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The Least Burdensome Provisions - Activities Related to Implementation



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The Federal Food, Drug, and Cosmetic Act as Amended by FDAMA of 1997

FDAMA added the following two provisions to the Federal Food, Drug, and Cosmetic Act. These two provisions are commonly referred to as the "Least Burdensome Provisions."

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

"Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation 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."

Posted **Least Burdensome Final Guidance**

9/30/2002 • [The Least Burdensome Provisions of the FDA Modernization](#)



Act of 1997: Concept and Principles; Final Guidance for FDA and Industry

IDE and PMA Documents

- | | | |
|-----------|---|----------|
| 5/29/2001 | • Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and CDRH Staff | PDF |
| 9/9/2000 | • Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997 | TEXT PDF |
| 7/12/1995 | • "Goals and Initiatives for the IDE Program" (Blue Book #D95-1) | TEXT |
| 3/25/1999 | • "Pre-IDE Program: Issues and Answers" (Blue Book #D99-1) | TEXT |
| 2/28/2001 | • "Early Collaboration Meetings under the FDA Modernization Act (FDAMA)" Final Guidance for Industry and for CDRH Staff | PDF |

510(k) Documents

- | | | |
|------------|---|----------|
| 5/28/2002 | • Invitation to Preparers of Abbreviated 510(k)s for Selected Devices re: Summary Reports | TEXT |
| 11/16/2001 | • "Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA" - This guidance updates review procedures to bring consistency with Least Burdensome concepts and ODE procedures. | TEXT PDF |
| 3/12/2000 | • "Guidance for Industry and for FDA Staff – Use of Standards in Substantial Equivalence Determinations" | TEXT |
| 2/19/1998 | • "Guidance for Industry and CDRH Staff -- New Section 513(f) (2) – Evaluation of Automatic Class III Designation" (Blue Book #G98-1) | TEXT |
| 3/20/1998 | • The New 510(k) Paradigm –Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" | TEXT |
| 10/22/1998 | • "Frequently Asked Questions and Answers on the New 510(k) Paradigm" | TEXT |

Lessening Regulatory Burden - Related Documents

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|-----------|---|----------|
| 5/3/2001 | • The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Draft Guidance for FDA and Industry (Issued on May 3, 2001) | TEXT PDF |
| 11/2/2000 | • Guidance for Industry and FDA Staff: Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA. (Issued on November 2, 2000) | TEXT PDF |

- 9/11/2000
 - Guidance for Industry: A Suggested Approach to Resolving Least Burdensome Issues (Issued on September 11, 2000)  
 - After November 1, 2000, all letters in which additional information is requested for pending 510(k)s, PMAs, IDEs, and HDEs will contain boilerplate Least Burdensome language. This language will indicate that the Agency considered the least burdensome approach to resolving the outstanding issues associated with the application. Similar language will also appear in all CDRH final guidance documents issued after the above date. The following is an example of the least burdensome language as it will appear in the 510(k) letters in which additional information is requested 
- 7/17/2000
 - "A Systems Approach to Premarket Review"  
- 11/15/2001
 - Special Controls Guidance Documents to Reduce Regulatory Burden 

CDRH/Industry Collaborative Efforts

- 3/20/2000
 - "The Least Burdensome Provisions of the FDA Modernization Act of 1997 – Concept and Principles" – a Document Prepared by Representatives of the Least Burdensome Industry Task Force and FDA  

Training Materials

- Staff Update: The Least Burdensome Provisions of FDAMA- April 4, 2000 - An overview of the least burdensome provisions and an update on CDRH progress in implementing these changes in the statute.  
- Least Burdensome training for the CDRH's Advisory Panels 
- Least Burdensome training for CDRH staff 

Updated 10/10/2002