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Food, Drug & Device Law Alert - FDA Issues Draft Guidance On Significant Decisions And Substantive Summaries For CDRH Appeals

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In response to industry complaints about the length of time it can take to appeal matters within the FDA, and the lack of documentation for the basis of some decisions, last summer Congress included provisions in the FDA Safety and Innovation Act (FDASIA) to address these matters. 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, and IDE, by FDA's Center for Devices and Radiological Health (CDRH). Further, section 603 establishes certain time frames for supervisory reviews of such decisions.

FDA recently issued a draft Guidance interpreting "substantive summary" and "significant decision" as used in section 603. The draft Guidance limits a "significant decision" to the following:

- 510(k): Not substantially equivalent; Substantially equivalent
- PMA/HDE: Not approvable; Approvable with conditions; Approvable
- IDE: Disapproval; Approval
- Failure to reach agreement on a protocol under section 520(g)(7) (IDE)

The draft Guidance expressly states that decisions such as refusals to accept or file an application or requests for additional information are not "significant decisions" for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 a person 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 to schedule the meeting or teleconference, if requested. Finally, it gives 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 The draft Guidance states that these time frames will apply to all requests for supervisory review within the Center (but presumably not beyond).

The draft Guidance also defines a "substantive summary" under Section 603 of FDASIA as including the following elements:

- An explanation of the rationale for the regulatory decision;
- Documentation of significant controversies or differences of

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opinion, i.e., ones the resolution of which had a direct bearing on the regulatory decision; and,

- References to published literature and consensus standards upon which the decision-maker relied.

The draft Guidance does not state when a “substantive summary” will be issued. For one to be of any use to the applicant, it will have to be well before the appeal deadline.

On the same day it released this draft Guidance, the FDA issued a final Guidance on CDRH Appeals Processes. The draft Guidance, which can be found here, will ultimately become an Appendix to the appeals Guidance. Our Alert on the draft of the Appeals Guidance can be found here.

FDA is accepting comments on the draft Guidance until August 15, 2013.

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.

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