FDA Update

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Office of In Vitro Diagnostics

- One organizational unit to regulate all IVDs through their Total Product Life Cycle using Knowledge Management
- One stop shopping
- Regulation from common technical base

Office of In Vitro Diagnostics

- Goal – to better connect
  - **Premarket review**
  - **Compliance/Enforcement actions**
  - **Postmarket monitoring**

Office of In Vitro Diagnostics

- Three divisions support all technical decision making
- Compliance in matrix form
- MDR analysts are embedded in divisions
- Cross hires with postmarketing and research groups
- Total regulatory staff now about 85 FTE

Multi-Tasking Work Force

- Premarket Review -- 650 actions/ year
- Compliance Actions – 130 to 150/ year (range from recalls to enforcement letters to seizures)
- MDR surveillance – 10,000 reports/ year

CLIA Initiatives

- Waiver guidance
  - **Expected summer 2005**
  - **Tri-agency effort**
  - **Build off of CLIAC recommendations**

CLIA Initiatives

- Re-delegation of authority
- Tri-agency agreement
- SOPs in place

Current CLIA

- 2000 classifications per year
- Waived – 8 %
- Moderate – 80%
- High – 12%

Current CLIA -- good news

- New tracking system
- Personnel well trained in process

Current CLIA -- bad news

- Lack of guidance produces regulatory uncertainty for both sponsors and FDA
- Lack of guidance produces problem reviews for FDA and sponsors

Other Initiatives -- the OIVD Web Page

- Primary goal is transparency
- Standardized review template posted
- Public compliance actions posted
- Laboratory safety information posted

Other Initiatives -- the OIVD Web Page

- Recent face lift -- new tranquil blue look
- Try it, you may like it

www.fda.gov/cdrh/oivd

Guidance Document Development

- Son (daughter) of Multiplex
- Joint Drug and Diagnostic
- Future documents in area of genomics/genetics
- Current revision of older documents

Turbo 510(k)

- First three submissions
- Others in pipeline
- Move toward paperless and streamlined future

Refinement of Review Tools

- Promotion of Pre-IDEs (protocol reviews)
- Use of expedited reviews for new technologies
- Use of de novos for some cutting edge technologies (allows automatic down-classification of devices which by default would be class III)

Fruit of This Labor

Rapid introduction of new technologies such as

- West Nile antibody testing
- Tandem Mass Spec for Inborn Errors of Metabolism
- Affymetrix Reader/ Roche P450 AmpliChip

Loose Ends -- ASRs/Home brews

- Awkward product specific queries
- Ongoing compliance evaluation, issues, and actions
- Issues of non-parity and non-congruity between CLIA and FDA processes unresolved

ASRs/Home brews

- FDA commitment to work toward clarity
- AdvaMed Developed Q and A’s now being shared with professional groups; basis for possible future guidance

Loose Ends -- Informed Consent

- Discussion of issue is both hierarchial and broad
- Multiple players within and outside CDRH
- Increased appreciation of non-congruence between HHS (common) rule and FDA requirements

Loose Ends -- Informed Consent

- Clear work plan
- Move toward guidance or changes in regulation if appropriate
- Unclear time line
- High level HHS interest in harmonization

Future Goals

- Continue to re-balance programs to reflect Total Product Life Cycle regulation
- Better coordination of patient safety efforts
- Clarify or develop clearer regulatory positions

Critical Path

- Generated out of the Office of Commissioner
- Available on web page
- Focused on improving flow of new technology from research bench to clinical bed side

Critical Path

- Not IVD specific (more drug focused)
- Does refer explicitly to Biomarkers
- As valuable diagnostic tools
- As valuable tools to assist in drug development

Critical Path

- Does resonate with IVD industry
- Weighed in with comments to docket
- Weighed in at last IVD Round Table
- Model for IVDs may be somewhat different than for therapeutic products

Critical Path for Medical Product Development*
Concept Model for IVD Roundtable Discussion

Model Presented in FDA Report

Basic Research – fundamental understanding of the biology and disease

Prototype/Design & Discovery – creates or selects molecules

Preclinical/translational Research – drives discovery to clinical evaluation, pre-IND

Clinical Development/Critical Path – proves safety/utility/ effectiveness, improves R&D process, establish tools, scale-up, IND

FDA Filing – final application review, approval, postmarket activities

* From: Innovation/Stagnation, FDA report on Challenge and Opportunity on the Critical Path to New Medical Products, March 2004

Regulation May Not Be Only or Predominant Obstacle

- Science – nuanced and complex; methods and materials poorly standardized
- Economic – competing choices, disincentives, patents, and conflicting cultures
- Legal and social issues

OIVD Goals

- Wisely use existing regulatory tool box
- Ensure review transparency and clear labeling
- Meet the letter and spirit of the law to have a “least burdensome” review threshold
- Proactively partner in translational phase of product development

OIVD

- Unique product line
- Unique organizational program
- Unique policy challenges

OIVD

- Government partners (NIH, CDC, CMS, HRSA)
- Professional partners
- Industry partners

OIVD

- Right resources
- Right regulatory support
- Right communication
- Potential for success or interesting failures

Concerns

- Translating work products into reality
- Finding the right balance
- Keeping our eye on the ball

Winning Hand

- Passionate cadre of innovative scientists
- Regulate an industry with imagination, energy, verve and healthy competitive spirit
- Clear public health vision
- Public commitment to good science