BARNES & THORNBURG LLP

ALERTS

Food, Drug & Device Law Alert - FDA Releases Draft Guidance On Using Clinical Data From Studies Conducted Outside The United States To Support Approval Of Medical Devices

May 11, 2015 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The Food and Drug Administration (FDA) recently issued a draft guidance titled "Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States." The draft guidance arises out of § 1123 of the FDA Safety and Innovation Act (FDASIA), enacted in July 2012. This section requires FDA, in deciding whether to approve or clear a device, to accept data from clinical investigations conducted outside the United States (OUS) if the applicant demonstrates that the data are adequate under FDA's applicable standards to support clearance or approval of the device. Under § 1123, if FDA finds that such data are inadequate to support clearance or approval of the device, then FDA must provide the sponsor with written notice of the finding, including the agency's rationale for the finding.

Currently, FDA regulations specifically address OUS studies in support of premarket approval (PMA) applications, and do not address their use in other device submissions, such as 510(k) submissions, Humanitarian Device Exemption (HDE) applications, or Investigational Device Exemption (IDE) applications. Under 21 CFR 814.15(a), FDA will accept OUS clinical studies conducted under an IDE as a part of a study that includes U.S. sites and is submitted in support of a PMA. To be considered, such a study must comply with part 812-Investigational Device Exemptions, which includes part 50-Protection of Human Subjects and part 56-Institutional Review Boards.

In the draft guidance, FDA encourages sponsors seeking to initiate or rely on an already-conducted OUS device study to use the pre-submission process to seek input from the relevant Center for Devices and Radiological Health (CDRH) or Center for Biologics Evaluation and Research (CBER) review division at the earliest stage possible. Early collaboration on the clinical trial design between FDA and the sponsor can facilitate the submission of adequate OUS data and minimize the possibility for additional or duplicative U.S. studies.

Per the draft guidance, important considerations when relying on clinical data resulting from OUS studies include:

Differences in clinical conditions: Differences between the clinical conditions in an OUS country and those in the U.S. can affect the relevance of the data to the intended U.S. population. OUS countries may have different standards of care, which can affect the analysis of the benefits and risks of the studied device relative to standard practice.

Differences in study populations: To the extent a device has

RELATED PEOPLE

Lynn C. Tyler, M.S.
Partner
Indianapolis

P 317-231-7392
F 317-231-7433
lynn.tyler@btlaw.com

RELATED PRACTICE AREAS

Food, Drug and Device Law

disparate safety effects or benefits in different demographic groups, differences in the race, ethnicity, age, gender and sex of a foreign population can affect the applicability of the study to the intended U.S. population.

Differences in regulatory requirements: When studies conducted OUS are initiated to satisfy the requirements of foreign countries, rather than, or in addition to FDA requirements, the studies may not be designed to address the questions necessary to satisfy FDA requirements.

The draft guidance includes multiple examples analyzing these considerations.

Pursuant to § 1123 of FDASIA, FDA has also issued a proposed rule which, when finalized, would require that foreign clinical studies in support of PMAs, IDEs, HDEs and 510(k)s be conducted in accordance with good clinical practice (GCP). The proposed rule is intended to help ensure the protection of human subjects and the quality and integrity of data obtained from these studies, regardless of the application type. In the proposed rule, FDA defines GCP as "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. GCP includes 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 (or a subject's legally authorized representative, if the subject is unable to provide informed consent) before initiating a study."

A copy of the final guidance document 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; or Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

Visit us online at www.btlaw.com/food-drug-and-device-law-practices.