Published on *The National Law Review* https://natlawreview.com

FDA to Hold Webinar on Electronic Submission of Dimethylformamides

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The ***Food and Drug Administration (FDA)*** announced that it will hold a webinar on February 4, 2016, regarding the new requirements for electronic submission of ***Drug Master Files (DMFs)***. Most DMFs must be submitted electronically to FDA in electronic format beginning May 15, 2017.

Section 745A(a) of the *Federal Food, Drug, and Cosmetic Act* requires that certain drug and biologic submissions be submitted in electronic format within 24 or 36 months after FDA's issuance of final guidance on that topic. The final version of FDA's Guidance on Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD [Electronic Technical Document] Specifications was published on May 15, 2015.

The Guidance states that submissions for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and certain biologics license applications (BLAs) must be submitted in electronic format using the Agency's online gateway beginning on May 15, 2017, and that investigational new drug applications (INDs) must be submitted in electronic format beginning May 15, 2018. FDA considers Drug Master Files (DMFs) to be submissions to an NDA, ANDA, BLA, or IND, and therefore to fall within the scope of the requirements set forth in Section 745A(a).

An announcement on the webinar can be found on FDA's website.

National Law Review, Volume VI, Number 20