FDA Issues Analysis of Premarket Review Times Under 510(k) Program

By Lynn Tyler

Barnes & Thornburg's *Food, Drug & Device Update*, Fall 2011

The FDA's 510(k) procedure is the most common regulatory review pathway for medical devices to reach the market. In response to recent reports sponsored by the medical device industry that the amount of time the FDA takes to complete premarket review applications for medical devices, the FDA issued an analysis of such applications and the causes of the delay. The analysis acknowledges that the time to complete 510(k) reviews has increased from 90 days in 2005 to 140 days in 2010, an increase of over 50 percent. Nevertheless, FDA contends that "FDA is meeting or exceeding its goals for 510(k) review times agreed to with industry under the Medical Device User Fee Act (MDUFA)" because the delay is largely attributable to poor quality submissions by manufacturers.

The FDA analysis states that the primary reason for the additional review time is applicant delay in responding to FDA requests for additional information (AI). Further, the number of times per application the FDA seeks additional information and the percentage of applications in which it requests additional information has also increased. To determine the cause of the increased AI letters, the FDA studied two "cohorts" of AI letters, one related to incoming submission quality (Cohort 1) and one for the increased number of AI letters per application (Cohort 2). The FDA determined that 83 percent of the letters in Cohort 1 and 82 percent of the letters in Cohort 2 were issued because of a poor quality submission as defined in the report.

Further, in Cohort 1, 52 percent of the quality issues involved the device description, *i.e.,* the sponsor either did not provide sufficient information about the device to determine what it was developed to do, or the device description was inconsistent throughout the submission. According to FDA, the Cohort 2 analysis showed that roughly 50 percent of submissions that received at least one AI letter lacked an adequate device description. The Cohort 2 analysis also showed that a second AI letter was most often sent because the applicant's response to the first letter was incomplete or because the response raised new questions, such as safety questions based on test results submitted with the first letter. Other common deficiencies included problems with indications for use, failure to follow or otherwise address current guidance documents or recognized standards, or missing performance testing and required clinical data for certain devices.

The FDA did acknowledge some contribution to the problem. The Cohort 1 analysis showed that 8 percent of the FDA reviewers' requests for information were inappropriate and the Cohort 2 analysis showed that 2 percent of the requests were inappropriate. The FDA also stated that it is taking steps, including enhanced training for its reviewers and for industry, to reduce the total review time.

The full text of the FDA's analysis can be found at the following website: www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm263385.htm.

For more information about Barnes & Thornburg LLP's Food, Drug & Device Law group, contact Lynn Tyler, Chair of the Food, Drug & Device Law practice group at lynn.tyler@btlaw.com or 317-231-7392; Nicolette R. Hudson at nicolette.hudson@btlaw.com or 614-628-1417; or Hae Park-Suk at hae.park.suk@btlaw.com or 202-408-6919.

Visit us online at www.btlaw.com.