FDA-Industry IVD Roundtable

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MDUFA I &II Performance Goals

- 510(K)s
- PMAs/PMSs
- BLAs/BLSs

MDUFA III

FY 2013 to 2017

CBER Reviewer Training

- Mandatory training in September and October 2012
- Emphasis on the key features of the commitment letter
- Key changes
- Importance of interactive review

Refuse to Accept

- Guidance with checklists has not yet published. Reviewers and RPMs will be trained once the document is published.

- The MDUFA III goals for Total Time to Decision increases the importance of the acceptance review. CBER will now place an emphasis on the quality of submissions in order to limit the number of review cycles and reduce the probability of a major amendment being submitted.

Substantive Review

- During MDUFA III training CBER management emphasized the need for early, and, if necessary, frequent interaction, with the applicant.

- Deficiencies conveyed to the applicant during Interactive Review do not stop the review clock. FDA will communicate to the applicant the response timeframes along with the deficiencies.

- CBER's internal goals have contributed to our success in the past in meeting MDUFA goals and will continue to be used to support the new MDUFA III goals.

MDUFA III – Device BLAs

For Medical devices subject to regulation under the PHS Act:

- No changes to performance goals or review procedures
- eCopy requirements apply, but waived if the true electronic submission sent in
- MDUFA III BLAs are not subject to the "program" and other changes under PDUFA V

Meeting with sponsors/applicants

- CBER strongly recommends that applicants request pre-submission meetings. This will increase the quality and completeness of the submission and will decrease the probability of an RTA or RTF.

- Meetings
  - SOPP8101.1(BLAs)
  - Draft Guidance for Industry and FDA Staff Medical Devices: The Pre-Submission Program and Meetings with FDA Staff (510ks and PMAs)

Thank you!