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FDA issues draft guidance on providing regulatory submissions in electronic format

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On 26 September 2019 the U.S. Food and Drug Administration (FDA or the agency) published a draft guidance document entitled "Providing Regulatory Submissions for Medical Devices in Electronic Format – Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act," which is available for public comment.

FDA issued the draft guidance in compliance with the statutory mandate to provide draft guidance before 1 October 2019, but limited the scope of this document to describing how FDA interprets and plans to implement the requirements of section 745A(b)(3) of the Federal Food, Drug, and Cosmetic Act (FDC Act). In short, the draft provides a general statement of the agency's intent to establish standards for electronic format submissions and issue individual final guidances covering the electronic format and timetables for each specific submission type. Under the authority granted by legislation, the final guidances will be binding with respect to standards for submission, timetables, and criteria for waivers and exemptions.

Submissions required to be provided solely in electronic format

The draft guidance identifies the following medical device submissions that will be required by statute to be solely provided in electronic format:

- Premarket Notifications (510(k)s)
- De Novo classification requests
- Premarket approval applications (PMAs) – all types
- Product development protocols (PDPs)
- Investigational device exemption (IDE) applications (with some exemptions as discussed below)
- Humanitarian device exemption (HDE) applications
- Emergency Use Authorizations (EUAs)
- Certain investigational new drug applications (INDs) under section 351 of the Public Health Service (PHS) Act

- Certain biologics license applications (BLAs) under section 351 of the PHS Act
- Pre-submissions

Notably, electronic format requirements apply to all submission materials, regardless of length, and include original submissions, amendments (including add-to-files and appeals), supplements, and reports (annual/progress and postapproval). Unless exempted or waived, "a submission that is not in electronic format as described by the relevant guidance document will not be filed or received."

With respect to pre-submissions, the guidance notes that although electronic format is not mandatory for Q-submission types other than pre-submissions, FDA is recommending that they be submitted in electronic format in order to facilitate efficient review.

Exemptions

The draft guidance also identifies the following types of submissions that will be exempted from the electronic format requirement:

- IDE compassionate use requests
- Adverse event reports

FDA nonetheless encourages electronic submissions for these once submission templates become available.

Similarly, electronic formats are not required, but may be recommended as templates become available, for Master Access Files (also commonly referred to as "Device Master Files,"), 513(g) Requests for Information, and Clinical Laboratory Improvement Amendments (CLIA) categorization requests and Waiver Applications. Other exemptions may be established in individual guidances.

Conclusion

In essence, this draft guidance reiterates those submission types that FDA will require to be submitted in electronic format, per section 745(b) of the FDC Act, and sets the stage for a forthcoming slew of additional guidances specific to submission types that will set forth the standards for the submission by electronic format, a timetable for establishment of the standards, and criteria for waivers and exemptions. The timing for issuance of these planned draft guidances has not been provided.

The draft guidance is open for public comment for 60 days (25 November 2019) under docket number FDA-2019-D-3769.

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