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FDA Issues Draft Guidance on "Refuse to Accept" Policy for 510(k)s

On August 13, 2012, the Food and Drug Administration ("FDA" or "Agency") announced the availability of a draft guidance titled "Refuse to Accept Policy for 510(k)s" ("Draft Guidance"). The Draft Guidance describes the procedures and criteria FDA intends to utilize in assessing whether a premarket notification for a medical device submitted pursuant to section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") meets the minimum threshold of acceptability and should be accepted for substantive review. Upon issuance as a final guidance document, the Draft Guidance will replace two existing guidance documents that were issued prior to 1995.

The Draft Guidance modifies the Agency's policy on refusing to accept 510(k)s. Per the Draft Guidance, FDA policy now includes an early review of 510(k) submissions against specific acceptance criteria and provides that FDA will inform the submitter within 15 days of receipt of the submission that the submission is administratively complete or, if it is not complete, identify the submission's missing elements. If the submitter provides the missing information, FDA then would have an additional 15 days to conduct its acceptance review. The Draft Guidance states that the submitter should provide the information under the originally assigned 510(k) number; the Agency will not require a complete new submission, nor is the submitter required to pay a new user fee for purposes of providing the missing information. The Draft Guidance explains that if FDA fails to complete the acceptance review within 15 days, the 510(k) should be considered accepted, but "FDA may ask for any information during the substantive review that may have been unintentionally overlooked during the acceptance review." The review clock for purposes of the Medical Device User Fee Amendments of 2012 ("MDUFA III") does not begin until FDA determines that the submission is administratively complete.

Agency staff and industry are advised to consider the following principles in determining whether a 510(k) submission is complete:

- Acceptance should not be based on a substantive review of the submission;
- Staff should consider the submitter's rationale for any alternative approaches; and
- Submitters should review any applicable guidance and standards to ensure the submission contains all necessary information for the specific device type.

The Draft Guidance also provides preliminary questions to be addressed by the reviewer in connection with the acceptance review. These questions include:

1. Is the product a device or a combination product with a device constituent part?
2. Was the 510(k) submitted to the correct center (e.g., the Center for Devices and Radiological Health ["CDRH"] or the Center for Biologics Evaluation and Research ["CBER"])?
3. Is a 510(k) the appropriate regulatory pathway?

4. Is there a pending premarket approval application ("PMA") for the same device with the same indications?

5. If clinical studies have been submitted, is the submitter subject to the Application Integrity Policy ("AIP")?

If these preliminary questions are answered appropriately, the FDA reviewer should then turn to the items enumerated in the corresponding Acceptance Checklist. The Draft Guidance includes checklists for traditional, abbreviated and special 510(k)s, based largely on the regulatory requirements for 510(k)s outlined in section 807.87 of title 21 of the Code of Federal Regulations. Included in each Acceptance Checklist are elements that will not necessarily be applicable to all devices, e.g., biocompatibility testing. If a submitter believes that a particular element is not relevant to its submission, it should provide a justification for not including that information.

The Draft Guidance largely reflects the recently issued draft guidance for PMAs titled "Acceptance and Filing Review for Premarket Approval Applications (PMAs)." Interested persons may submit comments on these draft guidances by September 27 and September 14, 2012, respectively.

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