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Food and Drug Administration
Center for Devices and Radiological Health

**The Least Burdensome Provisions
of the FDA Modernization
Act of 1997**

OUTLINE

- I. References to Least Burdensome Requirements
- II. FDA Implementation
- III. Mechanisms to Lessen Regulatory Burden

I. References to "Least Burdensome" Requirements

Section 205 of FDAMA amended the FD&C Act to incorporate two references to "least burdensome" decision threshold

- Section 513(a)(3)(D)(ii)
- Section 513(i)(1)(D)

Section 513(a)(3)(D)(ii)

“Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating reasonable assurance of device effectiveness shall be specified as the result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in conjunction with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.”

Section 513(i)(1)(D)

“Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such requests, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.”

FDAMA did not change the standard for premarket clearance and approval

- Reasonable assurance of safety and effectiveness (PMA)
- Substantial equivalence (510(k))

II. FDA Implementation

- Open public meeting
 - January 4, 1999 meeting in Rockville, MD
- Internal communication and scientific reviewer training
- Draft agency guidance document entitled, "Evidence Models for the Least Burdensome Means to Market"
 - Federal Register Vol. 63, No. 169, Sept. 1, 1999
 - <http://www.fda.gov/ohrms/dockets/98FR/090199g.pdf>
 - Comment period ended Nov. 30, 1999

Task Force Proposal

"The Least Burdensome Industry Task Force Proposal"

- Proposal dated March 11, 1999
- Incorporated in Appendix D of FDA guidance document - subject to same comment period

An "Interim" FDA Definition

Least Burdensome - a successful means of addressing a premarket issue that involves the smallest investment of time, effort, and money on the part of the submitter and FDA.

Least Burdensome Requires a Change in FDA Culture

- Recognize that there are multiple approaches to satisfying regulatory requirements.
- Communicate, collaborate, and compromise in the interest of public health.
- Understand not just the letter of the law, but also the spirit of the law.
- Consider "time, effort, and money" in decision-making.

Least Burdensome vs. Scientific Integrity

- All scientific endeavors are affected by the availability of resources.
- Good science includes cost-effectiveness.
- Compromise is a necessity for successful research.
- Lessening regulatory burden may serve to enhance scientific progress and advance medicine.

III. Mechanisms to Lessen Regulatory Burden

- Insure that all regulatory decisions are made in accordance with the relevant statutory criteria.
- Use the tools provided by FDAMA and reengineering (i.e., exemptions, early collaborative meetings, and third party reviews).
- Factor in all relevant publicly available information in the decision-making process.

**Mechanisms to Lessen
Regulatory Burden (con't)**

- Rely on non-clinical testing for decision-making when possible.
- Rely on conformance to recognized standards in decision-making.
- When clinical data is needed, consider alternatives to RCT's, (i.e., rely on literature and/or non-active controls).
- Use of surrogate endpoints whenever possible to demonstrate effectiveness.

The Bottom Line

- Factor least burdensome concepts into all premarket activities (e.g., guidance document use and development, regulation development, and advisory panel review and recommendations).
- Remain open-minded to alternative proposals for satisfying all regulatory requirements.
