CDRH Update

IVD Roundtable 11/29/2012

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New Product Evaluation

OIR

Summary

- Program Activities
- MDUFA III
- OIVD to OIR Reorganization

Program Activities

Program Activities

- 2012 Happenings:
  - **3rd Party Review program oversight moved from ODE to OIVD**
  - **Artificial Pancreas Program lead moved from ODE to OIVD**
  - **CDRH's entire Radiological Health program moved from OC/OSB/OCER to OIR (formally OIVD)**

Program Activities

- Things to keep an eye on:
  - **Innovation Pathway**
  - **UDI**
  - **eCopy**
  - **RTA**
  - **Pre-Submissions**
  - **De novo changes**
  - **Any/All Final Guidances**

Program Activities

- Internal Program updates:
  - **OIR - Triage Pilot**
  - **ODE - Corrective and Preventive Action (CAPA) System Pilot (may soon be coming to OIR)**
  - **510(k) deletions after 180 days on hold**
  - **SOPs (Administrative file, Scientific Disputes, Assigning files)**
  - **Exemptions Enforcement Discretion Guidance**

MDUFA 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 – What to Expect

- A lot of internal changes for staff to learn
- More Touch Points (after RTA screening, after SI, after MMD, during IR)
- Electronic correspondence, digitally signed (won't have to wait for the mailman)
- Less review cycles to reach a final decision (more decisive which means less flexible)
- A better documented/tracked database (better performance data available to stakeholders which means a more formalized process)

MDUFA III status

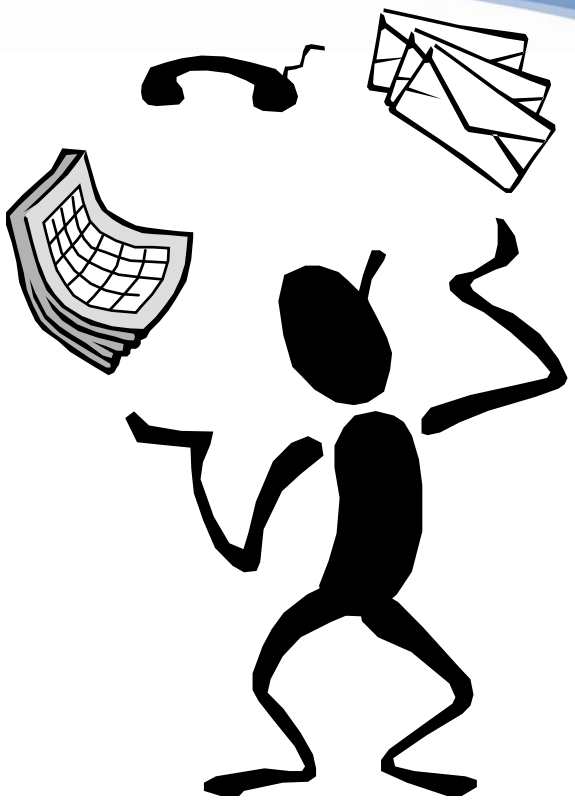
- 1st quarter (10/1 – 12/31)
  - mostly beta testing new IT systems and processes (very frustrating for staff, please be patient)
  - Try to finalize MDUFA guidances (eCopy and RTA) so can implement in January
- 2nd quarter (1/1 – 3/31)
  - Cross your fingers (call/email with questions or if encountering problems)

Reorganization

Effective October 1, 2012, OIVD became OIR (**O**ffice of **I**n Vitro Diagnostics and **R**adiological Health)

Big changes

- Adding branches
  - Consistent with the rest of the Center
  - More manageable (10-15/branch)
- Adding Post-market Radiology (from OC and OSB)
- Adding all RH (from OCER)
- Adding MQSA (from OCER)



When in doubt, just ask:

Email (preferred) or phone

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