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Food, Drug & Device Law Alert - FDA Issues Plan Of Action On Recommendations For Medical Device Reviews

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As reported in a previous alert, one of the things the medical device industry obtained in exchange for agreeing to higher user fees in 2012 was an independent review and analysis of FDA's medical device review procedures. A preliminary report was issued in December 2013, and the final report was just issued. In response, the FDA's Center for Devices and Radiological Health (CDRH) has issued a Plan of Action.

The Plan of Action is organized around the following four recommendations from the independent review:

- Develop criteria and establish mechanisms to improve consistency in decision making throughout the review process
- Provide mandatory full staff training for the three primary IT systems that support MDUFA III reviews
- Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes
- Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews

The good news is that the Plan of Action is only nine pages long and a quick read. The bad news is that it is written in an outline, summary fashion and thus is not amenable to further summarization. It is also general and not particularly informative. The independent management review is 147 pages and considerably more detailed and may provide insight into likely changes.

A pdf copy of the Plan of Action is available here

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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