MDUFMA: Agenda and Materials From April 20, 2010 FDA Performance Report

U.S. Food & Drug Administration

Welcome. Barbara Zimmerman, CDRH-ODE.

Guidance Development

- FDA issued 1 medical device guidance document during the second quarter. *Barbara Zimmerman, CDRH-ODE; Leonard Wilson, CBER; Don St. Pierre, CDRH-OIVD*

Strategic Plan Update

- Transparency Initiative update. *Barbara Zimmerman, CDRH-ODE*

FDA MDUFMA / MDUFA Performance - Actions through March 31, 2010

- Reports on all decision goals for the FY 2003 - FY 2010 cohorts.
    - CBER: *Leonard Wilson, CBER.*
    - CDRH: *Barbara Zimmerman, CDRH.*

Registration Update

- Number of Device establishments registered and by type. *David Racine, CDRH-OC*

Training

- FY 2010 MDUFA-related training - *Laura Stewart, CDRH-OCER-Staff College*

Qualitative Update on Finances and Use of Resources Ã¢?? 2st Quarter of FY 2010

- User fee receipts through the 1st Quarter of FY 2010, compared with expectations. *David Miller, FDA-OFM.*
- Update on Budget Requests and appropriations. *Daniel Montgomery, CDRH-OMO.*

Discussion

- Questions from industry.
- Set date for next meeting, following close of Q2. Target: Week of 7/27/2010.

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[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm212870.htm