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ALERTS

# Food, Drug & Device Law Alert - FDA Releases Final Guidance On Medical Device Pre-Submission Program

February 25, 2014 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently issued a final Guidance document titled “Medical Devices: Pre-Submission Program and Meetings with FDA Staff” (the “Guidance”) to provide advice to medical device manufacturers who want FDA’s input before submitting an IDE, HDE, 510(k), or PMA. The Guidance notes that it arises out of, and broadens, the former pre-IDE meeting program to cover the other stated types of applications or notification and also to extend the program to CBER (in addition to CDRH). In light of the increased scope, FDA is changing the name of the program from Pre-IDE to Pre-Submission or Pre-Sub.

According to the Guidance, “the main purpose of the Pre-Sub program” is “to provide the opportunity for an applicant to obtain FDA feedback prior to intended submission of an IDE or marketing application.” The FDA states that it “intends to provide the best possible advice in accordance with the information provided” and to “ensure it is captured accurately in the meeting minutes drafted by the” applicant. Most importantly, however, FDA will “commit to that advice unless the circumstances sufficiently change such that our advice is no longer applicable, such as when a sponsor changes the intended use of their device after we provide feedback” (emphasis added).

The Guidance provides several examples of when a medical device manufacturer might want to request a Pre-Submission meeting. For example, an applicant may want such a meeting before conducting an important study, or submitting an IDE or marketing application, where the new device involves novel technology or is an IVD device that involves a new intended use, new analyte, or new clinical questions. The Guidance provides several other examples as well.

The Guidance stresses that the Pre-Sub program is designed to answer specific questions an applicant may have before it undertakes some important step in the development process for a device. In contrast, the Guidance states that the program is NOT intended to be, among other things, purely informational or an opportunity for (1) a preview or re-review of data, (2) obtaining general information, including about FDA policies or procedures, (3) clarifying technical guidance documents, or (4) interactions during the actual review of a marketing application.

The Guidance contains a section on the information that should be included in a Pre-Sub package, including the following:

- A cover letter clearly stating the reason for the submission in the reference line, e.g., Pre-Sub for 510(k)

## RELATED PEOPLE

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## RELATED PRACTICE AREAS

Food, Drug and Device Law

- A Table of Contents showing items and page numbers
- A device description
- Propose intended use or indications for use
- A summary of any prior discussions or submissions
- A summary of the product development process to date
- The specific questions the applicant wants FDA to answer
- The preferred means for obtaining FDA's feedback (e.g., in-person meeting or teleconference)
- Other logistical information, e.g., for an IDE exempt device of ex-US study, the entire protocol

For several of these components, the Guidance gives further instructions or examples to identify the information that should be included.

The Guidance also includes some discussion on different types of meetings between FDA and industry, including informational, Pre-Sub, and submission issue meetings, and some details on how they are actually conducted and memorialized. As noted above, the Appendix includes several sections devoted to fairly specific instructions, including proposed questions, for each type of Pre-Submission meeting including IDE, NSR (non-significant risk), Exempt, or ex-US study, 510(k), PMA, HDE and IVD.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; and Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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