FDA/Industry IVD Roundtable Meeting

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CBER Medical Devices Performance for FY -2011

The data* indicate CBER has met or has the potential to meet or exceed MDUFA performance goals for the following submission types:

- 510(k)s
- PMAs
- Device BLAs

*Note - includes completed and pending reviews for Tiers 1and 2 performance goals through May, 2011

CBER Medical Device Performance for FY2011 (thru 5-31-2011)

Submission Category	Number of Submissions Received	Number of Submissions Compl./pend.	Goal Date Reached-% Or Current Projected % Within Goal
510(k)s	21 (1 withdrawn)	6/14	100% within goal (89.5 days Av. RT)
PMA/PMAs	11	3/8	100% within goal
BLAs BLS (m) PAS Resub.	1 87 20 3	0/3 55/32 15/5 1/2	100% within goal 100% within goal 100% within goal 100% within goal

Regulatory Review/Meetings

- CBER will continue to incorporate an interactive review process, collaborates closely with stakeholders on the development of guidance, and provide educational materials to improve communication. These efforts are expected to improve the quality of submissions by applicants and provide more timely and consistent reviews by CBER.

- CBER strongly encourages pre-submission meetings.
  - *Follow SOPP 8101.1 Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants*

Regulatory Review/Meetings (1)

- CBER's current goal is to issue via fax or e-mail pre-meeting feedback/responses to sponsors' questions two business days before the scheduled face-to-face/t.con meetings. The sponsor may decide to cancel the meeting if satisfied with FDA's feedback/response.
- If the meeting is conducted, CBER will issue meeting minutes to sponsors within 30 calendar days after the meeting.

Regulatory Review/Meetings (2)

- Important agreements, disagreements, issues for further discussion, and action items from the meeting will be clearly outlined in the minutes
- Sponsors should include in their subsequent submissions any CBER prior commitments made during these meetings.
- Sponsor may contact the CBER to obtain clarification regarding deficiencies cited in a formal hold letter (IR and CR letters), however…

Regulatory Review/Meetings (3)

- It is important to note that applicants should not contact CBER to request the review of proposed responses addressing the cited deficiencies for adequacy. Instead, the applicant should submit its official response to FDA for review when the response is complete in order to remove the submission from its on-hold status.
- *Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements February 28, 2008*

CBER Current Regulatory Challenges

- This past year many new regulatory issues have come up and been discussed publicly that will have a significant impact on how FDA will regulate devices in the future. These include areas that need continued dialogue to create consistent policy. Such issues include the 510(k) process, companion diagnostics, lab-developed tests, research use only IVDs
- *Draft Guidance for Industry and FDA Staff - Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions - June 1, 2011*

CBER Current Regulatory Challenges (1)

- Novel and emerging technologies using multiplex assays for the detection of pathogens and heritable markers and the regulatory challenges they will create are another important area that is being discussed within CBER.
- In addition, new international initiatives such as the role of FDA in combating Neglected Tropical Diseases and Emerging Infectious Diseases, an area that will help bring safe and effective therapeutics, vaccines and diagnostics to the world market, are currently being considered.

Update from CBER

- April BPAC agreed with FDA recommendation to screen source plasma with HBV NAT
- We are seeing increased activity in the area of HIV Ag/Ab combo assays

QUESTIONS?