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ALERTS

Food, Drug & Device Law Alert - FDA Releases Final Guidance On Expedited 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, in 2012 Congress included provisions in the FDA Safety and Innovation Act (FDASIA) to address these matters. Section 603 of FDASIA required 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 established certain time frames for supervisory reviews of such decisions.

FDA recently released a final guidance interpreting "substantive summary" and "significant decision" as used in section 603. The 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 for an IDE
- Placing a clinical hold on a trial

The latter was an addition compared to the draft version of this guidance.

The guidance expressly states that decisions such as (1) refusals to accept or file an application, (2) requests for additional information, (3) a "major deficiency letter" for a PMA, (4) a CLIA waiver decision, and (5) a warning letter, are not "significant decisions" for these purposes.

Under FDASIA, a person has 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. FDASIA then gives the FDA 30 days 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 guidance states that these time frames will apply to all requests for supervisory review within the Center (but presumably not beyond).

The 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;

RELATED PEOPLE

Lynn C. Tyler, M.S.
Partner
Indianapolis

P 317-231-7392
F 317-231-7433
lynn.tyler@btlaw.com

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- documentation of significant controversies or differences of 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 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.

In 2013, the FDA issued a final guidance on CDRH Appeals Processes, which can be found here. This most recent guidance, which can be found here, will become an appendix to the Appeals Guidance.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys: Lynn Tyler, Chair of the firm’s Food, Drug & Device Law group at (317) 231-7392 or lynn.tyler@btlaw.com, or Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.