FDA-Industry IVD Roundtable Meeting

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Medical Devices Review Responsibilities in CBER

- **Office of Blood Research and Review**
  - Blood and blood derived products
  - Medical devices used to test, collect, process or store donated blood
  - Retroviral diagnostic tests
  - Blood bank test kits (red blood cell antigens and antibodies)
  - HLA test kits (antigens and antibodies)
- **Office of Cellular, Tissue, and Gene Therapies**
  - Cell/tissue/gene therapy related devices
- **Office of Compliance and Biologics Quality**
  - Inspections, review of advertising and promotional labeling, and Lot release
  - Limulus Amebocyte Lysate tests
- **Office of Biostatistics and Epidemiology**
  - Statistical Review

CBER MDUFA III PRIORITIES

MDUFA III - Key Features of the Commitment Letter

I. Process Improvement
   - Pre-Submissions Process
   - Submission Acceptance Criteria
   - Interactive Review
   - Guidance Document Development

II. Review Performance Goals

III. Shared Outcome Goals

IV. Infrastructure

V. Independent Assessment of Review Process Management

VI. Discretionary Waiver

CBER Priorities

- Invest resources strategically to support the priorities of the Agency and CBER
- CBER is systematically working to lay the groundwork to strengthen the managed review process to meet the mandated MDUFA III goals
  - Build a Center-wide culture that emphasizes coordination, cooperation and accountability
  - Issuance of new or revised guidance documents in a timely manner
  - working on priority list of topics for developments

CBER Priorities (2)

- CBER is working closely with CDRH on Device down classification
- Working on issuing new guidance and updating existing guidance documents for CBER specific devices
- Reviewer Training on MDUFA III
- CBER Device Reviewer Training
- Issuance of new and or revised Center SOPPs

MDUFA III Review Performance Statistics

CBER - FY2013 510(k) Receipt Cohort

as of April 30, 2013

510(k) type	Number Received
Traditional	25
Special	6
Abbreviated	2
Total Received	33

Time to Final Decision

(SE/NSEs only) as of April 30, 2013

510(k) Type	n	FDA Time (days, Avg)	Total Time (days, Avg)
Traditional	4	79.3	84.0
Special	4	26.8	26.8
Abbreviated	0	0	0
Total	8	53.0	55.4

CBER 510(k) Cycles
(from Receipt to Final Action)

510(k) Type	SE/NSEs	Average	Under Review	1st cycle Completed
Traditional	4	1.25	10	11
Special	4	1.00	2	0
Abbreviated	0		1	1
Total	8	1.13	13	12

CBER-510(k) Acceptance Review Decision (as of March 31, 2013)

Performance Metric	FY13	FY14	FY15	FY16	FY17
Number Received	33				
Closed before RTA action	0				
Number Accepted	23				
Number w/o a RTA review and over 15 days since received	2				
Number w/o a RTA review and less 15days since received	3				
Number not accepted	5				
Rate of submissions not accepted for substantative review	17.9%				

CBER-510(k) Substantive Interaction Performance Goals (as of March 31, 2013)

Substantive Interaction (SI) Performance Goals	**FY13**	**FY14**	**FY15**	**FY16**	**FY17**
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	26				
SI within 60 days	16				
SI over 60 days	5				
SI pending within 60 days	5				
SI pending over 60 days	0				
510(k)s NSE without SI	0				
Current SI Performance within 60 days	76.0%				

CBER-510(k) MDFA III Decision performance Goals (as of March 31, 2013)

Performance Metric	FY13
	91% within 90 FDA days
Number accepted	23
Non-MDUFAIII decisions	13
MDUFA III decisions (SE/NSE)	8
MDUFA III decisions within 90 days	8
510(k)s Pending MDUFA III Decision	18
Current performance percent within 90 FDA days	100%

CBER-510(k) Annual General Metrics

(as of March 31, 2013)

Performance Metric	FY13	FY14	FY15	FY16	FY17
Number Accepted	23				
Number of traditional submissions	18				
Number of special submissions	4				
Number of abbreviated submissions	1				
Average number of days to Accept/Refuse to Accept	11				

CBER-510(k) Annual General Metrics

(as of March 31, 2013)

Performance Metric	FY13	FY14	FY15	FY16	FY17
Number Accepted	23				
Currently under review	15				
Number with non-MDUFA Decision	13				
Number with MDUFA decision	8				
Percent of cohort closed	35%				
Number with MDUFA decision after trimming the upper and lower 2%	6				
Average total time to MDUFA III decision	55				

CBER – PMAs Received by Type

as of March 31, 2013

PMA Submissions Received	Number Received
Original PMAS	0
Real Time Supplements	3
180-Day Supplements	1
Total Received	4

Real Time PMA Supplements MDUFA III Performance Goals (as of March 31, 2013)

Performance Goals	FY13	FY14	FY15	FY16	FY17
	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
Real time suppl. received	3				
MDUFA III Decisions	2				
MDUFA III Decisions within 90 Days	2				
Supplements Pending MDUFA III Decision	1				
Supplements Pending MDUFA III Decision over 90 days	0				
Current Performance % within 90 FDA Days	100%				

MDUFAIII Biologic Devices Performance Goals

(as of March 31, 2013)

Application Type	Number of Application		Actions	Goal Review time	FY-2023 Goal	Within Goal		
	Rec'd	Filed				Comp	Pend	Total
BLAs-Standard	14	14	Review and issue a complete action letter	10	90%		14	14
BLAs-Priority	0	--	Review and issue a complete action letter	6	90%			
BLA Supplement Standard Efficacy	0	--	Review and issue a complete action letter	10	90%			
BLA Supplement Priority Efficacy	0	--	Review and issue a complete action letter	6	90%			
BLA Suppl. Prior Approval Manuf.	8	8	Review and issue a complete action letter	4	90%	6	2	8
BLA/BLS Resubmissions	0		Class 1: Review and issue a complete action letter	2	90%			
			Class 2: Review and issue a complete action letter	6	90%			

MDUFAA III
The Pre-submission Program

The Pre-submission Program

- Pre-submission process/program formerly known as the Pre-IDE program
- More structured approach to guiding and clarifying product specific requirements/issues for IDEs, 510(k)s and PMAs prior to submission of application to FDA.

The Pre-submission Program

- The Pre-Sub Program is a formal written request from a submitter/sponsor for feedback from FDA to be provided in the form of a formal written response or, if the chooses, a meeting or teleconference in which the feedback is documented in meeting minutes.
- It is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation.

The Pre-submission Program

- The Pre-submission program is NOT applicable to device IND/BLA meetings.
  - Continue to use CBER SOPP 8101.1

CBER Pre-submission Performance

(as of March 31, 2013)

Performance Metric	FY13	FY14	FY15	FY16	FY17
Number of all qualified Pre-submissions received	24				
Number requesting a meeting or teleconference	22				
Number with meeting or teleconference granted	18				
Number w/ meeting granted and sponsor cancelled	7				
Number w/ meeting granted and FDA cancelled	0				
Number w/ meeting or teleconf. held	4				
Average days to meeting	64				

Summary: Pre-sub Program

Applicants are strongly encouraged to seek regulatory guidance and discuss planned content of applications with the appropriate CBER review Office/Division at a pre-IDE, IND, 510(K), PMA or BLA meeting

Questions