BARNES & THORNBURG LLP

ALERTS

Food, Drug & Device Alert - FDA Issues Draft Guidance On Decisions For IDE Clinical Investigations

June 27, 2013 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently issued a draft guidance titled “FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.” This guidance, initially issued in November 2011, to promote clinical investigations to for medical devices, has been revised and reissued because the Food and Drug Administration Safety and Innovation Act (FDASIA), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to specify certain situations in which the FDA cannot disapprove an IDE.

FDASIA amended the FD&C Act to specify certain situations in which the FDA cannot disapprove an IDE. Section 520(g)(4)(C) of the FD&C Act now provides that the FDA shall not disapprove an IDE because: (1) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device; (2) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or (3) an additional or different investigation may be necessary to support clearance or approval of the device. The draft guidance states that if FDA believes that additional modifications to the study design are needed, which are unrelated to subject safety, for the study design ultimately to support a marketing application, these suggested modifications will be noted in the “study design considerations” section of FDA's letter. Sponsors are not required to modify the investigational plan to address study design considerations. If these considerations are not addressed, however, the study design may not support the study goals (e.g., a future marketing application).

To satisfy the sponsor’s potential interest in knowing whether a clinical trial will support a marketing application, the draft guidance proposes a new, voluntary “Pre-Decisional IDE Process” to allow device manufacturers to engage with the FDA in the development of trial designs that may support a marketing approval or clearance. The draft guidance states that the program will enable sponsors to obtain timely feedback from review staff on a near-final IDE application, with the opportunity for a mid-cycle interaction with the review team to promote clearer understanding and quicker resolution of major issues with device or subject safety, as well as study design. The Pre-Decisional IDE process is different from the similarly-named Pre-Submission process, which is appropriate for focused discussions with the FDA early in device development or when nonclinical testing is underway. According to the draft guidance, Pre-Submission discussions are generally limited in nature, as they focus on the proposed protocol and the specific questions

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

for which the sponsor is requesting FDA feedback.

Additionally, the draft guidance notes that the FDA does not typically review data from nonclinical bench, animal, or other studies when providing feedback on a clinical study protocol as part of a Pre-Submission. In contrast, Pre-Decisional IDEs will include data and full-study protocols and reports where appropriate, and will be reviewed in a manner similar to an IDE, allowing for more complete and meaningful feedback from review staff. FDA intends to adhere to the feedback and decisions reached during the Pre-Decisional IDE review. The draft guidance states that the Pre-Decisional IDE process is intended to reach an unconditional approval more quickly, and will help to address several commonly reported challenges in the initiation of clinical trials, such as delays in institutional review board approvals and reimbursement from third-party payers.

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.

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