Pharmacogentic tests and Genetic Tests for Heritable Markers

- Draft Guidance for Industry and FDA staff – February 2006 -- 90 day comment period
- http://www.fda.gov/cdrh/oivd/guidance/1549.html

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- Replaces “Multiple Tests for Heritable DNA Markers, Mutations and Expression Patterns” – February 2003
- Lively comments – re-issue of draft not final
- Ducks expression arrays

Pharmacogentic tests and Genetic Tests for Heritable Markers -- purpose

- Help to shorten development and review timelines
- Facilitate rapid transfer of new technology from the research bench to the clinical laboratory
- Encourage informed use of pharmacogenomic and genetic diagnostic devices

To Whom Directed

- Manufacturers (diagnostic device companies) – traditional sponsors
- FDA staff
- Venture capitalists and PHARMA companies with interest in diagnostics – non-traditional sponsors
- Academics, government researchers, entities funding translational research

Key Elements – Intended Use

- Importance and options
- Clinical purpose
- Target population
- Acknowledges challenge – rare events, low prevalence, defining performance for predictive tests

Key Elements – Device Design

- Information needed for a quality submission
- Description
- Information on samples
- Information on methods
- Information on controls

Key Elements – Analytical Studies

- Core studies to establish diagnostic performance
- Sample characterization and specifications
- Precision
- Analytical specificity
- Cut-offs

Key Elements – Software and Instrumentation

- Sources of information on these elements when appropriate
- Data processing
- Validation of instrumentation

Key Elements – Clinical Studies

- Clinical evaluation of test – general overview with citation to international methodology: STARD (Standards for Reporting of Diagnostic Accuracy) statement
- Defers to clinical information in draft concept paper on co-development of drugs and diagnostics; currently being revised for issue as draft guidance

Key Elements -- Labeling

- Directions for use
- Quality control
- Interpretations and precautions
- Stability
- Performance

How FDA Ensures Quality

- Comprehensive device authority assures minimum data and labeling thresholds prior to marketing of new diagnostics
- Quality system regulations assure consistency in manufacture of product over time
- Medical device reporting requirements assure patient safety problems identified and addressed

Ongoing Series of Documents

- http://www.fda.gov/cder/guidance/5900dft.pdf

--Voluntary Genomic Data Submissions

- http://www.fda.gov/cder/genomics/pharmacoconceptfn.pdf

--Concept paper on co-development

- http://www.fda.gov/cdrh/osb/guidance/1428.html

-- Statistical methods for test evaluation

Next Steps

- Continued publication and evolution of guidances
- Mechanisms for early informal and formal interactions (CDER voluntary genomic data submissions and CDRH pre-IDE meetings)
- Continue to consider ways to better communicate existing regulatory options and requirements (ASR guidance under development)

Good Science

- Promote public health
- Protect public health
- Tension
- Regulatory focus