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ALERTS

Food, Drug & Device Law Alert - FDA Issues Proposed Rule On Acceptance Of Data From Clinical Studies On Medical Devices

February 28, 2013 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

Earlier this week, the Food and Drug Administration (FDA) issued a proposed rule amending its regulations on the acceptance of data from clinical studies on medical devices. The proposed rule requires that clinical studies outside the United States as support for any device-related application or submission – investigational device exemption (IDE), premarket notification (510(k)), premarket approval (PMA), product development protocol (PDP), or humanitarian device exemption (HDE) – have been conducted in accordance with good clinical practices (GCP).

The proposed rule also requires GCPs to have been followed in clinical studies conducted inside the US for FDA to accept the data in support of an IDE or 510(k). For purposes of the proposed rule, GCPs include "a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected." GCPs further include "review and approval (or provision of a favorable opinion) by an independent ethics committee (IEC) before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject … before initiating a study." An institutional review board (IRB) qualifies as an IEC.

FDA offered four general reasons in support of the proposed rule: (1) to update its standards for accepting data from clinical studies on medical devices conducted outside the US; (2) to ensure the quality and integrity of data; (3) to standardize protections for human subjects; and, (4) to clarify the requirements for FDA acceptance of data from clinical studies in support of IDEs and 510(k)s.

A copy of the proposed rule can be found 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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