 31 December 2013**

MDUFA II Quarterly (Non expedited PMA Original and Panel-track Supplements)
For Submissions Filed Between Year 2008 to 2012 as of 12/31/2013 11:59:00 PM

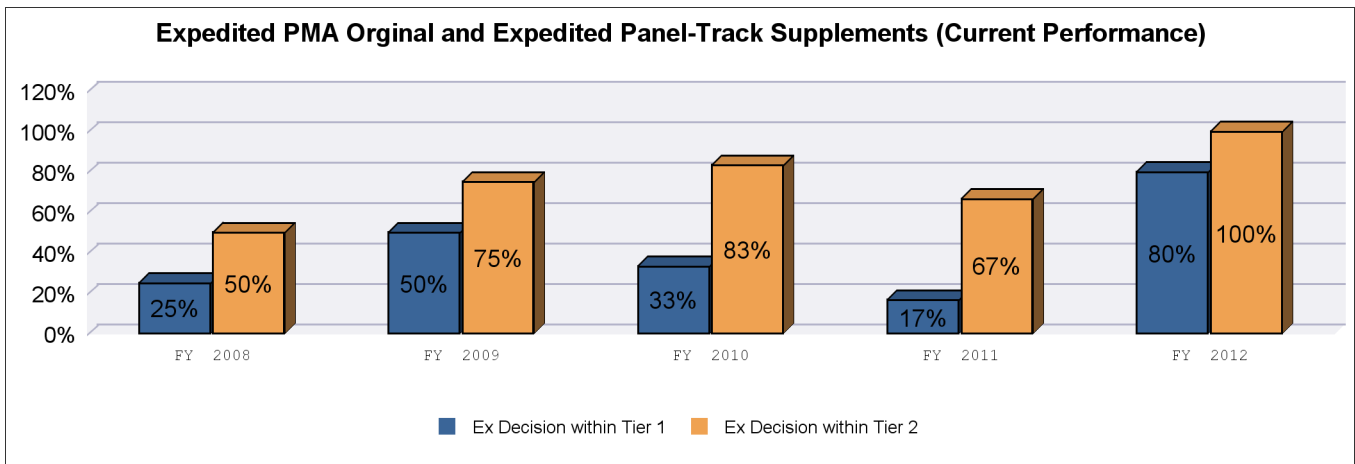
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	33	39	53	44	29
Total FDA Decision	33	39	53	44	29
Tier 1 goal -- Percent within 180 Days	60%	60%	60%	60%	60%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	64%	77%	79%	77%	79%
Pending Performance-Worst Case	64%	77%	79%	77%	79%
Tier 2 goal -- Percent within 295 days	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	no	no	yes	yes	yes
Pending Performance-Best Case	79%	85%	96%	95%	97%
Pending Performance-Worst Case	79%	85%	96%	95%	97%
Cohort status	Complete	Complete	Complete	Complete	Complete



MDUFA II Quarterly (Expedited PMA Original and Expedited Panel-Track Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 12/31/2013 11:59:00 PM

