FDA's Draft Guidance of "Least Burdensome Provisions" for Medical Devices

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Regulations/Standards

In 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA)[1] in an effort "to ensure the timely availability of safe and effective new products that will benefit the public and to ensure that our Nation continues to lead the world in new product innovation and development." Central to that legislation was the addition of section 513(i)(1)(D) and 513(a)(3) (D)(ii) to the Food Drug and Cosmetic Act, which advocated that the agency must consider the least burdensome means of demonstrating substantial equivalence and request information accordingly. With the issuance of this guidance, both industry and the FDA have been grappling with a reasonable definition of "Least Burdensome."

Recently passed U.S. laws, including the FDA Safety and Innovation Act (FDASIA) and the 21st Century Cures Act, have renewed the discussion on clarifying the Least Burdensome Provision concepts. In response to this rising pressure the FDA issued an updated draft guidance[2] in December 2017, which is intended to supersede the 2002

guidance.

Shifting emphasis and scope

This new draft guidance dramatically broadens the scope of the impacted device submissions to include:

- Premarket submissions
  - PMAs
  - 510(k)s and de novo requests
  - Humanitarian device exemption (HDE) applications
  - Investigational device exemption (IDE) applications
- Q-submissions
- Panel review and recommendations
- Informal or interactive inquiries regarding device development
- Reclassifications and exemptions
- Additional Information and Major Deficiency letters
- Post-market surveillance and post-approval studies
- Guidance documents and their application
- Compliance-related interactions
- Regulation development

In short, the guidance states it applies to "all products that meet the statutory definition of a device."

Also, the guidance has taken a decided shift in definition away from the 2002 definition of least burdensome principles, previously defined as "a successful means of addressing a premarket issue that involves the most appropriate investment of time, effort and resources on the part of industry and FDA." Instead, the new guidance focuses on minimizing the amount of information or data needed to "adequately address a (pre- or post-market) regulatory question or issue through the most efficient manner at the right time."

Seven principles of "least burdensome"

The new draft guidance defines the seven guiding principles

to be followed by both FDA and the medical device industry when taking a least burdensome approach to a regulatory issue, as follows:

1. FDA intends to request the minimum information necessary to adequately address the regulatory question or issue at hand.
2. Industry should submit material, including premarket submissions, to FDA that are least burdensome for FDA to review.
    a. Industry should submit well-organized, clear, and concise information.
3. FDA intends to use the most efficient means to resolve regulatory questions and issues.
    a. FDA intends to use all reasonable measures to streamline processes and policies, as well as render regulatory decisions within appropriate timeframes, such as Medical Device User Fee Amendments (MDUFA) performance goals
    b. FDA intends to routinely use interactive approaches, whenever possible, to resolve questions and issues
    c. FDA intends to, and industry should, use tailored approaches that have been adapted to individual circumstances and needs to address regulatory questions and issues
    d. FDA intends to take appropriate consideration of the time and resource implications of its requests.
4. The right information should be provided at the right time (e.g., just-in-time data collection) to address the right questions.
    a. FDA intends to, and industry should, consider post-market data collection to reduce pre-market data collection whenever possible or feasible
5. Regulatory approaches should be designed to fit the technology, taking into account its unique innovation cycles, evidence generation needs, and timely patient access.
6. FDA intends to leverage data from other countries and decisions by, or on behalf of, other national medical device regulatory authorities to the extent appropriate and feasible.
7. FDA intends to apply least burdensome principles in international medical device convergence and harmonization efforts.

Applying the guidance

Lastly, the draft guidance provides examples to illustrate ow least burdensome principles may be applied within the product development lifecycle, involving least burdensome sources of clinical data, including the use of real world data; alternative models for deriving non-clinical data including bench level studies and computer modeling studies; the use of benefit-risk analyses; and balancing pre and post marketing commitments.

While this new guidance brings greater clarity and simplicity in device submissions, the success of this new philosophy will be greatly dependent upon sponsors' ability to effectively lead and collaborate with the FDA to confirm alternative solutions that can address the agency's regulatory questions.

This new draft guidance is a significant expansion of the FDA's commitment to streamline the device submissions and does address many shortcomings of the original 2002 guidance. Given the high-profile nature of increasing access to new, innovative medical devices, the door is now open for industry to dialogue with the agency to consider novel less burdensome approaches as part of the development and submission process.

References

1. The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry, 2002. https://bit.ly/2jfWuS2
2. The Least Burdensome Provisions: Concepts and Principles-Draft Guidance for Industry. https://bit.ly/2w2fInA

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