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Mintz Reminds Drug Manufacturers of Looming Deadline to Submit Data to FDA

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Last week, Mintz released an **Advisory** reminding holders of **New Drug Applications** (NDAs) and **Abbreviated New Drug Applications** (ANDAs) of the February 14, 2018, deadline to submit data to the U.S. Food and Drug Administration (FDA). The Advisory summarizes the notification requirements as well as the risks associated with failing to provide the required information, including removal of a manufacturer's drug products from the active section of FDA's **Orange Book**. The data submission requirements are part of the FDA Reauthorization Act (FDARA), which aims to improve FDA's ability to track drug products in the commercial marketplace and represents one of Congress' attempts to control drug pricing and address patient access issues for prescription drugs.

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