

FDA Platform Technology Draft Guidance Highlights Utility of Obscure Patent Term Extension Provision



As discussed in a [prior Goodwin Alert](#), the US Food and Drug Administration (FDA) recently released [Draft Guidance for designating a platform technology for drug development](#) pursuant to § 560k of the Federal Food, Drug, and Cosmetic Act. The platform technology program was included as part of the PREVENT Pandemics Act “to bring significant efficiencies to the drug development or manufacturing process.” Specifically, a platform technology must have the “potential to be incorporated in, or utilized by, **more than one drug** without an adverse effect of quality, manufacturing or safety.”

Read the full insight [here](#).