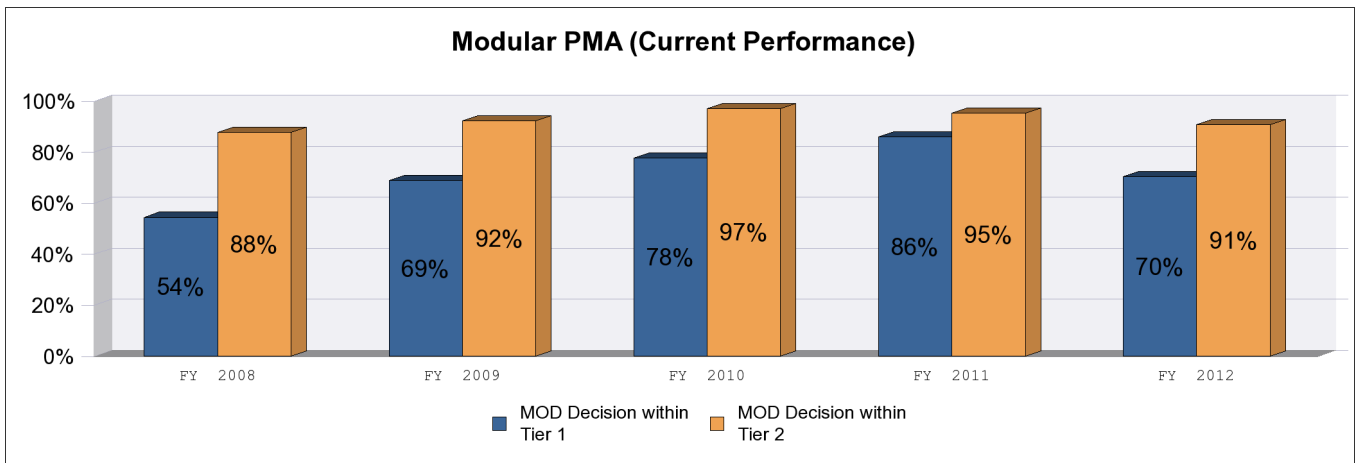
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	4	4	6	7	5
Total FDA Decision	4	4	6	6	5
<i>Tier 1 goal -- Percent within 180 Days</i>	50%	50%	50%	50%	50%
Goal met(yes/no/unknown)	no	yes	no	no	yes
Pending Performance-Best Case	25%	50%	33%	14%	80%
Pending Performance-Worst Case	25%	50%	33%	14%	80%
<i>Tier 2 goal -- Percent within 280 days</i>	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	no	no	no	no	yes
Pending Performance-Best Case	50%	75%	83%	57%	100%
Pending Performance-Worst Case	50%	75%	83%	57%	100%
Cohort status	Complete	Complete	Complete	Open	Complete



MDUFA II Quarterly (Modular PMA)

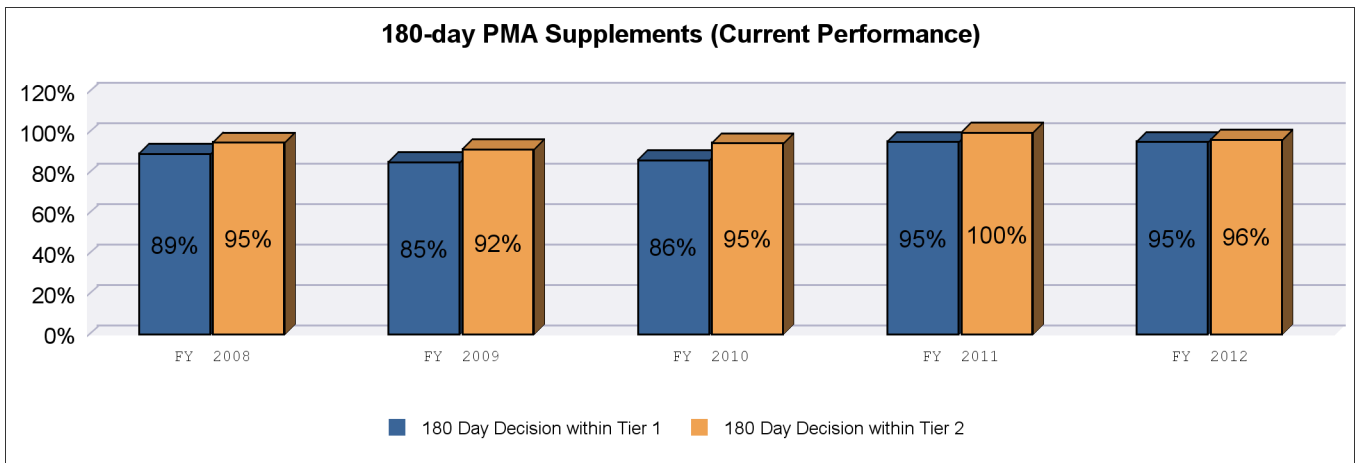
For Submissions Filed Between Year 2008 to 2012 as of 6/30/2013 12:00:00 AM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Cycle Started)	57	90	104	85	64
Total FDA Decision	57	90	103	85	64
Tier 1 goal -- Percent within 90 Days	75%	75%	75%	75%	75%
Goal met(yes/no/unknown)	no	no	yes	yes	no
Pending Performance-Best Case	54%	69%	78%	86%	70%
Pending Performance-Worst Case	54%	69%	78%	86%	70%
Tier 2 goal -- Percent within 120 days	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	no	yes	yes	yes	yes
Pending Performance-Best Case	88%	92%	97%	95%	91%
Pending Performance-Worst Case	88%	92%	97%	95%	91%
Cohort status	Complete	Complete	Complete	Complete	Complete



