FDA Update

CLIAC – September 7, 2005

Waiver Guidance

- Now public
- CDRH web page
- Comment period

Waiver Guidance

- Proposed guidance
- Non-binding
- Intended for input
- Path forward – final guidance and then regulation

Waiver Guidance

- Few surprises
- Based on CLIAC recommendations
- Very detailed
- Detail implies scientific issues but does not preclude flexibility

Waiver Guidance

- Builds off of AdvaMed construct – not to re-invent the wheel
- Stress studies – risk management based
- Performance – traceability based; uses concept of total error
- Studies – real world

Waiver Guidance

- Context changes
- Best practices document
- Renewed interest in patient safety

Waiver Guidance

- Common Core
- Simplicity
- Insignificant risk of error (accuracy)
- Fail safe design
- Clear labeling

Field of Dreams

- Once clear target established
- Design possibilities are beguiling
- Menu of tests will expand
- Objective is to allow access while assuring quality

Critical Path

- FDA interest in innovation
- Biomarkers central to this initiative
- Diagnostic use – personalized medicine
- Use in drug development – personalized medicine but technology innovation (good business)

Concept Paper

- Co-development of drugs and diagnostics
- Tri-center enterprise
- Excellent comments focused on need for flexibility
- Development of draft guidance

Regulatory Toolbox

- Pre-IDE
- Expedited reviews
- De novo classifications
- Real time reviews

New Products

- Roche AmpliChip
- TM Biosciences Cystic Fibrosis
- Third Wave UGT1A1

Informed Consent

- Non-congruent in approaches with NIH
- Not new but news
- Sharp response
- Working on remedy

ASRs

- Lack of clarify in parameters
- Lack of parity in regulatory processes
- FDA is working on options
- AdvaMed is working on FAQ’s

OIVD

- Approaching third anniversary
- Total product life cycle
- Combined regulatory functions (premarket, compliance, surveillance) from common technical base

OIVD

- One stop shopping
- Coordination of activities
- Stronger knowledge base

OIVD

- Lessons learned
- Geography is power
- Organizational ownership
- Job enrichment

OIVD

- TPLC makes for good regulation
- Devil is in detail
- Scorecarding is a challenge

Facing the Future

- MDUFMA trigger fix – better resources; sharper time commitments
- Elephant in the room (patient safety issues and the limits of premarket review)
- Critical path construct – opportunity cost of technology delay

Good Science

- Broader mission and focus
- Familiar challenge
- Risk based, focused, and relevant