FDA-Industry IVD Roundtable Meeting

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MDUFA II

2008 -2012

CBER MDUFA Performance - Receipt Cohort by Fiscal Year

Application Type / MDUFA Goal for FDA Decision	FY	Filed	Completed Within Goal	Completed Not Within Goal	Pending	Goal Met
PMAs 180 days (60%) 295 days (90%)	2008	0	NA	NA	NA	NA
	2009	2	2 2			100% 100%
	2010	0				NA
	2011	1	1 1			100% 100%
	2012 *	1			1 1	100% 100%
180-day Suppls: 180days (85%) 210days (95%)	2008	5	4 4	1	0 0	100% 80%
	2009	7	6 7			100% 100%
	2010	7	7 7			100% 100%
	2011	9	9 9			100% 100%
	2012 *	6	1 2		4 4	100% 100%

*Submissions Received from October 1, 2011 to April 30, 2012. Actions through April 30, 2012.

CBER MDUFA Performance - Receipt Cohort by Fiscal Year

Application Type / MDUFA Goal for FDA Decision	FY	Filed	Completed Within Goal	Completed Not Within Goal	Pending	Goal Met
Real-Time Suppl. 60 days (80%) 90 days (90%)	2008	2	2 2	0 0	0 0	100% 100%
	2009	4	4 4	0 0	0 0	100% 100%
	2010	2	2 2	0 0	0 0	100% 100%
	2011	1	1 1	0 0	0 0	100% 100%
	2012	1	1 1	0 0	0 0	100% 100%
510(k)s 90 days (90%) 150 days (98%)	2008	53	47 48	0 1	0 0	100% 98%
	2009	50	38 40	0 0	0 0	100% 100%
	2010	55	42 43	0 0	2 2	100% 100%
	2011	44	26 27	0 0	10 10	100% 100%
	2012	26	8 8	0 0	17 17	100% 100%

CBER MDUFA Performance - Receipt Cohort by Fiscal Year

Application Type / MDUFA Goal for FDA Decision	FY	Filed	Completed Within Goal	Done Not Within Goal	Pending	Goal Met
BLAs – Review & Act 10mo(90%)	2008	15	15		0	100%
	2009	8	8		0	100%
	2010	1	1		0	100%
	2011	1	1		0	100%
	2012	0			0	NA
BLA Efficacy Supplement	2008	0			0	NA
	2009	1	1		0	100%
	2010	0			0	NA
	2011	1			1	100%
	2012	0			0	NA
BLA Mftg. Supplements - 4mo(90%)	2008	227	227		0	100%
	2009	95	95		0	100%
	2010	83	83		0	100%
	2011	37	37		0	100%
	2012	20	11		9	100%

*Submissions Received from October 1, 2011 to April 30, 2012. Actions through April 30, 2012.

CBER MDUFA Meetings Workload - Cohorts by Fiscal Year

		Meeting Requests Received from Sponsors				Meetings Held With Sponsors			
Meeting Priority Type - MDUFA	FY	Type A	Type B	Type C	All	Type A	Type B	Type C	All
	2008	2	28	41	71	1	26	32	59
	2009	3	26	28	57	2	18	21	41
	2010	0	33	31	64	1	24	19	44
	2011	1	48	33	82	1	32	18	51
	2012*	0	15	7	22	0	11	5	16

*Submissions Received from October 1, 2011 to April 30, 2012. Actions through April 30, 2012.

Selected Examples of CBER MDUFA Approvals

- **ADVIA Centaur® HIV-1/O/2 Enhanced Assay 2.0.** An in vitro diagnostic immunoassay for the qualitative determination of antibodies to HIV-1, including group O, and/or HIV-2 in serum or plasma using the ADVIA Centaur System.

- **GS HIV Combo Ag/Ab EIA.** An enzyme immunoassay kit for the simultaneous qualitative detection of HIV p24 antigen, antibodies to HIV-1 groups M and O, and HIV-2 in human serum or plasma. An aid in the diagnosis of infection with HIV-1 and/or HIV-2 in both adult and pediatric subjects. Intended for manual use and with the Bio-Rad EVOLIS Automated Microplate System.

