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Food, Drug And Device Law Alert - FDA Proposes Defining 'Significant Decision' In Safety And Innovation Act

January 23, 2018 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | New York | South Bend

The Food and Drug Administration (FDA) recently issued a proposed rule that would define terms in Section 603 of the FDA Safety and Innovation Act (FDASIA) regarding appeals of decisions within the Center for Devices and Radiological Health (CDRH).

In the summer of 2012, Congress included provisions in FDASIA to address industry complaints about the time it takes to appeal issues within CDRH and the lack of a written explanation for decisions rendered on appeal. Section 603 of FDASIA requires FDA to furnish, upon request, a "substantive summary of the scientific and regulatory rationale for any significant decision" regarding a 510(k), PMA, HDE, or IDE. Further, Section 603 established certain timeframes for supervisory reviews of such decisions. In December 2016, the 21st Century Cures Act added decisions regarding breakthrough devices to the list.

The FDA's proposed rule adds a new section, § 800.75, to 21 C.F.R. and defines "significant decision" as used in Section 603. FDA is accepting comments on the proposed rule until April 17, 2018. Instructions for submitting comment are in the proposed rule.

The proposed rule limits a "significant decision" to the following:

- 510(k): Not substantially equivalent; substantially equivalent
- PMA/HDE: Not approvable; approvable; approval; denial
- Breakthrough devices: Grant; denial of request for breakthrough designation
- IDE: Disapproval; approval
- Failure to reach agreement on a protocol under Section 520(g)(7) (IDE)
- "Clinical Hold" determinations under Section 520(g)(8) of the FD&C Act

In a May 2013 draft guidance, the FDA expressly stated that decisions such as refusals to accept or file an application or requests for additional information are not "significant decisions" for these purposes.

FDASIA gives an interested party 30 days from a "significant decision" to seek supervisory review under 21 C.F.R. § 10.75 and to request an in-person meeting or teleconference. It then gives the FDA 30 days to

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schedule the meeting or teleconference, if requested. Finally, it gives the FDA 45 days to issue a decision on the supervisory review from the date of the initial request or, if a meeting or teleconference was requested, 30 days from the meeting or teleconference. The proposed rule adopts these timeframes, unless the matter is referred to CDRH by external experts, such as an advisory committee.

The FDA also proposes to add language to 21 C.F.R. § 10.75(e) to clarify that requests by interested persons outside the FDA for internal agency review of a decision within CDRH must also comply with proposed § 800.75. In other words, proposed § 10.75(e) would encompass review of decisions other than significant decisions.

A request for supervisory review of a CDRH decision other than a significant decision must be received no later than 60 days after the date of the decision. Requests received after 60 days in these cases will be denied as untimely, unless CDRH, for good cause related to circumstances beyond the control of the submitter, permits the request to be filed after 60 days.

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

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