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ALERTS

FDA Issues Final Rule On Appeals Of Medical Device Decisions

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In 2012, as part of the FDA Safety and Innovation Act (FDASIA), Congress required the FDA to furnish, upon request, a "substantive summary of the scientific and regulatory rationale for any significant decision" made regarding medical devices by the FDA's Center for Devices and Radiological Health (CDRH). In particular, the rules affected decisions related to a 510(k) premarket notification, premarket approval (PMA), humanitarian device exception (HDE), and investigational device exception (IDE). The FDASIA also established certain time frames for supervisory reviews of such decisions. The FDA issued two guidance documents discussing these requirements and a final rule to implement them.

Amendments to Section 10.75

The FDA amended 21 C.F.R. Part 10 to add Section 10.75(e), which provides that requests by interested parties outside the FDA for internal agency review or appeal of a decision within the CDRH must also comply with new Section 800.75. The amendments to Section 10.75(e) are not limited to significant decisions under Section 517A of the Federal Food, Drug, and Cosmetic (FD&C) Act, rather Section 10.75(e) also encompasses supervisory review within the CDRH of decisions other than 517A decisions made by CDRH.

New Section 800.75

The FDASIA did not originally define "significant decision." According to the FDA, Section 800.75 uses the term "517A decision" (after the relevant

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statutory section) rather than the term “significant decision” because the FDA does not want to imply that any other decisions of the CDRH that do not fall within Section 517A of the FD&C Act are not significant. Similarly, the FDA does not use the term “non-significant decision” to refer to decisions outside of the scope of Section 517A, as that might imply some unintended assessment concerning the importance of these types of decisions.

Under the new Section 800.75, the following are considered “significant decisions” under FDASIA and are defined for purposes of the rule as “517A decisions”:

- 510(k): Not substantially equivalent; Substantially equivalent.
- PMA/HDE: Not approvable; Approvable; Approval; Denial.
- Breakthrough Device Designation Request (request for breakthrough designation for devices subject to premarket notification, premarket approval, or De Novo classification process).
- IDE: Disapproval; Approval.
- Failure to reach agreement on protocol under Section 520(g)(7) of the FD&C Act.
- “Clinical Hold” determinations under Section 520(g)(8) of the FD&C Act.

Timing for Review

Under the final rule, a request for review of a “significant decision” must be submitted to the FDA no later than 30 days after the decision. In responding to this request, if the requester seeks an in-person meeting or a teleconference, the FDA is required to schedule the requested interaction no later than 30 days after the request is made. The FDA is required to issue a decision no later than 30 days after the interaction, or, if an in-person meeting or teleconference review is not requested, the FDA is required to issue a decision no later than 45 days after the request for supervisory review is received by the FDA. There is an exception to the time frame for cases that are referred to experts outside of the FDA.

Parties may use Section 10.75 to request review of decisions other than 517A decisions. The FDA also provided procedural requirements for internal agency supervisory review within the CDRH under Section 10.75 of non-517A decisions. A request for supervisory review of a CDRH decision other than a 517A decision is to be received no later than 60 days after the date of the decision that is subject to review. Requests received after 60 days will be denied as untimely, unless the CDRH, for good cause related to circumstances beyond the control of the submitter such as snow emergency, federal government shutdown, or other unforeseen emergency event, permits the request to be filed after 60 days.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, chair of the firm’s Food, Drug & Device group, at 317-231-7392 or lynn.tyler@btlaw.com.