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Food, Drug & Device Law Alert - FDA Issues Final Guidance On Refuse To Accept Policy For 510(k)s And PMAs

January 14, 2013 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently issued two final medical device guidance documents titled, “Refuse to Accept Policy for 510(k)s” and “Acceptance and Filing Reviews for Premarket Approval Applications (PMAs).” Draft versions of these two guidance documents had been issued last summer in response to the FDA Safety and Innovation Act. The FDA was able to finalize the documents promptly because they did not receive many adverse public comments.

In addition to explanation of the new policy, the 510(k) guidance includes three checklists – one each for traditional, abbreviated, and special 510(k)s – for use by FDA staff in determining whether to accept a 510(k) for filing. The 510(k) guidance explains that two prior guidance documents, which this one replaces, and its current checklist “deal[t] largely with administrative elements but [did] not address specific content that is essential for 510(k) review.” FDA hopes that that the new guidance and checklists “will clarify the content needed in traditional, special, and abbreviated 510(k) submissions to allow FDA to conduct a substantive review, thereby enhancing the quality of received 510(k) submissions and improving overall review time.”

Further, the guidance states that the acceptance review should be conducted and completed within 15 calendar days of FDA’s receipt of a 510(k). If FDA refuses to accept the filing, it will notify the submitter and send the submitter a copy of the completed checklist to help the submitter identify the deficiency. The submitter may submit the additional information identified in the checklist and FDA will perform the acceptance screening again, also within 15 calendar days of receipt of the information. If FDA refuses to accept the filing a second time, the submitter is again notified and given the new checklist. If FDA accepts the filing, the submitter is notified and FDA will begin a substantive review of the 510(k). If FDA does not respond within the 15 days, the 510(k) is deemed accepted and FDA will also notify the submitter and begin a substantive review.

The checklists include five preliminary questions to be answered before the content of the 510(k) is compared to the acceptance criteria: Is the product a device or a combination product with a device component? Is the application with the appropriate Center (CDRH or CBER)? Is 510(k) the appropriate regulatory submission? Is there a pending PMA (pre-market approval application) for the same device and indications for use? And, if clinical studies have been submitted, is the submitter the subject of the Application Integrity Policy?

The PMA guidance also replaces a prior document, in this case one from

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2003. The PMA guidance also includes checklists for the acceptance decision and follows the same 15 day scheme as the 510(k) guidance. It has the same five preliminary questions as the 510(k) guidance to be answered before the content is compared to the acceptance criteria, only modified for the PMA context. In other words, the third question is whether a PMA is the appropriate regulatory submission and the fourth is whether there is a pending 510(k) for the same device and indications for use.

The PMA guidance identifies several grounds for refusing to accept a tendered PMA application. FDA will not accept a PMA if it is incomplete because it does not on its face contain all information required under section 515(c)(1)(A)-(G) of the FD&C Act. Another reason a PMA will not be accepted is if it does not contain each of items required under 21 C.F.R. § 814.20 and any justification for the omission of any item is inadequate. FDA will not accept a PMA if the Applicant has a 510(k) pending for same device, and the FDA has not determined whether the device falls within the scope of 21 C.F.R. § 814.1(c). A PMA will not be accepted if it contains a false statement of material fact or is not accompanied by a statement of either certification or disclosure as required by 21 CFR Part 54.

A copy of the 510(k) guidance can be found here and a copy of the PMA guidance can be found here.

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