FDA Update

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MDUFA III

Medical Device User Fee Act III

Key Points of MDUFA III

- Shared Outcome Goal – Total Time
- 1 Tier System
- No Submission Left Behind
- Refuse to Accept policy
- Substantive Interaction goals
- PMAs separated: panel vs no panel

Submission Type		MDUFA III (2013-2017) - all in FDA Days except Average Total Time				
		FY13	FY14	FY15	FY16	FY17
510(k)s	Performance Goal	91% in 90 days	93% in 90 days	95% in 90 days	95% in 90 days	95% in 90 days
	Interaction Goal	65% in 60 days	75% in 60 days	85% in 60 days	95% in 60 days	95% in 60 days
	Average Total Time (shared)	**135 days**	**135 days**	**130 days**	**130 days**	**124 days**
Original PMAs & Panel Track Supplements (including Expedited)	Performance Goal (no panel mtg)	70% in 180 days	80% in 180 days	80% in 180 days	90% in 180 days	90% in 180 days
	Performance Goal (with panel mtg)	50% in 320 days	70% in 320 days	80% in 320 days	80% in 320 days	90% in 320 days
	Interaction	65% in 90 days	75% in 90 days	85% in 90 days	95% in 90 days	95% in 90 days
	Average Total Time (shared)	**395 days**	**395 days**	**390 days**	**390 days**	**385 days**
180 Day PMA Supplements	Performance Goal	85% in 180 days	90% in 180 days	90% in 180 days	95% in 180 days	95% in 180 days
	Interaction	65% in 90 days	75% in 90 days	85% in 90 days	95% in 90 days	95% in 90 days
Real Time PMA Supplements	Performance Goal	90% in 90 days	90% in 90 days	95% in 90 days	95% in 90 days	95% in 90 days
CLIA Waiver Applications	Dual CLIA/510(k)	90% in 210 days				
	CLIA (no panel)	95% in 180 days				
	CLIA (with panel)	95% in 330 days				

MDUFA III status

- Quarterly reports
  - google – mdufma reports
  - Everything you wanted to know, but were afraid to ask
- So far all looks good….

MDUFA II Quarterly (Non expedited PMA Orginal and Panel-track Supplements)

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 (Filed to Date)	33	39	53	44	30
Total FDA Decision	33	39	53	43	26
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%	83%
Pending Performance-Worst Case	64%	77%	79%	77%	73%
Tier 2 goal -- Percent within 295 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	yes	yes	unknown
Pending Performance-Best Case	79%	85%	96%	95%	100%
Pending Performance-Worst Case	79%	85%	96%	95%	87%
Cohort status	Complete	Complete	Complete	Open	Open

Table 1.5.OIR 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	6				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
PMAs pending MDUFA III Decision	5				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 1.6.OIR 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	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 320 FDA Days	1				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	100%				

MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received 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 (Received to Date)	3,848	4,103	3,880	3,833	3,991
MDUFA Cohort	3,259	3,402	3,144	3,197	3,369
Total FDA Decision	3,259	3,399	3,144	3,194	3,215
Tier 1 goal -- Percent within 90 Days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	94%	90%	90%	95%	97%
Pending Performance-Worst Case	94%	90%	90%	95%	92%
Tier 2 goal -- Percent within 150 Days	*98%*	*98%*	*98%*	*98%*	*98%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	98%	98%	98%	99%	100%
Pending Performance-Worst Case	98%	98%	98%	99%	95%
Cohort status	Complete	Open	Complete	Open	Open

Table 6.4.OIR OIR – 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	533				
Non-MDUFA III Decisions	15				
MDUFA III Decisions (SE/NSE)	286				
MDUFA III Decisions within 90 FDA Days	284				
510(k)s pending MDUFA III Decision	232				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

CLIA Waiver Metrics

- Nothing to report since the agreement is for annual reports

CLIA Waiver by Application

MDUFA II Cohort Summary as of 7/12/2013					
	FY08	FY09	FY10	FY11	FY12
Received	12	7	5	6	6
Approved	5	3	2	3	2
Denied	6	3	3	0	4
No Response Necessary	0	0	0	1	0
Deleted	1	1	0	0	0
Under Review	0	0	0	2	0

CLIA Categorizations

Year	2008	2009	2010	2011	2012	2013
High Complexity	110	183	194	267	149	181
Moderate Complexity	1246	1223	891	2498	1258	532
Waived	389	401	714	420	505	557

PMA Approvals

- Roche's cobas® EGFR Mutation Test
  - Aid in selecting patients with NSCLC for whom Tarceva® (erlotinib) is indicated.
- bioMérieux's THxID™ BRAF Kit
  - Aid in selecting melanoma patients for treatment with dabrafenib [Tafinlar®] and for treatment with trametinib [Mekinist ™]

PMA Approvals

- Abbott's RealTi*me* HCV Genotype II
  - Aid in the management of HCV-infected individuals and in guiding the selection of therapeutic treatment indicated for genotypes 1, 1a, 1b, and 2-5
- Qiagen's therascreen® EGFR RGQ PCR Kit
  - To select patients with NSCLC for whom GILOTRIF™ (afatinib) is indicated

De Novo Downclassifications

- Roche's COBAS INTEGRA 800 Tina-quant HbA1cDx Gen.2
  - This test is to be used as an aid in diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes

De Novo Downclassifications

- CDC's Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS
  - To detect and measure the concentration of specific organophosphate metabolites in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning

De Novo Downclassifications

- Abbott's Vysis EGR1 FISH Probe Kit
  - The Vysis EGR1 FISH Probe Kit – SC assay results characterize bone marrow specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted by a qualified pathologist or cytogeneticist. This device is not intended for high-risk uses such as selecting therapy, predicting therapeutic response or disease screening. The use of this product for diagnosis, monitoring or risk assessment has not been established.

De Novo Downclassifications

- Cepheid's Xpert® MTB/RIF Assay
  - The Xpert® MTB/RIF Assay, performed on the GeneXpert® Instrument Systems, is a qualitative, nested real-time polymerase chain reaction (PCR) *in vitro* diagnostic test for the detection of *Mycobacterium tuberculosis* complex DNA in raw sputum or concentrated sediments prepared from induced or expectorated sputum. In specimens where *Mycobacterium tuberculosis* complex (MTB-complex) is detected, the Xpert MTB/RIF Assay also detects the rifampin-resistance associated mutations of the *rpoB* gene

Guidances

- Humanitarian Use Device (HUD) Designations
- Types of Communication During the Review of Medical Device Submissions
- Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi
- Molecular Diagnostic Instruments with Combined Functions

Guidances

- Assay Migration Studies for In Vitro Diagnostic Devices
- FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens

Notable Panel Meetings

- Classification Panel, April 25, 2013
  - Methotrexate Test Systems
  - PCP Test Systems
  - Isoniazid Test Strips

Notable Panel Meetings

- Flu up-classification, June 13, 2013
  - Minimum performance criteria that should be required for clearance of the rapid influenza detection devices
  - Appropriate reference method to be used for evaluation of clinical performance
  - Annual post-market reactivity testing of device performance due to the continuous genetic changes of seasonal influenza viruses and, how to communicate the ability of previously cleared rapid influenza detection devices to detect novel influenza virus strains
  - Testing when a new influenza strain with a potential to become a public health emergency emerges.

Notable Workshops

- Clinical Flow Cytometry in Hematologic Malignancies, February 25-26, 2013
- Summit on Color in Medical Imaging, May 8-9, 2013
- Diabetes Technology Society's meeting on performance of glucose meters, May 21, 2013

Thanks