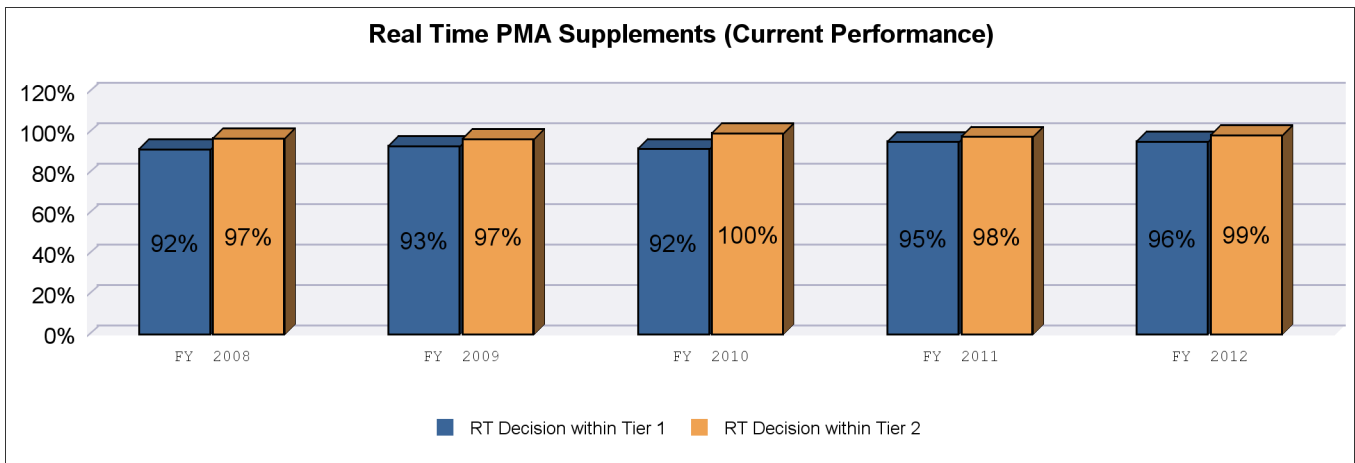
MDUFA II Quarterly (180-day PMA Supplements)
For Submissions Filed Between Year 2008 to 2012 as of 12/31/2013 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	171	164	157	147	216
Total FDA Decision	161	157	132	130	194
<i>Tier 1 goal -- Percent within 180 Days</i>	85%	85%	85%	85%	85%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	89%	85%	86%	95%	95%
Pending Performance-Worst Case	89%	85%	86%	95%	95%
<i>Tier 2 goal -- Percent within 210 days</i>	95%	95%	95%	95%	95%
Goal met(yes/no/unknown)	yes	no	yes	yes	yes
Pending Performance-Best Case	95%	92%	95%	100%	96%
Pending Performance-Worst Case	95%	92%	95%	100%	96%
Cohort status	Complete	Complete	Complete	Complete	Open



MDUFA II Quarterly (Real Time PMA Supplements)
For Submissions Filed Between Year 2008 to 2012 as of 12/31/2013 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	249	296	269	245	304
Total FDA Decision	241	281	257	235	293
<i>Tier 1 goal -- Percent within 60 Days</i>	80%	80%	80%	80%	80%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	92%	93%	92%	95%	96%
Pending Performance-Worst Case	92%	93%	92%	95%	96%
<i>Tier 2 goal -- Percent within 90 days</i>	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	97%	97%	100%	98%	99%
Pending Performance-Worst Case	97%	97%	100%	98%	99%
Cohort status	Complete	Complete	Complete	Complete	Complete



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2012 as of 12/31/2013 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	3,848	4,103	3,880	3,833	3,991
MDUFA Cohort	3,259	3,401	3,144	3,197	3,323
Total FDA Decision	3,259	3,399	3,144	3,196	3,300
<i>Tier 1 goal -- Percent within 90 Days</i>	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	94%	90%	90%	95%	96%
Pending Performance-Worst Case	94%	90%	90%	95%	96%
<i>Tier 2 goal -- Percent within 150 Days</i>	98%	98%	98%	98%	98%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	98%	98%	98%	99%	100%
Pending Performance-Worst Case	98%	98%	98%	99%	99%
Cohort status	Complete	Open	Complete	Open	Open

