



**Division of Clinical Laboratory
Devices -- an update**



DCLD Summary

- ◆ People
- ◆ Workload
- ◆ Performance
- ◆ Implementation of Least Burdensome Program
- ◆ Strategic Plan



People

- ◆ New Deputy Commissioner – Dr. Crawford
- ◆ Seasoned Chief Counsel – Dan Troy
- ◆ New Associate Director Science - Norris Alderson
- ◆ Seasoned Center Director – Dr. Feigal
- ◆ New Center Organization – Linda Kahan and Lillian Gill



People

- ◆ 60 FTEs
- ◆ New Genetics Hires
- ◆ No Growth



People -- Programs

- ◆ Premarket Review
- ◆ CLIA categorization
- ◆ Pharmacogenomics working group
- ◆ Bioterrorism initiatives
- ◆ TPLC initiative



510(k) Program

- ◆ Heart of workload
- ◆ 650 submissions
- ◆ Review times average 65 days (target 90)



Decreasing Workload

- ◆ Replacement reagent policy
- ◆ ASR policy
- ◆ Clarification in modification policy
- ◆ Business environment



PMA Program

- ◆ Variable workload
- ◆ Approved approximately 6
- ◆ Meeting all review targets



Protocol Review (pre IDE) Program

- ◆ Currently projected at 90/year
- ◆ High octane stuff
- ◆ 60 day reviews
- ◆ Multiple interactions



CLIA Review Program

- ◆ Active – more than 2000 determinations/year
- ◆ Remains program in evolution



FDAMA

- ◆ Improved market access
- ◆ Least burdensome pathways
- ◆ Premarket to postmarket balance
- ◆ Increased interaction with industry



Least Burdensome

- ◆ Appropriate questions
- ◆ Appropriate thresholds
- ◆ Non-academic pursuits



Least Burdensome

- ◆ Matter of law
- ◆ Matter of policy
- ◆ Matter of spirit



Least Burdensome

- ◆ Two Guidance Document
- ◆ Systems Approach – ensure appropriate process applied to use of regulatory tools
- ◆ Review Guidance



Least Burdensome

- ◆ Review changes are profound
- ◆ Parallel genetics initiative
- ◆ Shift to data summaries
- ◆ Shift to more focused labeling review
- ◆ Shift to use of clinical literature
- ◆ Shift to postmarket analysis



Strategic Plan -- Goals

- ◆ Mission related
- ◆ Total Product Life Cycle
- ◆ Knowledge Management



Total Product Life Cycle

- ◆ Cradle to grave
- ◆ Seamless oversight



Intellectual Appeal

- ◆ **Premarket review limitation**
- ◆ **Outdated law**
- ◆ **Snapshot approach**
- ◆ **Impact of scale-up**
- ◆ **Impact of wide-use**



Intellectual Appeal

- ◆ **Postmarket review strengths**
- ◆ Quality system regulations
- ◆ Require quality assessment
- ◆ Require process controls
- ◆ Require corrective actions
- ◆ Unrealized potential



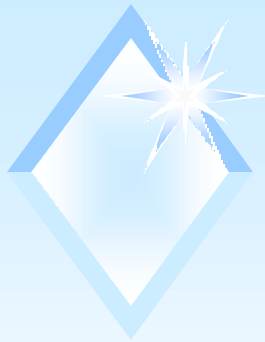
Intellectual Appeal

- ◆ **Need for harmonization**
- ◆ **IVD directive**
- ◆ **ISO labeling initiative**
- ◆ **Growing regulatory program in Canada**



TPLC IVD Pilot

- ◆ Ideal target
- ◆ Stereotyped review issues
- ◆ Cadre of like minded scientists
- ◆ Engaged communities interested in partnering



Goals

- ◆ Increased transparency
- ◆ Expedited technology transfer
- ◆ Provide support and improvements application of ASRs
- ◆ Improve surveillance and use of surveillance



Core Mission

- ◆ Promote public health
- ◆ Apply good science
- ◆ Evolving program
- ◆ Relevant, focused, safe and effective