# DuVal Client Alert

## Passing on Tribal Knowledge of FDA Law

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## 2021 Retrospection Highlight


**Kathy Herzog, BSME**

*Senior Regulatory, Quality & Compliance Consultant*

The year 2022 marks the 25th year since Congress first directed FDA to use a "least burdensome" (LB) approach when reviewing device applications with the enactment of FDAMA in 1997[1]. ***The intent of the LB approach is to hold FDA accountable to require only the minimum information needed to establish a new or modified device has reasonable assurance of safety and effectiveness during review of premarket applications***. Unfortunately, FDA's implementation followed Lou Holtz's quote "When all is said and done, more is said than done."

Within the last decade, Congress reinforced the requirement for a LB approach to premarket application review through additional updates to the LB provisions of the FD&C Act[2] with FDASIA[3] enacted in July 2012, and the 21st Century Cures Act enacted in Dec 2016. On February 5, 2019, FDA issued guidance entitled *The Least Burdensome Provisions: Concept and Principles* to identify approaches to implement the LB provisions of the FD&C Act. In this guidance, ***FDA defines least burdensome as "the minimum amount of information necessary to adequately address a relevant regulatory questions or issue through the most efficient manner at the right time."*** The term "necessary" means ***the minimum required information that would support a determination that an application provides reasonable assurance of the effectiveness of the device***.

The LB concept applies across the total product lifecycle (TPLC) of any product that meets the statutory definition of a medical device per Section 201(h) of the Act, applies to all premarket regulation activities (e.g., 510(k)s, PMAs, pre-submission meetings), and is intended to expedite regulatory

[1] Food and Drug Administration Modernization Act is referred to as "FDAMA".
[2] *See* Sections 513(i)(1)(D)(i), 513(a)(3)(D)(ii), and 515(c)(5)(A) of the Food, Drug, and Cosmetic (FD&C) Act.
[3] Food and Drug Administration Safety and Innovation Act is referred to as "FDASIA".

clearances and approvals but does not change applicable premarket submission requirements or the requirement for valid scientific evidence.

*Our experience has shown that FDA's implementation of the LB provisions of the Act has not been consistent and the impact to device sponsors on time and money is as significant as the lost opportunity to serve public health.* Key areas where LB issues more frequently arise relate to requirements for biocompatibility testing and clinical performance data. Negotiating LB evidence needs with FDA can be quite challenging and can feel more like "Most Burdensome." This is particularly true when FDA requests more evidence to clear or approve a new device than required of a predicate or similar device without scientific rationale, or does not respond in kind to a reasoned and scientific proposal for performance testing. In those situations, we encourage industry to leverage the "LB Flag" to seek upper management input on a LB issue for deficiency requests that do not have NSE (not substantially equivalent) potential but where the requested information is not considered by the sponsor as LB or not required of a predicate device and the issue is not resolvable with the lead reviewer (must request within 60 days of receiving the deficiency).

*Key strategies for device sponsors to help facilitate a LB approach with their premarket submissions include*:

1) Use of pre-submission process to promote early and collaborative discussions between FDA and a device sponsor;
2) Clear and concise premarket submissions;
3) Completion of thorough benefit-risk analyses, to identify serious risks and to compare with the safety profile of similar devices;
4) Use of FDA-recognized voluntary consensus standards when completing testing;
5) Judicious consideration of LB and alternative approaches to clinical and non-clinical performance data (*e.g.*, use of non-US data, literature analysis, and/or real-world evidence (RWE) for

clinical data; use of prior testing or use of computational modeling to reduce bench or animal performance testing);

6) Clear and sound justification for why the performance data plan (clinical and non-clinical) is sufficient to support a determination of reasonable assurance of safety and effectiveness;
7) Consideration and justification for the use of post-market data collection to reduce the premarket data collection when appropriate and feasible; and
8) Use of available actions to address LB issues, including trying to resolve a LB issue with the lead reviewer, throwing a LB Flag to involve upper management, submitting a Submission Issue Request (SIR) to address one or two critical topics that involve LB, and submitting a formal appeal to address FDA decisions on premarket applications where FDA law was not followed, including LB provisions of the Act.

*FDA's implementation of the LB provisions is evolving.* Increased FDA staff training and transparency through FDA-self and third party audits[4] and public performance metrics, and industry actions to identify and address LB issues will help to reinforce the importance of the LB principles and hold FDA accountable to effective and consistent implementation of these principles during review of premarket applications.

[4] *See* FDA's Report to Congress entitled *Least Burdensome Training Audit*, dated June 8, 2018 (required under the Cures Act). See also the United States Government Accountability Office (GAO) FDA Medical Device Review report entitled *Evaluation is Needed to Assure Requests for Additional Information Follow a Least Burdensome Approach,* dated December 2017.

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Drug, Device and Food Law

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