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Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Final Guidance Documents on FDA's eCopy Program for Medical Device Submissions

On December 31, 2012, FDA issued a final guidance document entitled "eCopy Program for Medical Device Submissions" ("eCopy guidance").[i]

Section 745A(b) of the Federal Food, Drug, and Cosmetic (FDC) Act, which was added by Section 1136 of the July 2012 FDC Act amendments known as the Food and Drug Administration Safety and Innovation Act (FDASIA), requires that most medical device submissions include an eCopy of the submission upon issuance of a final guidance document by FDA. That requirement took effect on January 2, 2013. An eCopy is an electronic copy and not a submission that is submitted electronically. It is an exact duplicate of the paper submission that is provided to FDA on a compact disc (CD), a digital video disc (DVD), or a flash drive, except that the eCopy may include information that cannot reasonably be provided on paper. According to the eCopy guidance, "[t]he critical attribute of an eCopy is that it must include in electronic form all data required for that submission type. In other words, the eCopy must include all of the required information for FDA review, whereas the paper copy can include a placeholder cross-referencing the location of certain information in the eCopy." The eCopy guidance describes the requirements regarding eCopies, including the specific naming and formatting conventions that must be used for FDA to accept them. The inclusion of an eCopy in almost all types of medical device submissions is expected to make the review process more efficient.

The eCopy requirements apply to the following submission types: premarket notification submissions (510(k)), including third party 510(k)s; evaluation of automatic class III designation petitions (de novo); premarket approval applications (PMA), including transitional PMAs; modular PMAs; product development protocols (PDP); investigational device exemptions (IDE), with some exemptions as described below; humanitarian device exemptions (HDE), including Humanitarian Use Device designation requests (HUD); certain investigational new drug applications (IND); certain biologics license applications (BLA); and pre-submissions. An eCopy must be submitted for subsequent submissions to an original submission of a submission type listed above, including amendments, supplements, and reports, even if the original was submitted to FDA prior to implementation of the eCopy requirements. Responses to deficiency

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letters are logged as amendments or supplements, and are therefore subject to the eCopy requirements.

The following three submission types are exempt from the eCopy requirements, due to the potentially urgent nature of the submissions: compassionate use investigational device exemption (IDE) submissions, emergency use IDE submissions, and all emergency use authorization (EUA) submissions. While eCopies are not required for these submissions, FDA encourages the inclusion of eCopies to facilitate the review process. FDA additionally encourages, but does not require, submission of eCopies for Master Access File submissions, 513(g) Requests for Information, and Clinical Laboratory Improvement Act Categorization–Exempt Device submissions. FDA has not waived the eCopy requirement for any type of submission for which an eCopy is mandatory as the software to create is widely available at little or no cost, including the free eSubmitter-eCopy tool that is available on the Agency's website at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm317334.htm.

All device premarket submissions that include a mandatory or voluntary eCopy must also include:

- At least one complete paper copy, which must include a placeholder cross-referencing any information that appears only in the eCopy because it is not "practical or appropriate" to provide it in paper format, *e.g.*, raw data, statistical analyses, x-rays, and videos; and

- A cover letter with an ink or digital signature that includes one of the following eCopy statements: (1) The eCopy is an exact duplicate of the paper copy; or (2) The eCopy is an exact duplicate of the paper copy except [specify all differences from the paper copy or copies].

The eCopy guidance also includes additional requirements for third party 510(k) submissions.

FDA encourages the use of the Agency's eSubmitter-eCopy tool to create an eCopy that complies with the formatting and naming requirements specified in the eCopy guidance. The guidance recommends the use of volumes (folders) if the paper copy is multi-volume so that they match. PDF files are the primary file format to be used for an eCopy. FDA currently will accept only eCopies submitted using Adobe Acrobat 10.0 or below. Each PDF file must be 50 MB or less, not have any attachments or security settings, and conform to specified naming conventions, including that they be sequentially numbered with three digits throughout the entire single volume submission or within each volume in a multi-volume submission. FDA allows the inclusion of documents to which the Agency might suggest changes, *e.g.*, 510(k) summaries, and summaries of safety and effectiveness, in Word format under a "Misc" folder. FDA encourages the use of bookmarks and hyperlinks in eCopies. The eCopy cannot be transmitted electronically to FDA's Center for Devices and Radiological Health via that tool or any other gateway.

There is no change in the total number of required copies for each type of submission. A submission for which an eCopy is required must include at least one eCopy and one paper copy. The eCopy will serve as one of the required copies. Any other required copies can be any combination of paper copies and eCopies. The eCopy, with the cover letter, is considered the official record.

The eCopy or eCopies, along with the signed cover letter, must be submitted simultaneously with the paper copy or copies to FDA's Document Control Center. A submission that includes an eCopy that does not conform to FDA's standards or requires an eCopy but one is not provided will be placed on eCopy hold until an eCopy that meets the standards is submitted. FDA will notify the submitter of the eCopy hold in writing via letter, email and/or fax. FDA review, including FDA's acceptance reviews of 510(k) notices, PMAs and panel track PMA supplements, will not begin until a valid eCopy has been received and, if applicable, the user fee has been paid. In addition, undisclosed differences between the paper copy and eCopy must be corrected and could delay submission review.

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King & Spalding is happy to answer questions regarding the eCopy Guidance.

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[i] *Guidance for Industry and Food and Drug Administration Staff: eCopy Program for Medical Device Submissions, 78 Federal Register 102-04 (January 2, 2013). See http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.*