- **Platelet PGD Test System.** For the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in LRAP and pools of 6 units of Leukocyte reduced and non-leukocyte reduced whole blood derived platelets.

Selected Examples of CBER MDUFA Approvals (1)

- **ULTRAQUAL HBV PCR Assay 2, Hepatitis B Virus (Hepatitis B Virus/ Nucleic Acid Pooled Testing/ Synthetic).** For the qualitative detection of HBV DNA in individual or pooled samples of human Source Plasma (or plasma samples obtained from Source Plasma donors at the time of donation).

- **Avioq HTLV-I/II Microelisa System 1 (Human T-Lymphotropic Virus Types I & II (HTLV-I and HTLV-II/Enzyme Immuno Assay (EIA)/Lysate).** Intended for screening individual human donors, including volunteer donors of whole blood and blood components, organ donors when specimens are obtained while the donor's heart is still beating.

Selected Examples of CBER MDUFA Approvals (2)

- **PROCLEIX ULTRIO PLUS Assay**. A qualitative multiplex donor screening test to simultaneously detect HIV-1 RNA, HCV RNA, and HBV DNA in human plasma/serum specimens from donors of whole blood, blood components, and source plasma, and from other living donors. Also intended for use in testing plasma/serum specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, and in testing blood specimens from cadaveric (non-heart-beating) donors.

CBER Device Guidance Documents for Industry

- Draft Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus.11/2011

- Guidance for Industry: "Lookback" for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV. 12/2010

- Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc). 5/ 2010.

CBER Device Guidance Documents for Industry (1)

- Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle. 11/29/2007, Updated 3/2011.

- Guidance for Industry: Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay. 8/08/2007, Updated 3/2011.

- Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion. Issued January 2001. Updated 1/2011.

CBER Device Guidance Documents for Industry (2)

- Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products. 5/2010

- Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry. 5/2010

- Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc). 5/2010

CBER Device Guidance Documents for Industry (3)

- Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion. 11/6/2009

- Draft Guidance for Industry and FDA Staff Assay Migration Studies for In Vitro Diagnostic Devices. 1/5/2009

- Draft Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products. 3/2009

CBER Device Guidance Documents for Industry (4)

- Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion, 1/ 2011

- Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle, Updated 3/ 2011

MDUFA III

2013 -2017

Process Improvements

1. Pre-Submissions
2. Submission Acceptance Criteria
3. Interactive Review
4. Guidance Document Development
5. Third Party Review
6. Low Risk Medical Device Exemptions
7. Emerging Diagnostics

Process Improvements (1)

1. **Pre-Submissions:**

   CBER has instituted a structured process for managing Pre-Submissions.

2. **Submission Acceptance Criteria:**

   To facilitate a more efficient and timely review process, CBER will implement revised submission acceptance criteria. The Agency will publish guidance documents outlining electronic copy of submissions (e-Copy) and objective criteria for revised "refuse to accept/refuse to file" checklists.

   Examples:

   Refuse to Accept Checklist for traditional, abbreviated and special 510(k)s

   Checklist for Acceptance and Filing Reviews for PMA Guidance

Process Improvements (2)

3. Interactive Review:

CBER will continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and applicants to facilitate timely completion of the review process based on accurate and complete information.

Process Improvements (3)

4. Guidance Document Development:

CBER will apply user fee revenues to supplement the improvement of the process of developing, reviewing, tracking, issuing, and updating guidance documents.

5. Third Party Review:

The Agency will continue to support the third party review program and agrees to work with interested parties to strengthen and improve the current program while also establishing new procedures to improve transparency.

Process Improvements (4)

6. **Low Risk Medical Device Exemptions:**

   CBER, in collaboration with CDRH, will propose additional low risk medical devices to exempt from premarket notification.

7. **Emerging Diagnostics:**

   CBER, in collaboration with CDRH, will work with industry to develop a transitional *In Vitro* Diagnostics (IVD) approach for the regulation of emerging diagnostics.

Questions ?