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ALERTS

FDA Issues Final Guidance On Least Burdensome Provisions For Medical Devices

February 7, 2019 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | San Diego | South Bend | Washington, D.C.

Congress has directed the FDA to conduct premarket evaluations of medical devices in the least burdensome manner possible, consistent with maintaining the statutory requirements for clearance and approval. As a result, the FDA recently issued a final guidance document titled "The Least Burdensome Provisions: Concept and Principles." Congress first added a least burdensome provision to the Federal Food, Drug & Cosmetic Act in 1997, and more recently in the FDA Safety and Innovation Act and in the 21st Century Cures Act.

Definition of Least Burdensome

In the final guidance, the FDA defines "least burdensome" to mean "the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time." The final guidance added the word "relevant" to the definition in the draft version to emphasize the FDA's regulatory burden throughout the total product life cycle. The definition considers the type of information, different ways to generate or provide information, and when information should be generated or provided to the FDA during the total product life cycle.

The core of the guidance is found in its "guiding principles." Here is a summary of those principles:

1. The FDA will request the minimum information necessary to adequately address the regulatory question or issue at hand.

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2. The industry should submit material, including premarket submissions, to the FDA that are least burdensome for the FDA to review that:

- Is well-organized, clear, and concise
- Is not unrelated to the regulatory decision
- References applicable FDA guidance documents where FDA recommendations were considered

3. The FDA will use the most efficient means to resolve regulatory questions and issues including:

- All reasonable measures to streamline processes and policies, as well as render regulatory decisions within appropriate timeframes, such as MDUFA performance goals
- Routinely using both formal and informal interactive approaches, whenever possible, to resolve questions and issues
- Reasonable, tailored approaches that have been adapted to individual circumstances and needs to address regulatory questions and issues, which industry should also do
- Considering 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.

- The FDA will, and industry should, consider the use of postmarket data collection to reduce premarket data collection whenever appropriate and 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. The FDA will 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. The FDA will apply least burdensome principles in international medical device convergence and harmonization efforts.

- The FDA will actively engage in the development, recognition, and use of voluntary consensus standards published by international and other standards development organizations.

The final guidance has sections expanding on each of these principles and also provides examples for both premarket and postmarket settings to demonstrate approaches the FDA and industry can take to ensure the least burdensome principles are implemented for all device-related applications and interactions with the FDA.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, chair of the firm's Food, Drug and Device group, at 317-231-7392 or lynn.tyler@btlaw.com.